#### DEVELOPMENT AND VALIDATION OF AN OUTCOME MEASURE FOR ORTHOPAEDIC TRAUMA INPATIENTS

By

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#### ABSTRACT

#### Introduction

In clinical physiotherapy, there is a growing importance for the accuracy and reliability of assessment and outcome measures. The purpose of this study is to develop a valid outcome measure for orthopaedic trauma inpatients. Item generation was done by conducting a systematic review of published functional outcome measures and patients' interview. Item reduction was conducted by using a panel of physiotherapists and patients.

#### Objectives

The overall study objectives were: 1) To determine if a functional outcome measurement scale for trauma inpatients exists and has been published; 2) To generate functional items for the construction of a new outcome measurement tool for trauma inpatients; 3) To construct a new outcome measurement tool for trauma inpatients and assess elements of validity and reliability (face and content validity, response to change, internal consistency and floor and ceiling effects) of the new developed outcome measure.

#### Methodology

Convenience sampling was applied to collect data from 35 trauma inpatients in trauma wards at Rashid Hospital in Dubai, UAE. 88% of the trauma inpatients were male (total sample n= 100), mean age =34.75, and the standard deviation = 14.46. 21 functional activity items were generated from the collated results of the patient interviews. Internal consistency reliability, responsiveness and floor and ceiling effect were assessed. Data analysis was conducted using Statistica Version 7.

#### Results

The final number of functional activity items included in the newly developed Functional Scale outcome measure was 29 activity items relevant for trauma inpatients. A Cronbach's alpha ranged between 0.76 and 0.97. The lowest alpha result was for the 'ADL' activities at follow-up (0.76). The highest alpha result was for 'out of bed' activity at admission and discharge (0.97).

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The response to change of the Functional Scale for trauma inpatients over time results illustrates that there was a significant difference in the mean scores over three administrations of 'Bed', 'Out of bed' and 'ADL' activity items of Functional Scale for trauma inpatients (p=0.0000). In general, there was no significant floor and ceiling effects at admission or discharge for 'bed', 'out of bed' and 'ADL' activities, except there was a floor effect noted at discharge for 'bed' activities and 'ADL' activities, and a ceiling effect noted at admission for 'out of bed activities' only.

#### **Discussion and Conclusion**

The newly developed Functional Scale outcome measurement for trauma inpatients has been shown to be internally consistent and appears to be valid with respect to response to change in this sample of trauma inpatients. The results of this study thus suggest that the Functional Scale for trauma inpatients may be an appropriate tool when the goal is the assessment of change in disability functions in trauma inpatients, although further psychometric testing may be required.

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DEDICATION I dedicate this thesis to the memory of: My Family,

#### LIST OF DEFINITIONS

**Acceptability:** is the extent to which the range of health measured by a scale matches the distribution of health in the study sample. It is determined by examining score distributions. Mean score should be near the scale midpoint, and floor and ceiling effects should be small (Hobart and Thompson 2001).

**Activity:** the execution (performance) of specific tasks or actions by an individual (Haley et al 2004).

**Activity limitation:** inability of an individual to perform a task or activity in the way it is done by most people (O'Sullivan and Schmitz 1994).

**Activities of daily living:** task concerned with daily self care; feeding, dressing, hygiene, and physical mobility (O'Sullivan and Schmitz 1994).

**Consecutive sampling:** a strict version of convenience sampling where every available subject is selected, i.e., the complete accessible population is studied. Thus in study the best choice of the no probability sampling techniques is by studying everybody available; a good representation of the overall population is possible in a reasonable period of time (Portney and Watkins 2000).

**Construct validity:** refers to the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the constructs that are measured. The association of the instrument with other variables that measured the ability to function during the acute hospital care was extracted from the retrieved studies. Construct validity was considered to be adequately tested if hypotheses were specified and the results corresponded with the hypotheses. An adequate measure was used (Williams et al 2007).

**Content validity:** examines the extent to which the domain of interest is comprehensively sampled by the items in the instrument. Items in the

measure should reflect areas that are important to patients who are unable to function during the acute hospital care. For this review, the identified instruments received a positive rating for content validity when patients were either involved during item selection and/or item reduction when patients tested the instrument for reading and comprehension in a pilot study (Williams et al 2007).

**Convenience sampling**: the use of conveniently available people as study participants (O'Sullivan and Schmitz 1994).

**Cronbach's alpha:** A reliability index used for estimating internal consistency in an instrument's composed list of several items or questions (Portney and Watkins 2000).

**Floor or ceiling effects:** are considered to be present if more than 20% of respondents achieved the lowest or highest possible score, respectively. If floor or ceiling effects are present, it is likely that items assessing the extremes of attribute are missing from the scale. The consequence of a floor effect is that deterioration may be missed and for a ceiling effect, improvement may be missed (Costa et al 2007).

**Intra-class correlation co-efficient (ICC):** A reliability coefficient based on an analysis of variance (Portney and Watkins 2000).

**Internal Consistency:** a measure of the homogeneity of the items comprising a scale or subscale. It indicates the extent to which items in a (sub) scale are inter-correlated, thus measuring the same construct. For this study, a positive rating for internal consistency was achieved when the dimensional structure of the instrument was explored by both Cronbach's alpha and factor analysis, and Cronbach's alpha was greater than 0.70 (Williams et al 2007).

**Outcome measurement:** An outcome measure is a "test or scale administered and interpreted by physical therapists that has been shown to measure accurately a particular attribute of interest to patients and therapists and is expected to be influenced by intervention". Outcome measures are tools that enable the treating physiotherapist to undertake an evaluation of physiotherapy treatment (Australian Physiotherapy Association 2003).

**Psychometric properties**: based on the following criteria: (1) content validity; (2) construct validity; (3) internal consistency; (4) test–retest reliability; (5) responsiveness; (6) respondent burden (i.e., time to administer); and (7) administrator burden (i.e., ease of scoring) (Williams et al 2007).

**Reliability:** is the extent to which an instrument is measuring something in a reproducible and consistent fashion. Reliability indicates the stability of a measure and is commonly assessed by rating test–retest reliability and internal consistency. The calculation of the intra-class correlation coefficient (ICC) for each domain is considered to be an adequate method for test–retest reliability. For this study, group comparison was rated as positive if: (1) the ICC >0.70 and (2) time interval and confidence interval were presented (Williams et al 2007).

**Responsiveness (sensitivity to change):** refers to an instrument's ability to detect meaningful important changes over time in the concept being measured (Gabel et al 2006). Sensitivity to change is a form of validity, and it is defined as the capacity of a test or measure to distinguish among patients or groups of patients whose health status has improved, deteriorated and remained stable and to quantify the amount of true change when it has occurred (Chatman et al 1997).

**Respondent Burden and Administrative Burden:** Respondent burden refers to any undue physical or emotional strain placed on the respondent, such as the time needed to complete the questionnaire. Lengthy questionnaires can place unacceptable burden on respondents which can lead to respondent fatigue and may result in the presence of missing data even when the measure is psychometrically valid. Administrative burden considers the time needed to administer, score, or analyze the measure. For this study, group comparison was rated as positive if the time needed to

complete the questionnaire was less than 10 minutes and easy to sum up (Williams et al 2007).

**Self-report Outcome Measures (SROMs):** a questionnaire completed by the patient to indicate the status of functional loss in a specific area or condition (Gabel et al 2006).

**Trauma inpatients**: the patients who are admitted to the hospital with a primary diagnosis of trauma (Government of Dubai, Copyright Act 2007).

**Traumatic neuro-musculoskeletal disorders:** refer to acute orthopedic trauma conditions. This includes fractures and dislocations as well as severe soft tissue injuries caused by traumatic events. Common orthopedic traumatic injuries include femoral and tibial shaft fractures, acetabular and pelvic fractures, hand and upper extremity injuries, foot and ankle injuries, among many others. Poly-traumatized patients are those unique individuals with numerous skeletal and other organ injury usually caused by high energy traumatic events (Haley et al 2004).

**Validity:** is the degree to which an instrument measures what it is supposed to measure. In this study review, the measures in the retrieved studies were evaluated for both content and construct validity (Williams et al 2007).

#### ABBREVIATIONS

APA:	Australian Physiotherapy Association
CSP:	Chartered Society of Physiotherapy
DOHMs:	Department Of Health and Medical Services
D/C:	Discharge
RH:	Rashid Hospital
RTA:	Road Traffic Accident
U.A.E:	United Arab of Emirates
WHO:	World Health Organization

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#### **CHAPTER 1**

#### INTRODUCTION

Trauma is the leading cause of death in the United States (Bener and Crundall 2005). The World Health Organization (World Health Organization 2001) statistics indicate that one million people die and between 15 and 20 million people are injured annually in Road Traffic Accidents (RTA) (Sankaran-Kutty et al 1998). RTA's is the second major cause of deaths in the UAE and generally cause more serious trauma. This is reflected in the greater numbers of fatal and serious injuries in UAE (7509 RTA's patients in 2005) than in the USA or UK (Bener and Crundall 2005).

Trauma patients are admitted to the hospital through the accident and emergency (A/E) departments, and then transferred to the trauma wards as inpatients. Physiotherapy is part of the trauma team who provides care for this patient population in the hospital. The role of physiotherapy is to help patients achieve readiness for discharge by restoring independence in ambulation and transfers (Oldmeadow et al 2002). Patient care can be optimized by clear and accurate documentation (Horner and Larmer 2006). Patient documentation is incorporated into the clinical decision-making process by clinicians (Australian Physiotherapy Association 2003).

In 1994 the Chartered Society of Physiotherapy in the United Kingdom, as part of a quality assurance initiative, indicated the growing importance of taking accurate tests and measurements within the patient's documentation (Horner and Larmer 2006). In order to decide appropriate treatment strategies patient assessment is an essential part of physiotherapy management. The purpose of assessment procedures is to gather data on the status of the patient at specific times and develop physiotherapy outcomes to establish the patient's level of function (O'Sullivan and Schmitz 1994). Thus, the progressive evaluation of physiotherapy treatment outcomes is an integral part of professional credibility (Australian Physiotherapy Association 2003).

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Internationally the physiotherapy profession has been actively involved in promoting the use of outcome measures (Horner and Larmer 2006). Therefore, the implementation of best practice in the clinical setting also requires the importance of the clinician monitoring patient progress using standard outcome measures, in order to demonstrate and reflect on the effectiveness of an intervention (Rothstein 2005). A health outcome measure has been described as a measure of health change, at a defined point in time, as a result of one or more health care processes (Akinpelu et al 2007).

Outcome measures are tools that enable the treating physiotherapist to undertake an evaluation of physiotherapy treatment (Australian Physiotherapy Association 2003). The majority of outcome measurement tools have been developed and validated for outpatient orthopedic patient populations (Donnelly and Carswell 2002). The choice of outcome measurement tools is based on the need for simple, inexpensive and efficient mechanisms for collecting standard information routinely on patient progress (Horner and Larmer 2006). Outcome measurement tools should be patient-centered where patients identify their most problematic areas of functioning (Binkley et al 1999). Another basic requirement of any outcome measurement tool is that it is reliable and valid for the target population (Donnelly and Carswell 2002). Therefore, adequate psychometric testing for outcome measurement tools is necessary to demonstrate the scale's usefulness in both clinical practice and research (Binkley et al 1999).

There are no gold standard criteria for assessing the psychometric properties of functional outcome measurement tools (Haley et al 2004). Therefore, one of the first steps to be taken is to validate an outcome measurement tool according to the needs of the target patient population, which should be reliable and valid for trauma inpatients. Since the available functional outcome measurement tools were not originally developed to provide a valid assessment for the functional level of trauma inpatients, the development and validation of a new functional outcome measurement tool for trauma inpatients population was required (Guermazi et al 2004). This would facilitate the use of standardized functional outcome measurement tools in clinical

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practice to monitor change of trauma in-patients' functional status over time (Horner and Larmer 2006). In addition, the type of functional items and scoring methods used in the available outcome measures applied in rehabilitation settings may not be appropriate for orthopaedic trauma inpatients (Guermazi et al 2004). Thus, the development of a new functional outcome measurement tool for orthopaedic trauma inpatients was warranted to assess and monitor the progress of the functional status of orthopaedic trauma inpatients (Haley et al 2004).

No single physical functional assessment instrument covers all areas of physical function (O'Sullivan and Schmitz 1994). Even items that appear to assess the same function may depend how the item is worded, be concerned with the different aspect of performance. Therefore, instrument should be chosen to match the specific needs of the clinician and the likely functional limitations of the clinical population served (O'Sullivan and Schmitz 1994).

The overall aim of this study was to develop a new functional outcome measurement tool that would yield reliable and valid functional measurements, and that would be appropriate for use as a clinical and research tool in orthopaedic trauma inpatients (Binkley et al 1999), taking into account the barriers identified for clinical implementation of outcome measurement tools. The following chapters report on the development and initial validation of a newly developed outcome measurement tool, the Functional Scale for trauma inpatients, including the assessment of the internal consistency reliability, sensitivity to change and floor and ceiling effects.

#### Objectives

The overall study objectives were:

- 1. To determine if an existing functional outcome measurement tool for trauma inpatients has been published.
- 2. To generate functional items for the construction of a new outcome measurement tool for trauma inpatients.
- 3. To construct a new outcome measurement tool for trauma inpatients

4. To assess elements of validity and reliability (face and content validity, response to change, internal consistency reliability and floor and ceiling effects) of the newly developed outcome measurement tool.

#### **CHAPTER 2**

#### SYSTEMATIC REVIEW

#### THE PSYCHOMETRIC PROPERTIES OF THE PHYSICAL FUNCTION OUTCOME MEASURES OF ACTIVITY LIMITATIONS IN ADULTS

#### 2.1 INTRODUCTION

In 1994, the Chartered Society of Physiotherapy in the United Kingdom, as part of a quality assurance initiative, indicated the growing importance of taking accurate tests and measurements within the patient's documentation (Horner and Larmer 2006). Deciding on the most appropriate treatment strategies for patient assessment is an essential part of physiotherapy management. The purpose of assessment procedures is to gather data on the status of the patient at specific times, to develop physiotherapy outcomes and to establish the patient's level of function (O'Sullivan and Schmitz 1994).Thus, the progressive evaluation of physiotherapy treatment outcomes is an integral part of professional credibility (Australian Physiotherapy Association 2003).

Internationally, the physiotherapy profession has been actively involved in promoting the use of outcome measures (Horner and Larmer 2006). As part of evidence-based practice and clinical decision-making processes, physiotherapists are required to assess the effectiveness of their interventions (Terwee et al 2007). The utilization of appropriate and high-quality outcome measures aid in this process (Rothstein 2005). For best practice in the clinical setting to be implemented, it is important for clinicians to monitor patient progress using standard outcome measures, in order to demonstrate and reflect on the effectiveness of an intervention (Rothstein 2005).

A health outcome measure has been described as a measure of health change, at a defined point in time, as a result of one or more health care processes (Akinpelu et al 2007). Specifically, physiotherapy outcome

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measures have been described as a scale utilized and interpreted by physical therapists (Australian Physiotherapy Association 2003). Outcome measures are tools that enable the treating physiotherapist to undertake an evaluation of physiotherapy treatment (Australian Physiotherapy Association 2003).

The choice of outcome measures is based on the need for a simple, inexpensive and efficient mechanism for collecting standard information routinely on patient progress (Horner and Larmer 2006). Currently the information being collected by physiotherapists is non-standardized, collected at variable time frames throughout the episode, and is usually handwritten in patient notes, which makes it inefficient and impractical for clinical benchmarking (O'Sullivan and Schmitz 1994).

A basic requirement of any outcome measurement is that it is reliable and valid (Donnelly and Carswell 2002). Therefore, one of the first steps to be taken is to validate an outcome measure according to the needs of the target patient population. For some variables that physiotherapists measure, this decision is rather straightforward, such as when we want to measure range of motion (ROM) or strength, as we have a fairly traditional set of tools to employ (O'Sullivan and Schmitz 1994).

However, for more abstract variables such as function and quality of life, the movement to outcome measurement has generated a vast set of questionnaires that can be applied in different situations (O'Sullivan and Schmitz 1994). Therefore, if physiotherapists intend to use an outcome measure for evaluation, the outcome measure's validity and ability to detect change in the patient's condition over time are important elements to consider (Portney and Watkins 2000). The use of patient-based instruments for assessment and treatment monitoring enables clinicians to detect and treat functional problems that may not have been picked up. They also promote shared decision-making and communication with patients (Williams et al 2007).

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#### 2.2 OBJECTIVES

The purpose of this systematic review was:

**A)** To present a comprehensive assessment of the quality of psychometric properties of self-report outcome measures for patients with traumatic neuro-musculoskeletal disorders. More specifically, these measures were evaluated and compared with respect to their psychometric properties based on the following criteria: (1) content validity; (2) construct validity; (3) internal consistency; (4) test–retest reliability; (5) responsiveness; (6) respondent burden (i.e. time to administer); and (7) administrator burden (i.e. ease of scoring).

**B)** To identify the items list of the physical function activity limitations from the included instruments. This should reflect areas that are important to patients who are unable to function during the acute hospital care as a result of traumatic neuro-musculoskeletal disorders.

#### 2.3 REVIEW METHOD

Prior to commencing this study, thirteen electronic databases (Pubmed, Proquest, Science Direct, Cochrane Library, Web of Science, Ebschohost, Journals Ovid, Psycho info, Sport Discus, Pedro, Cinahl, Scirus, Biomed Central) were searched to verify that there is no published systematic review that reports on the psychometric properties of the physical function self-report outcome measures of activity limitations in adults.

#### § Inclusion criteria for selection of studies

This systematic review sought descriptive studies that described the development process, scoring methods and contents of physical functional self-report outcome measures used in adults with traumatic neuromusculoskeletal disorders. The psychometric properties of the physical function self-report outcome measures of activity limitations in adults were evaluated. A language restraint was set and only papers published in Arabic or English and presented in full-text format were accepted. No limit was set on the publication date. The participants included male and female adults aged 16 years and older. Articles which reported on physical function as an outcome measure were included (The items of the outcome measure must be reflective of assessing the ability to perform activities of daily living). Articles in which the developments of the physical function self-report outcome measures of activity limitations in adults were appropriately designed by the authors were eligible for this review.

#### § Exclusion criteria for selection of studies

Articles were excluded if:

 (1) The sample population included conditions which were not a direct result of trauma injury (i.e. neuro-medical conditions), for example Cerebral Vascular Accidents, Multiple Sclerosis, neuropathies, etc. (Haley et al 2004).
 (2) Only the development of the measurement was reported and no other aspects of psychometric properties were measured or evaluated.

(3) The article's study design was randomized controlled trials (RCT's), or any other experimental study i.e. case studies, etc.

(4) The outcome measure did not focus on physical function of daily activities.

#### 2.3.1 Search strategies and method

Two independent reviewers searched thirteen electronic databases that were available at the Stellenbosch University Library between July and September 2007. The databases were Pubmed, Proquest, Science Direct, Cochrane Library, Web of Science, Ebschohost, Journals Ovid, Psycho info, Sport Discus, Pedro, Cinahl, Scirus, and Biomed Central. All databases were searched up to September 2007; this study took place between July 2007 and September 2007. No restriction was set on the publication date. The search was limited to full-text articles published in Arabic or English. MESH terms were used only in PUBMED and when applicable in other mentioned databases. The following keywords were used: *Development, Physical Function, self-report outcome measures, psychometric properties and activity limitation.* The following limits were applied to the mentioned databases: Humans, Male, Female, English, Arabic, and All Adult: 16 years and older. In addition, secondary searching (PEARLing) was performed on the reference lists of retrieved articles.

On including articles for this review, two reviewers selected the eligible articles by firstly screening all the possible titles, secondly reading the abstracts and, finally, reading the full text articles. The complete search procedure is depicted in figure 2.1.



Figure 2.1 Flowchart to demonstrate the selection of studies

#### 2.4 Methodological quality appraisal

#### 2.4.1 Quality assessment for psychometric properties of the Outcome Measures

To evaluate the quality of the psychometric properties of the identified outcome measurement instruments used in the eligible studies, we used a checklist that was modified by Williams et al (2007) (Appendix- L). The seven criteria of the checklist would give sufficient psychometric information pertaining to the identified outcome measurement instruments. The psychometric properties of the identified outcome measurement instruments were evaluated on the following criteria: (1) content validity; (2) construct validity; (3) internal consistency; (4) test–retest reliability; (5) responsiveness; (6) respondent burden and (7) administrative burden. The psychometric properties that were evaluated, the definitions of the psychometric properties and the criteria that were used to rate the psychometric attributes of the identified outcome measurement instruments are displayed in Appendix-L.

Each psychometric property was rated by the reviewers as follows:

"+" which was given a value of 1.0, indicated that adequate methods and results were used

"±" which was given a value of 0.5, demonstrated that doubtful methods and results were used

"-" was given a value of 0.0, indicated that inadequate methods and results were used

"?" which was given a value of 0.0 showed that no information was found.

With this scoring system, the highest possible score that an instrument could achieve was 7.0.

#### 2.5 RESULTS

#### 2.5.1 Search Results

The comprehensive search for descriptive studies reporting on the development process, scoring methods and contents of physical functional self-report outcome measures used in adults with traumatic neuromusculoskeletal disorders, yielded 317 hits. The results of the search are depicted in figure 2.2. An additional four articles (Dodds et al1993; Hobart and Thompson 2001; Binkley et al 1999 and Chatman et al 1997) were obtained after screening the reference lists of retrieved articles (PEARLing). Consequently, eight articles were included in this review (Gabel et al 2006; Jette et al 2005a; Jette et al 2005b; Haley et al 2004; Hobart and Thompson 2001; Binkley et al 1999; Chatman et al 1997; Dodds et al 1993). These articles dated from 1993 to 2006 and were conducted in the USA (4), Canada (2), United Kingdom (1), and Australia (1) (see table 2.1).





#### 2.5.2 General description of eligible studies

In order to provide a clear description of each study, specific data was extracted from each retained article and is depicted in table 2.1. The headings were validated by the second reviewer (QL). Extracted data was stored on a Microsoft Excel XP database.

#### • <u>Sample size</u>

The sample size in the selected studies ranged from 11,102 subjects (Dodds et al 1993) to 38 (Chatman et al 1997). The larger studies were conducted in USA (see table 2.1).

#### • <u>Age</u>

The ages of the participants ranged from 100 to 16 years. One article did not provide the ages of the sample participants (Jette et al 2005) (see table 2.1).

#### • <u>Gender</u>

Six of the eight articles indicated that both male and female adults participated in the included studies. Two studies did not mention the gender of the sample (Gabel et al 2006; Jette et al 2005). Females formed a larger portion of the sample populations (see table 2.1).

#### • <u>Setting of study</u>

Four of the eight studies were conducted in inpatient settings only (Jette et al 2005; Jette et al 2005; Dodds et al 1993; Hobart and Thompson 2001); two studies were conducted in in- and outpatient settings (Haley et al 2004; Gabel et al 2006) and two studies were conducted in outpatient settings only (Binkely et al 1999; Chatman et al 1997). Thus, 50% of studies were conducted in in- and outpatients' settings and 25% were conducted in in- and outpatients' setting (see table 2.1).

#### • <u>Types of Participants (conditions included)</u>

The studies eligible for this review were conducted on patients, who were diagnosed with traumatic neuro-musculoskeletal disorders,

including acute orthopedic trauma conditions such as fractures and dislocations, as well as severe soft tissue injuries caused by traumatic events. Common orthopedic traumatic injuries include femoral and tibial shaft fractures, acetabular and pelvic fractures, hand and upper extremity injuries, foot and ankle injuries, among many others. Polytraumatized patients are those unique individuals with numerous skeletal and other organ injury usually

caused by high energy traumatic events (Haley et al 2004) (see table 2.1).

#### • <u>Outcome measurement instruments</u>

Eight outcome measurement instruments were identified from the eight eligible studies, namely the **BI (PADL):** Bathel Index measure of physical dependence in Personal Activities of Daily Living; **ULFI**: upper limb functional index; **FIM (a)**: functional independence measure; **FIS**: functional independence staying; **AM-PAC**: activity measure for post acute care; **FIM (b)**: functional independence measure; **LEFS**: lower extremity functional scale; **PSFS**: patient specific functional scale (Table 2.1). These outcome measurement instruments were used to assess outcome measures in neuromusculoskeletal disorders in in- and outpatient settings.

#### Table 2.1Results summary

Study	Country	Outcome	Study Design	Range of	Gender	Samolo ciza	Types of Participants		Settings	
		measurement tools		Age		Jampie size	Neuro	musculoskeletal	çetiniğe	
Gabel et al 2006	Australia	ULFI: upper limb	Qualitative -	18 years and	not	130	With upper limb s	ymptoms under	Public health, private health	
		functional index	validity study	older	mentioned		medical or allied I	nealth management.	(IN and OUT)	
Jette et al 2005a	USA	FIM: functional	Retrospective	76.1- 76.6	37.6 male	7536	Neurological	Orthopedic	Skilled Nursing Facilities	
		independence	analysis	years					(IN)	
		measure								
Jette et al 2005b	USA	FIS: functional	Retrospective	not	not	7526	Neurological	Orthopedic	Skilled Nursing Facilities	
		independence	analysis	mentioned	mentioned				(IN)	
		staying								
Haley et al 2004	USA	AM-PAC: activity	Qualitative study	19 years and	58% female	477	Neurological	Musculoskeletal	Post acute care settings	
		measure for post	(several focus	older			(e.g. brain	(e.g., fractures,	104 homes care, 195	
		acute care	groups, Factor				injury, spinal	joint	inpatient, 90 transitional	
			analysis) -				cord injury)	replacements,	cares, 88 ambulatory	
			validity study					orthopedic )	services	
									(IN and OUT)	
Hobart and	United	BI (PADL):Barthel	Qualitative study	mean=	55-58%	844	Spinal cord	Muscle disorder	National Hospital	
Thompson 2001	Kingdom	Index measure of	(using the	46.8 - 47	female		disorder		(IN)	
		physical dependence	Acceptability of				Peripheral			
		in Personal Activities	the patients) -				nerve			
		of Daily Living	validity study							

IN: inpatients, OUT: outpatients.

#### Table 2.1 (continue) Results summary

Study	Country	Outcome measurement	Study Design	Range of	Gender	Sample	Type of participants		Setting
		tools		Age		size	Neuro	musculoskeletal	
	<u> </u>					107			51 · · ·
Binkley et al	Canada	LEFS: lower extremity	Qualitative study	16 – 44	46 male,	107		Нір	Physical
1999		functional scale	(Clinician and	years	58 female,			Muscle strain 1, Knee/thigh/leg	therapy clinics
			patients surveys) –		3 missing			Ligament sprain 22, Muscle strain 5	(OUT)
			validity study					Meniscal injury 10, Patellofemoral pain 6	
								Fracture 3, Total joint replacement 8	
								Nonspecific sprain/strain 12	
								Foot/ankle	
								Ligament sprain 9, Muscle strain 1	
								Fracture 8, Nonspecific sprain/strain 2	
Chatman et al	Canada	PSFS: patient specific	Qualitative study	19-84	20 women	38		Knee dysfunction. Patellofemoral pain 12	Physical
1997		functional scale	(patients interview)	years	and 18			Total knee arthroplasty 4	therapy clinics
			- validity study		men			Medial meniscectomy/meniscal repair 4	(OUT)
								Collateral ligament sprain 3	
								Anterior cruciate ligament reconstruction 3	
								Arthroscopic loose-body debridement 2	
Dodds et al	USA	FIM: functional	Qualitative - validity	65 years	51% male	11,102	Brain	Orthopedic condition back pain,	General
1993		independence measure	study				injury		rehabilitation
							,spinal		inpatients
							cord		(IN)
							injury		

IN: inpatients, OUT: outpatients.

#### 2.5.3 Functional activity items generation

The eight eligible reviewed articles revealed eight outcome measurement tools. Functional activity items identified in each outcome measurement tool were extracted (Appendix- M). The identified items ranged between 41 and five items in each eligible study (41 items in Haley et al 2004, 25 items in Gabel et al 2006, 20 items in Binkley et al 1999, 18 items in Jette et al 2005a, six items in Dodds et al 1993 and five items in Hobart and Thompson 2001). Consequently, a total of 115 functional items were generated and were used in the construction of the newly developed outcome measurement tool for trauma inpatients (Chapter 4).

## 2.5.4 Critical appraisal of the quality of the outcome measurement tools used in eligible studies

Of the eight studies that met the eligibility criteria, five instruments achieved a score of 4.0 or higher. Overall, the highest quality ratings were given to the Gabel et al 2006 and Binkley et al 1999 (6.0 out of 0.7). Chatman et al 1997 were received (5.5 out of 7.0), and Hobart and Thompson 2001 given (5.0 out of 7.0). Haley et al 2004 (0.4 out of 0.7), but Jette et al 2005a; Jette et al 2005b and Dodds et al 1993 achieved a quality rating of 2.5, 2.5 and 2.0 out of 7.0 (see table 2.2).

#### 1) Content validity

Five out of eight instruments used in the eligible studies had information about content validity; four instruments achieved a rating of "+" adequate method and result used in their content validity (Gabel et al 2006; Chatman et al 1997; Binkley et al 1999; Haley et al 2004). Only one instrument (Hobart and Thompson 2001) achieved a rating of " $\pm$ " doubtful method and result used. In the other three instruments they were given a rating of "?" no information found about content validity (see table 2.2).

#### 2) Construct validity

All instruments used in the eligible studies had a "+" rating value in their constructs validity (see table 2.2).

#### 3) Internal consistency reliability

Only three instruments used in the eligible studies (Haley et al 2004; Jette et al 2005a; Binkley et al 1999) received a "+" quality rating for internal consistency (adequate method and result used in the internal consistency). Four instruments (Binkley et al 1999; Gabel et al 2006; Hobart and Thompson 2001; Dodds et al 1993) were given a "±" quality rating (doubtful method and result used for internal consistency). No internal consistency information was found in two instruments used in the eligible studies (Chatman et al 1997 and Jette et al 2005b) (see table 2.2).

#### 4) Test-retest reliability

Test-retest reliability was evaluated in four of the instruments used in the eligible studies (Gabel et al 2006; Hobart and Thompson 2001; Binkley et al 1999; Chatman et al 1997). They received "+" rating for test-retest reliability (adequate method and result used). No test-retest reliability information was reported in four studies; (Haley et al 2004; Jette et al 2005a; Jette et al 2005b; Dodds et al 1993). Consequently they were given a quality rating of "?" (No information found) (see table2.2).

#### 5) Responsiveness

Responsiveness was examined in six instruments used in the eligible studies (Gabel et al 2006; Chatman et al 1997; Binkley et al 1999; Hobart and Thompson 2001; Jette et al 2005b; Dodds et al 1993). They received a rating of "+" (adequate methods and results used). The remaining two instruments (Haley et al 2004; Jette et al 2005a) scored "?" for quality rating (no information found) (see table 2.2).

#### 6) Time to Administer/Respondent Burden

Information on the time to administer was found in only two instruments used in the eligible studies (Gabel et al 2006; Chatman et al 1997) received a rating "+" (complete the measure less than 10 minutes). The remaining six instruments scored "?" for quality rating (No information found) (see table 2.2).

#### 7) Ease of Scoring/Administrative Burden

Scoring information was found for seven out of eight instruments used in the eligible studies. (Haley et al 2004) was given a quality rating of "+" (easy; summing up of items). Hobart and Thompson 2001 achieved "+"(easy; summing up of items). Binkley et al 1999 received a rating of "+" (easy; summing up of items). Chatman et al 1997 received "±" (moderate; simple formula). Gabel et al 2006 received "±"(moderate; simple formula). Jette et al 2005a received "±" (moderate; simple formula). Jette et al 2005b scored "±"(moderate; simple formula). One instrument received "?" for quality rating (Dodds et al 1993) (No information found in the scoring method) (see table 2.2).

Authors	instruments	Content validity	Construct validity	Internal consistency	Test-retest reliability	Responsiveness	Time to administer	Ease of scoring	Total value =7.0
Gabel et al 2006	ULFI	+ 1.0	+ 1.0	± 0.5	+ 1.0	+ 1.0	+ 1.0	± 0.5	6.0
Jette et al 2005a	FIM	? 0.0	+ 1.0	+ 1.0	? 0.0	? 0.0	? 0.0	± 0.5	2.5
Jette et al 2005b	FIS	? 0.0	+ 1.0	? 0.0	? 0.0	+ 1.0	? 0.0	± 0.5	2.5
Haley et al 2004	AM- PAC	+ 1.0	+ 1.0	+ 1.0	? 0.0	? 0.0	? 0.0	+ 1.0	4.0
Hobart and Thompson 2001	ВІ	± 0.5	+ 1.0	± 0.5	+ 1.0	+ 1.0	? 0.0	+ 1.0	5.0
Binkley et al 1999	LEFS	+ 1.0	+ 1.0	+ 1.0	+ 1.0	+ 1.0	? 0.0	+ 1.0	6.0
Chatman et al 1997	PSFS	+ 1.0	+ 1.0	? 0.0	+ 1.0	+ 1.0	+ 1.0	± 0.5	5.5
Dodds et al 1993	FIM	? 0.0	+ 1.0	± 0.5	? 0.0	± 0.5	? 0.0	? 0.0	2.0

Table 2.2Summary of methodological critical appraisal

FIS: functional independence staying, AM-PAC: activity measure for post acute care, BI (PADL): Barthel Index measure of physical dependence in Personal Activities of Daily Living, LEFS: lower extremity functional scale. ("+" = 1.0, indicated that adequate methods and results were used, "±" = 0.5, demonstrated that doubtful methods and results were used, "-" = 0.0, indicated that inadequate methods and results were used, "?" = 0.0, showed that no information was found).

## 2.5.5 Description of methods used in eligible studies to assess the psychometric properties of outcome measurement instruments

#### 1) Content Validity

Five out of the eight eligible articles reported on content validity of the outcome measurement instruments (Gabel et al 2006; Haley et al 2004; Binkley et al 1999; Hobart and Thompson 2001 and Chatman et al 1997). Three of them used the generation and reduction method to establish content validity (Gabel et al 2006; Haley et al 2004; Binkley et al 1999). The data in these three articles were analyzed qualitatively (see table 2.3). Hobart and Thompson 2001 used the selection of the best items method for the content validity (see table 2.3).

Author	Methods used	Data analysis	Items list
Gabel et al	1)Generation: review of the literature using the	Qualitative analysis	Satisfactory
2006	electronic databases		25 items
	2) Reduction: survey of physiotherapy, occupational		
	therapy, and hand therapy clinicians and researchers		
	3) Exclusion: patients feedback ( Specificity to UL) and		
	Condensing similar items		
Haley et al	1) Generation: comprehensive review of ICF activities	Qualitative analysis	41 items
2004	relevant to persons in post acute care settings	several focus groups	
	2) Reduction: a review by 10 measurement, content	Factor analysis	
	experts, and suggestions solicited from several focus		
	groups of individuals with disabilities (patient's		
	interview)		
Hobart and	Selection of the best items from the original 10 items of	Qualitative analysis	Best 5 items
Thompson	Barthel index.	using the	
2001	Selection procedure by	Acceptability of the	
	1)Corrected item total correlations	patients	
	2) Effect sizes.		
Binkley et al	1) Generation: Reviewing existing questionnaires as	Qualitative analysis	Final 20-item
1999	well as surveying clinicians and patients.	Clinician and patients	questionnaire
	2) Reduction: grouping similar activities, the 22 items	surveys	
	reviewed by three orthopedic physical therapists and		
	given the opportunity to add additional items.		
Chatman et	Patients feedback ( patients interview)	Qualitative analysis of	No items
al 1997		patients interview	specified

#### Table 2.3 Content validity
#### 2) Construct validity

All eligible articles reported on how the construct validity of the instruments was assessed. Four of the eight studies used the hypotheses testing method with different ways of analyzing the data (Jette et al 2005b; Binkley et al 1999; Chatman et al 1997; Dodds et al 1993). Two studies used convergent and discriminate methods in their construct validity (Jette et al 2005a; Hobart and Thompson 2001) with different ways of data analysis. Three studies reported that factor analysis was used in their data analysis (Jette et al 2005a; Haley et al 2004; Binkley et al 1999). The table below illustrates summarized details for each identified instrument (see table 2.4).

Table 2.4	Summary of	i construct	validity
-----------	------------	-------------	----------

Authors	Data analysis and the Results
Gabel et al	1) Known group method applied: t-test was applied: exceeded 0.95 level supporting the construct
2006	validity of ULFI and DASH.
	2)response severity order: 20% increments of each remarked reference
	3) Distribution analysis: No "ceiling" or "floor" effect found for either the ULFI or the DASH.
Jette et al	1) Item level analysis had similar mean, SD's, response frequencies, not highly skewed), the all
2005a	response choices were endorsed for each item, with exception of 2 items in mobility domains (walking
	or wheelchair mobility and stairs) skewed to right (= 2.27, 7.83), SD=.50
	2) Factor analysis The results were: item fairly well correlated with a factor ( $\geq$ .40) 4 factors 73.4% of
	variance in functional independence : ADL(low level of physical function) = 24.5%, Sphincter = 12.2%,
	Mobility(high level of physical function)= 8.9%, Executive = 27.7%
	3) Convergent validity and Discriminate validity: Spearman P:
	ADL = 0.5880 , Mobility= 0.23- 0.71, Executive = 0.78-0.88, Sphincter= 0.84
	4) Stage ceiling and floor effects Less than 20% of patient's measurements show ceiling or floor
	effects Floor effect for sphincter = 34.4% & mobility= 43.1% ,Ceiling effect for executive= 26.7%
Jette et al	Hypothesis testing: Chi-squared test to determine if a difference existed between two levels of
2005b	medical complexity: Differences existed in the FIS the FIS scores (p<0.001)
	Logistic regression analysis: to determine the odds of being discharge: Odds ratios for discharge
	higher for patients higher in patients with higher FIS scores in sphincter function (1.32-1.76), mobility
	(1.93-4.66) and executive function (1.5-4.15)
Haley et al	1) Item internal consistency: Items correlation was above 0.40
2004	2) Item discriminate validity: Discriminate validity values was lower than item internal consistency-
	satisfactory discriminate validity
	3) Scale level reliability: Scaling success percentage was 100% for all 3 AM-PAC scales.
	4) Rasch analysis: Supported uni-dimensionality in each of the activity domains.
	5) Differential item functioning: Most items functioned similarly across diagnostic groups, severity or
	demographic characteristics.

#### Table 2.4(continue) Summary of construct validity

Authors	Data analysis and the Results
Hobart and Thompson 2001	The short 5 item Barthel Index correlated well with the 10 item version (0.93-0.96)
Binkley et al 1999	Pearson correlation applied to assess construct validity: LEFS correlated with F36: -physical function domain: r=80 -physical component domain: r=0.64
Chatman et al 1997	Pearson correlation applied to assess construct validity: PSFS correlated with SF36 -Physical function domain: r=0.34 (initial); 0.49 (follow-up) -Bodily pain domain: r=0.12 (initial); 0.4 (follow-up)
Dodds et al 1993	Hypothesized that FIM will vary with age, co-morbidity, discharge destination and impairment severity. FIM discriminated differences in age, co-morbidity and discharge desalination (p<0.0, 05)

#### 3) Internal consistency reliability

No internal consistency information was found in Chatman et al (1997) and Jette et al (2005) b. Only three of the eight retrieved instruments used in the eligible studies used Cronbach's alpha and factor analysis for internal consistency reliability (Binkley et al 1999; Haley et al 2004; Jette et al 2005a). The remaining three retrieved instruments used in the eligible studies were used only Cronbach's alpha in their internal consistency (Gabel et al 2006; Hobart and Thompson 2001; Binkley et al 1999; Dodds et al 1993). Cronbach's alpha was equal or above 0.70. Factor analysis was equal or above 0.40 (see table 2.5).

Table 2.5 Summary	of internal consistency
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Authors	Methods used and Data analysis	Results
Gabel et al 2006	Cronbach's alpha	α= 0.89
Jette et al 2005a	Cronbach's alpha and factor analysis	α=.70 ≥ .40
Haley et al 2004	Cronbach's alpha and factor analysis	α= 0.90- 0.95 ≥ 0.50
Hobart and Thompson 2001	Cronbach's alpha	α=0.80
Binkley et al1999	Cronbach's alpha and factor analysis	α=.96 0.44 to 0.86
Dodds et al 1993	Cronbach's alpha	Admission $\alpha$ =0.93 Discharge $\alpha$ =0.95

#### 4) Test-retest reliability

Test-retest reliability was evaluated in four of the eight identified instruments used in the eligible studies. An Intra-class correlation coefficient (ICC) was used to estimate test-retest reliability with 95% CI's and time intervals was presented in three articles (Gabel et al 2006; Binkley et al 1999; Chatman et al 1997). No test-retest reliability information was reported in the remaining 4 studies (Jette et al 2005a; Jette et al 2005b; Haley et al 2004; Dodds et al 1993) (see table 2.6).

Authors	Methods used and Data analysis	Results
Gabel et al 2006	Type 2,1 intra-class correlation coefficients	0.96 with 95%
	Time interval: 48-hours	Cl's
Hobart and Thompson	Bland and Altman method	(0.89 - 0.92) with
2001		95% Cl's
Binkley et al 1999	Type 2, 1 intra-class correlation coefficient	(0.86 - 0.94)
	Time interval: 24-48-hours	with 90% Cl's
Chatman et al 1997	Type 2,1 intra-class correlation coefficients	0.84
	Time interval: 48 -72 hours	with 95% Cl's

#### Table 2.6 Test retest reliability summary

#### 5) Responsiveness

Responsiveness was evaluated in six of the eight identified instruments used in the eligible studies. The six articles used hypothesis testing methods to evaluate the responsiveness (Gabel et al 2006; Jette et al 2005b; Hobart and Thompson 2001; Binkley et al 1999; Chatman et al 1997; Dodds et al 1993). No information was found regarding responsiveness evaluation in two of the eight identified instruments (Haley et al 2004; Jette et al 2005a) (see table 2.7).

Authors	Data analysis and results
Gabel et al 2006	Hypothesis: require that some sort of change has occurred and can be verified in some way so that a patient's score on any SROM can be tested against this change to determine if a true response has occurred.
	Standard response mean (SRM)=1.87 and effect size (ES)=1.28
Jette et al 2005b	Hypothesis: the discharge FIS scores would be greater than admission FIS scores and that a greater percentage of patients would be functioning at higher stages at discharge than at admission. Analyzed data by using Wilcoxon signed –rank test P<.001
Hobart and	Determined by using calculating effect sizes from admission and discharge total scores.
Thompson 2001	(effect size=mean change score divided by SD of admission score) Effect sizes of the four and five item Barthel Index was the same as the 10 item version ES= 0.70 - 0.71
Binkley et al1999	<ul> <li>Hypothesis: there would be a correlation between (1) the 1-week LEFS and SF-36 scores and 1-week prognostic ratings, and (2) the 3-weeks LEFS and SF-36 scores and prognostic ratings.</li> <li>1) Spearman Rank-order correlation (t=1.24, 1.67, 3.05, 2.13)</li> <li>2) prognostic rating of change results (p=.106, .05, .002, .019)</li> <li>3) MCID Minimal Clinical Important Difference approximately 9 scales points.</li> <li>ROC; Receiver operating characteristic =.76</li> <li>Clinician survey= 10 scale points</li> <li>sensitivity &amp; specificity= .81 and .70</li> </ul>
Chatman et al1997	<ul> <li>Hypothesis: Patients ability to perform easy functional activities will improve more than the ability to perform difficult functional activities</li> <li>1) Global Rating of Change Scale (GRC) score, the PSFS correlation coefficient was greater (P&lt;0.002) than the coefficients for the eight SF-36 dimensions.</li> <li>2) ANOVA was used to test the within-patient analysis ("activity difficulty" P&lt;0.001, P&lt;0.05 at both points in time. "time X activity difficulty" &lt;0.026)</li> </ul>
Dodds et al 1993	Temporal changes between admission and discharge were assessed using paired t- tests: significant improvement between admission and discharge (p<0.005)

#### 6) Time to Administer/Respondent Burden

Two of the eight instruments used in the eligible studies reported information about the respondent burden (Gabel et al 2006; Chatman et al 1997). Subsequently, scoring times reflected the tool format and the completion time reflected the tool length. In Gabel et al (2006), one page required on average 2.5 minutes and 20 seconds to score without computational aids. In Chatman et al (1997), therapists required approximately 4 minutes to administer the questionnaire. Chatman et al (1997) results show that "easier activity" scores were greater than the "harder activity" scores at both initial and follow-up assessments. It is evident that the amount of change for the "easier activity".

#### 7) Ease of Scoring/Administrative Burden

Scoring information was found in seven of the eight identified instruments used in the eligible studies. No information was found regarding scoring methods in only one study (Dodds et al 1993) (see table 2.8).

Authors	Tools	Scoring Methods												
Gabel et al	ULFI	Numerical type of scale (0- 10)												
2006		0	1	2	3	4	1	5	6	7	7	8	9	10
		(no	rmal p	re-injur	y sta	tus)						(wo	orst possi	ble)
Jette et al	FIM		Numerical type of scale (1- 7)											
2005a		1		2		3		4		5		(	6	7
		(tota	al depe	endenc	e)							(total in	depende	nce)
Jette et al	FIS					Num	erical	type	of sca	le (1-	7)			
2005b		1=	able t	o provid	de le	ss thar	n 25%	of effe	ort req	uired	to ac	complis	h the tas	sks
			4	= contr	ibute	975%	of effc	rt nee	ded to	acco	mplis	h the ta	.sks.	
			7:	= contri	bute	100%	of eff	ort nee	ded to	acco	mpli	sh the ta	asks.	
Haley et al	AM-		Ordinal or rank-order scale											
2004	PAC					(sl	light, r	nodera	ate, se	vere)				
Hobart and	BI		Mix	(Nume	erical	type	of sca	le and	d Ordi	nal o	r ran	k-order	scale)	
Thompson		(	)			1				2			3	
2001		Major help (1 or 2 Minor help (verbal or In						Independent						
		Unable people, physical) physical)												
Binkley et al	LEFS	Numerical type of scale (0- 4)												
1999		0		1			:	2			3			4
		(low	functio	on level	)							(high	function	level)
Chatman et	PSFS	Numerical type of scale(0- 10)												
al 1997		0	1	2		3	4	5		6	7	8	9	10
		(unat	ole to p	perform	ı activ	vity)				(able	to pe	rform a	ctivity at	same
		level as before injury or problem)												

 Table 2.8
 Summary of scoring methods

ULFI: upper limb functional index, FIM: functional independence measure, FIS: functional independence staying, AM-PAC: activity measure for post acute care, BI (PADL): measure of physical dependence in Personal Activities of Daily Living, LEFS: lower extremity functional scale.

#### 2.6 SUMMARY OF FINDINGS

#### Main finding of systematic review

This systematic review evaluated eight eligible articles which provided information on eight outcome measurement instruments. The majority of the outcome measurement tools reviewed were not tested or evaluated in orthopedic trauma inpatients during the acute hospital period, which is usually a relatively short period compared to outpatient rehabilitation periods (Binkley et al 1999). On the contrary, these outcome measures were administered to patients with central nervous system dysfunction in rehabilitation settings where the inpatient phase is usually longer. In addition, many of functional activity items identified in the systematic review were not appropriate for the use in trauma inpatients. For instance, the 'Lower Extremity Functional Scale' (Binkley et al 1999) was administered to outpatients with lower extremity musculoskeletal dysfunction, but most of the functional activities such as "squatting" listed in this outcome measure are inappropriate for trauma inpatients. Another example identified was that the 'Functional Independence Measure' (Jette et al 2005) was administered in skilled nursing facilities and comprised comprehensive assessment of other functional independence i.e. sphincter management, executive function, etc.

#### Other findings

- 1. A list of 115 activity items from the eight included outcome measurement instruments was produced (Appendix-M).
- 2. None of the identified instruments demonstrated satisfactory results for all psychometric properties.
- 3. None of the outcome measures that were identified in this review were tested with patients who had orthopedic trauma injury at acute hospital stay (e.g. short period of stay). The majority of the instruments used in the eligible studies were tested in various settings such as in a rehabilitation setting where patients with spinal cord injuries or head injuries were treated over a long period of stay.
- 4. One of the main findings of this review was that construct validity was available for all identified instruments.

- 5. In this review, hypotheses for responsiveness testing were stated in six measurement instruments out of the eight (Jette et al 2005b; Binkley et al 1999; Gabel et al 2006; Hobart and Thompson 2001; Chatman et al 1997;Dodds et al 1993).
- For test-retest reliability, an ICC of 0.70 or above was regarded as adequate for group comparisons of four measurement instruments (Gabel et al 2006; Chatman et al 1997; Binkley et al 1999; Hobart and Thompson 2001). Gabel et al 2006 achieved the highest value of an ICC which was 0.96. The time interval range was between 24 and 48 hours (Binkley et al 1999), 48 hours (Gabel et al 2006) and between 48 -72 hours (Chatman et al 1997) with 95% CI.
- 7. Only two measures (Gabel et al 2006; Chatman et al 1997) stated the administration time.

Two major limitations of this systematic review were:

- We used a modified version of the checklist developed by Williams et al 2007 to evaluate the quality of the psychometric properties of self-reported outcome measures for traumatic neuro-musculoskeletal disorders. Since there are no standardized criteria to evaluate the quality of self-reported heath measurement instruments, the criteria that were used to determine the quality of the identified outcome measures may be disputed. Guidelines are needed to set standards and define the criteria by which self-report physical function outcome measures should be assessed.
- Bias in choosing articles to evaluate may be a problem in systematic reviews. However, in an effort to minimize selection bias, when reviewing the articles we had a second and third reviewer who acted as independent evaluators when consensus could not be reached.

**Recommendation:** This systematic review indicates that there is a need for further studies to determine the psychometric properties of physical function

outcome measurement tools. It is also recommended that studies which utilize outcome measurement tools thoroughly assess the psychometric properties of the tools and report the methods of the assessments accurately.

#### 2.7 CONCLUSION

The results of this systematic review revealed that there are currently no functional outcome measurement tools appropriate for trauma inpatients. The systematic review did, however, provide psychometric information on available functional outcome measurement instruments for individuals with traumatic neuro-musculoskeletal disorders, and in addition contributed to the generation of a functional activity items list. This list of 115 functional activity items were reduced and included in the development of a new outcome measurement tool for trauma inpatients.

#### **CHAPTER 3**

## FUNCTIONAL ITEM GENERATION AND REDUCTION FOR THE DRAFT OUTCOME MEASURE

The overall aim of this project is to develop an outcome measurement tool, namely the Functional Scale for trauma inpatients. The process to develop the Functional Scale outcome measurement tool for trauma inpatients is divided into the following four main phases (see figure 3.1):

**Phase 1: Item generation:** a process of reviewing existing questionnaires by conducting a systematic review and patient interviews.

**Phase 2: Item reduction and exclusion:** removal of duplications and redundancies and selecting the more relevant items by surveying clinicians.

**Phase 3: Construction and validation of the draft outcome measure**: condensing similar items, construction and validation of the tool using an expert panel review and sample target population.

Phase 4: Validation of the new Functional scale for trauma inpatients (Chapter 5).

This chapter presents the study objectives, study setting, sample description and data collection procedures of Phase 1 (Item generation from patient interviews-qualitative study) and Phase 2 (Item reduction and exclusion) (see figure 3.1).



# Fig. 3.1 Representation of the process to develop a Functional Scale for trauma inpatients

## 3.1 PHASE 1: ITEM GENERATION

The objective of this phase is to generate the list of functional activities to be included in the proposed outcome measure for trauma inpatients. Two methods were selected in order to generate an appropriate list of functional outcomes for trauma inpatients. Firstly, a systematic review of the literature was conducted and is presented in Chapter 2. The list of items generated from the eligible papers reviewed in Chapter 2 is presented in Appendix-M. Secondly, functional items were generated by conducting a qualitative study to explore patient appropriate functional outcomes from a patient's perspective to generate items for the new outcome measure.

# QUALITATIVE STUDY: Patient interviews to generate list of functional outcomes

Two groups of patients were interviewed as limited information from the patients was obtained during the first round of interviews. The objective of the interviews for the first group of 25 patients was to gain insight into the important functional limitations associated with their trauma injuries. The second group consisted of ten patients and the objective was to obtain more detailed information about patient's perspectives related to their functional limitations. The same qualitative methodology was followed for both groups of patients.

#### 3.2 METHODOLOGY

This study took place between December 2007 and January 2008.

#### 3.2.1 Study design

A qualitative study incorporating semi-structured individual interviews was conducted.

## 3.2.2 Study setting

The study was conducted in the trauma wards of Rashid Hospital (RH) in Dubai, United Arab Emirates (UAE) (see appendix-I for Permission from Ethical committee in the hospital). RH was established 30 years ago and it is a member of the Department of Health and Medical Services (DOHMS). RH is the main emergency, trauma, critical care and ambulatory center in U.A.E. (Government of Dubai's Copyright Act 2007). The emergency department of RH registers about 400 new patients daily. RH has the capacity for 595 beds and 399 of these comprise the trauma wards, thus patients are discharged as soon as possible due to the limited bed capacity (Government of Dubai's Copyright Act 2007).

#### 3.2.3 Sample description

- The inclusion criteria were:
- 1. Male and/or female inpatients with the primary diagnosis of trauma.
- 2. Adult (age 17 years and above) trauma inpatients.
- 3. Patients who were proficient in the English or Arabic languages.
  - The exclusion criteria were:
- Inpatients with head and/or spinal/psychological trauma as cognitive deficits may hinder them from participating in the qualitative study (Jette et al 2005).
- 2. Inpatients with upper extremity injuries only (because it would not affect their ambulation. Ambulation is viewed as a primary outcome for trauma inpatients) (Gabel et al 2006).

#### 3.2.4 Sampling procedure and sample size

Convenience sampling was applied to collect data from the first 35 trauma inpatients admitted and referred to physiotherapy services in RH. The following patient types were recruited on a consecutive basis, which involves recruiting all patients who meet the inclusion and exclusion criteria as they become available (Portney and Watkins 2000):

- A. Patients with trauma to the lower extremity.
- B. Patients with trauma to lower extremity and upper extremity.
- C. Patients with pelvic trauma.
- D. Patients with any combination of the above injuries.

#### 3.2.5 Interview question design and procedure

#### • Interview questions design

A set of draft interview questions were developed in English by the principal researcher in December 2007, and have been reviewed and evaluated by two psychologists, who each have had at least 10 years of working experience. Their roles were to assist in sentence structuring in order to collect the most crucial information from the interviewees. Meetings with the psychologists were held at the Psychology Department at RH and lasted for about an hour. The interview questions were designed in a semi-structured format to allow the interviewees free independent input to specify the areas of their functional activities difficulty (Hogston, R.1995). This also facilitated the data collection procedure and saved the interviewees and researcher time during the data collection time (interview). The draft interview questions were then revised and reviewed during the meeting with the psychologists until consensus was reached.

The semi-structured interview questions included six questions for the first group and seven questions for the second group of the interviewees (see table 3.1 and table 3.2), and focused on whether the interviewee experienced any functional difficulty during his/ her stay in the hospital after the trauma injury was sustained.

#### Table 3.1 The semi-structured interview questions for the first group of interviewees

1,	What is your occupation?
2.	How has your trauma injury affected your occupation?
3.	Identify up to five important usual activities that you are unable to do or are having difficulty with as a result
	of your problem.
4,	Which physical/ functional activities from the above list are you currently able to do?
5.	Which physical/ functional activities from the above list are currently extremely difficult to do which you
	need to be able to perform by discharge?
6.	Do you have any comment or question?

#### Table 3.2 The semi-structured interview questions for the second group of interviewees

1. Identify up to 5 important activities that you are unable to do or are having difficulty with because of your
problem?
2. How much difficulty do you currently have with the mentioned activities?
Response choices included in a table below ( $\checkmark$ or X) :
(not at all, a little, somewhat, a lot, completely, can't do)
3. Do you think the trauma injury is affecting your regular daily physical functional activities?
4. In what way is your trauma injury affecting your daily functional activities?
5. What extent of physical functional activities would you like to achieve by discharge?
6. If you will be able toat discharge time will you be satisfied? If the answer No, please clarify.
7. Do you have any other questions or comments?

#### 3.2.6 Data collection

#### <u>Room setup</u>

All interviews were recorded using a digital tape voice recorder. The interviews were conducted in a small comfortable room at the trauma ward, at a mutually convenient time. The use of a tape recorder ensured that attention could be given unreservedly to the patients, thus guaranteeing accuracy of data collection, maximizing the flow of information and allowing the researcher to return to the raw data later on for verification.

Written informed consent for the interview was obtained from the eligible subjects/patients prior to the interview (see appendix-B). Prior to the interview, a data capture sheet was administered to collect the subject's name, age, gender, occupation, cause of trauma, diagnosis, length of stay and functional status at admission. Each interview lasted for about 20 minutes.

• Process (groupings and questions)

Numbered folders consisting of data collection forms were compiled. Each folder contained the data collection guideline, demographic forms, written informed consent forms, observer note forms and semi-structured interview questions for the first group of interviewees (see table 3.1) and second group of interviewees (see table 3.2).

<u>Research team (functions and duties)</u>

The interviews were conducted in English with individual patients, face-to-face by the principal researcher. The principal researcher has been working as a physiotherapist with trauma inpatients for the past 4 years. However, he has no personal experience of being a trauma inpatient and therefore was less

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likely to influence the interview process. The researcher is a staff member of RH, and as physiotherapist at the physiotherapy department could have influenced the responses from the patients. This was limited by creating an atmosphere of comfort and trust, emphasizing that the researcher wanted to listen and learn from the interviewees, and to prove the trustworthiness of data collection.

#### • Responsibilities of the research team

The principal researcher arranged the room, obtained consent, administered the data collection forms and conducted all the interviews. An independent observer (physiotherapist aid) was present at all interviews and his role was to take notes during the interviews to enable validity checks between observer notes and interview transcripts.

#### 3.2.7 Data transcription

The recorded interviews were downloaded from the digital voice recorder to a computer hard-drive. Two copies of the interview were made on audio compact discs. The researcher transcribed the interview data for analysis (see Appendix-N for an example of a transcript).

#### 3.2.8 Data validation

The observer notes were compared with the key themes for consistency, and the researchers' interpretations of the key themes were then compared for consistency in transcript interpretation. The transcripts were re-read and codes were assigned to functional items by the principal researcher and validated by the project supervisors.

#### 3.2.9 Data analysis

It was envisaged that a content analysis approached would be followed to analyze the qualitative information. However, due to the nature of the data of the first group of patients, the data was analyzed by frequency count. The data of the second group of patients were analyzed using a content analysis approach (Hancock, B. 2002).

## 3.3 RESULTS

• Interviewees' profile

The demographic information of the first and second groups of patients is presented in Table 3.3.

Table 3.3Sample descriptions

Diagnosis	Occupation	Age	Gender
First group			
1. # Rt. Tibia	Policeman	25	М
2. # Lt. Ankle	Businessman	35	М
3. # Rt. Ankle	Carpenter	30	М
4. # Rt. Inter-trochantric femur	Worker	29	М
5. # Lt. Tibia, # Lt. radius	Accountant	31	М
6. # Lt. Ankle	Security guard	45	М
7. # Lt. Tibia	Flight operator	29	М
8. # Bilateral tibia	Server	37	М
9. # Rt. Tibia, Lt. knee soft tissue Injury	Store keeper	29	М
10. # Bilateral tibia	Driver	35	М
11. # Lt. Calcanium	Engineer	26	М
12. # Lt. knee soft tissue injury	House wife	40	F
13. # Lt distal femur, Lt. Sacrum.	Officer at airport	35	F
14. # Neck of Rt. Femur	House wife	49	F
15. # Dislocation Rt. Ankle	Sales manager	61	М
16. # Lt. Inter-trochantric femur	Accountant	24	М
17. Rt. Patellar tendon partial tear.	Policeman	26	М
18. #Rt. Pubic Rami	Computer operator	32	М
19. # Rt. Neck of femur	Motorbike delivery	40	М
20. # Rt. Tibial Platu	Builder	30	М
21. # Lt. tibia &fibula	Student	21	М
22. # Rt. Patella	police-man	30	М
23. # Rt. Acetabulam	Police-man	38	М
24. # Rt. Femur	Student	18	М
25. # Lt.Tibia	Student	19	М
Second group			
26. # Rt. Radius, Lt. Calcaneum	Nurse	25	F
27. # Rt. Acetabulam, Rt. Shoulder	Sales-man	19	М
28. # Lt. Femur	Retired	65	М
29. # Rt. Femur	Driver	26	М
30. #Lt. Tibia , Fibula	Student	22	М
31. # Rt. Acetabulam, Lt.femur	Officer	34	М
32. # Rt. Acetabulam, Lt. hand	Businessman	28	М
33. # Rt. Femur	Worker	26	М
34. # Rt. Ankle, Lt. Acetabulam	Businessman	31	М
35. # Lt. Femur, Lt. Clavicle	Worker	31	М

LT: Left, RT: Right, #: Fracture, M: Male, F: Female.

#### • Functional items with which the most difficulty was experienced

Table 3.4 illustrates the frequency count of functional activities nominated by the sample with which the most difficulty was experienced. A total of 21 functional activities were nominated by the subjects and the most frequent functional activity with which the most difficulty was experienced was "walking" (85.7 %). "Wearing shoes, going out of house, motor bike driving and shopping" was only nominated by 2.8 % of the subjects as being difficult to accomplish (see table 3.4).

	First group	Second group	Total	Percentag
Function activities items	25 subjects	10 subjects	subjects=35	
1. Walking	22 R	8 R	30	85.7 %
2. Toileting	18 R	5 R	23	65.7 %
3. Showering	10 R	5 R	15	42.8 %
4. Wheelchair transfer	4 R	6 R	10	28.5 %
5. Sitting	8 R	1 R	9	25.7 %
6. Working	2 R	7 R	9	25.7 %
7 Getting out of bed	8 R	0 R	8	22.8 %
8. Standing	5 R	2 R	7	20.0 %
9. Driving	4 R	3 R	7	20.0 %
10. Rolling in bed	5 R	0 R	5	14.2 %
11. Bathing	5 R	0 R	5	14.2 %
12. Dressing	2 R	2 R	4	11.4 %
13. Eating	0 R	3 R	3	8.5 %
14. Praying	2 R	1 R	3	8.5 %
15. Sleeping	0 R	2 R	2	5.7 %
16. Reaching	0 R	2 R	2	5.7 %
17. Climbing stairs	2 R	0 R	2	5.7 %
18. Wear shoes	1 R	0 R	1	2.8 %
19. Motor bike drive	1 R	0 R	1	2.8 %
20. Shopping	1 R	0 R	1	2.8 %
21. Go out of house	1 R	0 R	1	2.8 %
Total items =21	18 items	13 items		

Table 3.4	Interviewees'	functional	items response
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R: patients' response

<u>Functional information obtained by second group of patients</u>

Quotations have been used as it was a accurate illustration of what interviewees said specifically about the category being described below (Hancock, B. 2002).

## 1) Walking activities

The majority of the interviewee patients had difficulty with walking activities as their most critical functional limitation. It was the first choice for them regarding the most difficult functional activity and prohibited them from being discharged from the hospital as soon as possible. The responses were as follow:

- "Oh, really, walking is the most difficult thing to me".
- "I can't walk obviously because of my foot fracture".
- "I can't walk alone".
- "To walk by using crutches or walking-frame, better than to be staying in the hospital".

## 2) Wheelchair transfer / Getting out of bed

In the event that the patient would not be ambulant, a wheelchair may have been the second means of mobility, which evidently may have lead to earlier discharge. The responses pertaining to wheelchair mobility (including bed-towheelchair transfer) were as follow:

- "If I'm using the wheelchair, I will be satisfied".
- "I need help in transferring from bed onto wheelchair".

## 3) Roll in bed

In changing position frequently for comfort (e.g. rolling over in bed) the patients' responses were as follows:

- "I can't turn in bed; I am just lying on bed most of the day".
- "I can't move out of bed, because of my both legs injury".

## 4) Toileting

The following patient responses were obtained regarding transferring to and from a toilet:

- "I have a lot of difficulty in using the toilet".
- "I can't go to the toilet, when I go to the toilet which is the most important thing I need a lot of help from the others".

## 5) Showering / Bathing

Difficulty pertaining to washing and drying the lower body and /or the upper body were reported as follows:

- "Washing myself has been very difficult".
- "In the first two weeks, I couldn't take a shower alone".

## 6) Working / Car or Motor bike drive / Shopping /Go out of house/ Praying

Regular daily activities (i.e. usual work, social contact, school activities, usual hobbies, recreational or sporting activities etc.) were expressed as functional limitations in the following manner:

- "I can't go to work".
- "I can't do anything with my leg".
- "Praying has also mostly affected".
- "I can't go to the university, definitely can't go to a restaurant".
- "I can't drive my car to go to the office".
- "I think about my family how they will survive, because I can't work now".
- "I need a month to go back to work".
- "If I stay in bed for three weeks, then all my life will change".

## 7) Sitting / Standing

Difficulty in standing and sitting was also expressed as functional limitations and examples to support this are illustrated below;

- "Sitting or standing for a long period of time causes pain of my leg".
- "I can't do what I use to do before, like standing for a long time".

#### 8) Dressing/ Wear shoes

Functional limitations to dressing were expressed as follows;

- "Also, to dress myself is difficult somewhat, but still I can manage my upper part ".
- "I can't dress myself like before".

## 9) Eating

Limitations when eating and /or using utensils (e.g. knife, fork, and spoon) were reported as follows:

- "I can't eat; I can't have my breakfast on my own like before".
- "In the first week I could not eat, somebody else had to feed me"

## 10)Reaching

Reaching for objects placed away from you or reaching overhead while standing (e.g. pulling a light cord while standing), received the follow response:

• "To reach an object around me, I need to walk to reach that, but I can't walk".

## 3.4 SUMMARY OF PHASE 1

- Walking was deemed the functional activity with which most patients experienced difficulty in accomplishing.
- Most patients felt that if they could walk they would be discharged from the hospital sooner.
- Most patients would have been happy to use a wheelchair as it would have meant that they would have been discharged earlier.
- 21 functional activity items were generated from the collated results of the patient interviews.

#### 3.5 PHASE 2: ITEM REDUCTION

The following phase describes the item reduction processes for reducing the functional items lists generated from the patient interviews and systematic review (136 Functional items were generated from the results of the systematic review (Chapter 2), and from the results of the patient interviews (phase 1) collectively). Section A; reports the item reduction of the results generated in the patient interviews, and section B; reports the methodology used to reduce the functional items generated from the results of the systematic review.

#### A: Item reduction of results generated from patient interviews

The results of the two groups of patient interviews yielded 21 items of functional limitations relevant to trauma inpatients, which were reduced to 12 functional items after the principle researcher reviewed the list. Duplicates and redundancies were removed and a total of 12 functional items were retained.

#### B: Item reduction of results generated from systematic review

This section presents the methodology applied to reduce the number of items generated from the systematic review, by removing the duplicates and redundancies. A panel of clinicians (physiotherapists) who have experience in working in the trauma wards were recruited to identify duplicates and redundancies, in order to reduce the number of items to be included in the proposed outcome measurement tool for trauma inpatients.

#### 3.5.1 Study design

The Nominal Group Technique (NGT) (Claxton et al 1980; Gabel et 2006; Binkley et al 1999; Haley et al 2004) was used to review the list of functional items generated and identify the most relevant activities to be assessed, based on the working experience of the recruited physiotherapists in the trauma wards.

## 3.5.2 <u>Study setting</u>

The physiotherapists reviewed the list of functional items in a seminar room, in RH, Dubai- UAE.

## 3.5.3 Ethical considerations

The Human Research Ethics Committee of Stellenbosch University (Appendix–F) and RH research ethics committee granted ethical approval for this research (Appendix-H, I) and informed consent was gained from all individuals who participated (Appendix–K).

## 3.5.4 <u>Recruitment of the Participants</u>

An accessible sample of five physiotherapists with a minimum of five years of working experience in the trauma wards, RH-Dubai-UAE were invited to participate in the study in February 2008 (Appendix-K).

## 3.5.5 The objectives of the study were:

- To review the list of functional items and remove duplicates and redundant documents.
- To nominate additional functional items deemed important for trauma inpatients.

## 3.5.6 <u>Procedure</u>

The principal researcher arranged and chaired a meeting with the physiotherapists invited to participate in the study. A demographic data capturing sheet was completed by the participating physiotherapists. Informed consent was obtained (Appendix-K) from the participants and the objectives were explained to the physiotherapists.

The list of 115 functional items generated from the results of the systematic review, was provided to each participant at the beginning of the meeting (Appendix-M). The physiotherapists took about 15 minutes to review the list of functional items. A consensus approach was followed, where items were removed from the list when at least four of the physiotherapists agreed. The meeting lasted approximately one hour.

#### 3.5.7 Data analysis

Data were analyzed quantitatively using frequencies and percentages.

#### 3.6 RESULTS

• Demographics information

All five physiotherapists who were invited to partake in this study, agreed to participate. The mean age was 39.2 (SD 7.75) and the mean years of working experience was 10.4 (SD 4.27) (see table 3.7).

Name and Staff No. Qualifications	Age	Position experience
1)PT 1 (113355) BSc.PT, MBA	29Y	5 years Physical therapist
2)PT 2 (113437) BSc.PT, Msc.PT	35Y	8 years Physical therapist
3)PT3 (105029) BSc.PT, Msc.PT	39Y	10 years Physical therapist
4)PT4 (109231) BSc.PT, Msc.PT	44Y	13 years Physical therapist
5)PT5 (106751) BSc.PT, MBA	49Y	16 years Physical therapist

 Table 3.7
 Physiotherapists' demographic information

PT: Physiotherapist, BSc: Bachelor, Msc: Master of science, MBA: Master business administration, Y: Year.

#### • List of functional items after clinician review

No additional items were identified from the clinicians' survey. The clinicians identified a list of 79 appropriate functional items for inclusion in the new outcome measure for trauma inpatients (Appendix-O). The principal researcher reviewed the items identified from the clinicians with respect to applicability to trauma inpatients. Seventy nine items from the systematic review and 12 items from the patients' interviews appropriate to trauma inpatients were identified. However, after further removal of duplicates, redundancies and inappropriate items, the final number of items was 29 functional activity items appropriate for construction of the proposed Functional Scale outcome measurement tool for trauma inpatients.

## 3.7 CHAPTER SUMMARY POINTS

- 115 items generated from systematic review reduced to 79 items by the panel of clinicians.
- 21 items generated from patients' interviews and were reduced to 12 items relevant to trauma inpatients after review by the principal research.
- After further removal of redundancies, duplicates and inappropriate items, 29 activity items were found appropriate for inclusion in the development of a new outcome measurement tool, the *Functional Scale for trauma inpatients*.

#### **CHAPTER 4**

# CONSTRUCTION AND VALIDATION OF THE DRAFT OUTCOME MEASURE FOR TRAUMA INPATIENTS

This chapter presents the construction and content validation of the new developed functional outcome measure for orthopedic trauma inpatients. The chapter is divided into the following three sections:

- A) Construction of the draft outcome measure
- B) Validation of the draft outcome measure
- C) Patient validation study

#### 4.1 A) Construction of the draft outcome measure

The principal researcher and research supervisors reviewed the list of functional items generated in the previous chapter. Removal of duplications and redundancies of the items based on the specificity to the orthopedic trauma inpatients and condensing similar items by grouping similar activities (Gabel et al 2006) revealed 29 functional activities items (Chapter 3).

Essentially, a core set of 29 functional activities items relevant to trauma inpatients (see table 4.1), were compiled and classified according to the International Classification of Function (ICF) and validated to develop a new functional outcome measurement tool for trauma inpatients. This study was conducted between April 2008 and May 2008

Authors	Tools	Items after clinicians' survey	Total
Jette et al 2005a	FIM	ADL:         1. Bathing.         2. Dressing upper body, dressing lower body.         3. Toileting.         Mobility:         1. Bed, chair, wheelchair transfer.         2. Toilet transfer, tub or shower transfer.         3. Walking or wheelchair mobility.	6 ITEMS
Haley et al 2004	AM- PAC	<ul> <li>Personal care &amp;instrumental: <ol> <li>Washing and drying your lower body while giving yourself a sponge bath, Washing and drying your hands</li> <li>Eating Using a spoon or fork to eat a meal. Drinking from a large full glass with no straw.</li> <li>Reach for objects next to bed.</li> <li>Shift in bed.</li> <li>Rolling over in bed.</li> </ol> </li> <li>Physical &amp;movement: <ol> <li>Getting up off of the floor (e.g. if you fell)</li> <li>Bending from a standing position to pick up something</li> <li>Reaching overhead while standing, as if to pull a light cord</li> <li>Carrying a large object, requiring 2 hands while walking</li> <li>Sitting down on and standing up from an armless straight chair</li> <li>Sitting out of bed.</li> </ol> </li> <li>Open cupboard door while standing.</li> <li>Open and close room door</li> </ul>	14 ITEMS
Hobart, Thompson, 2001	BI	<ol> <li>Going up and down stairs</li> <li>Transferring to and from a toilet</li> <li>Transfer from wheel chair to bed and return</li> </ol>	3 ITEMS
Binkley et al 1999	LEFS	<ol> <li>Walking between rooms.</li> <li>Walking on even ground</li> <li>Walking on uneven ground.</li> <li>Making turns while Walking</li> <li>Getting into or out of a car</li> <li>walk in the same room</li> </ol>	6 ITEMS
			ITEMS

#### Table 4.1A list of combined 29 items

FIM: functional independence measure, AM-PAC: activity measure for post acute care, BI (PADL): measure of physical dependence in Personal Activities of Daily Living, LEFS: lower extremity functional scale

#### 4.1.1 Classification of functional outcomes

The ICF (Impairment, Activity and Participation Restriction) (World Health Organization 2001) provides a conceptual framework and classification system for developing comprehensive outcome instruments for acute care (Haley et al 2004). The ICF attempts to provide an improved, internationally accepted taxonomy of function and disability with standard concepts and terminology (World Health Organization 2001).

An initial step in using the ICF to guide outcomes assessment is to determine the major domains of activity that are most critical to acute care services, and to develop a pool of activity items to examine each activity domain. In the ICF framework, the "activity" dimension is defined as the execution of specific tasks or actions by an individual (Gabel et al 2006).

To create the newly developed outcome measure items list, the principal researcher identified items based on the "Activity" domain of the ICF (World Health Organization 2001). Since the sample consists of individuals from hospital setting, we did not include items from 2 ICF domains (Impairment and Participation), as these domains were not relevant to trauma inpatients. We categorized the core set of 29 functional activity items according to the ICF's three functional categories: 7 items in "bed-activities", 18 items in "out of bed activities" and 4 items in "ADL's activities" (see table 4.2).

Table 4.2	List of 29 Items of the new developed outcome measure
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A) Bed activities (7 items)
1. Roll over in bed
2. Reach for objects next to bed
3. Shift in bed ( side to side or up and down)
4. Sit up from lying on bed
5. Maintain sitting on bed(e.g., long sitting)
6. Maintain sitting over edge of bed
7. Change position from edge of bed to sitting or lying in bed
B) OUT of bed activities (18 items)
8. Transfer from bed to wheelchair
9. Transfer from wheelchair to bed
10. Use (self-propelling) wheelchair
11. Stand up form bed / chair
12. Sit down from standing
13. Maintain standing position
14. Use arms while standing (example: open cupboard door while standing)
15. Bend from standing to pick up something on the floor
16. Walk short distance (e.g. around bed, walk in the same room)
17. Walk long distance (e.g. in corridor/ passage, between rooms)
18. Open and close doors
19. Walk on even ground/surfaces
20. Walk on uneven ground (e.g. on grass, incline surface, outside of the hospital)
21. Turn/change direction during walking
22. Get into or out of a car
23. Ascend stairs
24. Descend stairs
25. Get-up from the floor (e.g. if you fell)
C) Activity of Daily Living (Personal care activities) (4 items)
26. Able to use toilet
27. Able to wash and dry your body (upper and /or lower body)
28. Putting on and taking off clothes
29. Eat and drink from a full glass with no straw

## 4.1.2 Scoring Method

The scoring methods identified in Chapter 2 were reviewed for appropriateness by the principal researcher and research supervisors. The short duration of the inpatient hospital period, relatively fast progression to perform inpatient appropriate functional activities and assistance required to perform functional activities were the main factors considered when the scoring methods were reviewed. The scoring method deemed most appropriate for trauma inpatients is presented in Table 4.3

#### Table 4.3 Scoring proposed method

	Scoring	Method	
3= Unable	2= major help	1= minor help	0= independent

#### 4.2 B) Validation of the draft outcome measure

# 4.2.1 The experts panel validation of the new Functional Scale for trauma inpatients

#### 1. Recruitment of Expert Committee Participants

An expert committee had been assembled by the coordinator (researcher) in the beginning of April 2008. The Committee comprises the Outcome measures developer(Canada), Outcome measures researcher (South Africa), Quality Specialist (Canada), Quality clinical educator professional (UK) and Quality master in nursing (Australia) (see table 4.4). The potential individuals identified received an invitation letter via e-mail (Appendix -J) from the study coordinator to invite them to participate on this committee. All the potential individuals who received the email letter agreed to participate on this committee. All committee members were experts in the quality outcome measures design field.

## 2. The Expert Committee Objectives

The objectives of this committee were to:

- Review the functional activity items generated from the systematic review and patients' interview.
- To decide whether further functional activity items should be added to the new tool.

#### 3. Method

Consensus methodology was used to solve the discrepancies and to determine the required changes to produce the new Functional Scale outcome measure for trauma inpatients (Haley et al 2004; Gabel et al 2006).

## 4. Procedure

## <u>Responsibilities of Expert Committee</u>

The responsibilities of the expert committee were to examine and evaluate the following aspects: construct validity, content validity, scoring method (best score=0), and face validity of the new Functional Scale outcome measure for trauma inpatients.

#### • <u>Responsibilities of the researcher</u>

Responsibilities of the researcher were to e-mail the invitation letter to the experts panel members, write the experts reports and document suggested changes after consensus was reached, provide the committee participants with a soft copy of the newly developed Functional Scale outcome measure for trauma inpatients, collect the final changes made after consensus were reached and develop a soft copy of the pre-final new Functional Scale outcome measure for trauma inpatients. In addition, present the results of the pre-validation study to the pilot of trauma inpatients sample to review and produce the final new Functional Scale outcome measure for trauma inpatients, which was then validated.

The expert panel received a letter from the researcher inviting them to assist with the review of the new Functional Scale outcome measure for trauma inpatients in April 2008, and he gave them a period of two weeks for their feedback and comments (Appendix-J). This letter was circulated via E-mail to all experts' panel members by the principal researcher. All the potential individuals who received the invitation letter, agreed to participate in this panel.

#### 5. Results

#### • <u>Demographics</u>

The five expert volunteers, who participated in this review, were the outcome measures developer Prof. Paul Stratford and four experts in this field. The members' details are presented in table 4.4.

Table 4.4	Experts p	anel members	who partic	pated were

Name	Position	Contacts
Paul Stratford	Outcome measure developer(Canada)	stratford@mcmaster.ca
Ina Diener	Outcome measures researcher(SA)	idiener@icon.co.za
Evelina Dunlap	Quality Specialist manager (Canada)	edunlap@dohms.gov.ae
Merlinda Malubay	Quality Clinical Educador (UK)	MMEvangelista@ dohms.gov.ae
Nataline De Vos	Quality master in nursing (Australia)	ndevos@dohms.gov.ae

#### • Comments/suggestions from expert panel

A consensus was reached by all experts panel member, They commented on the scoring type which we proposed (scoring method (best score=0), was as a good way of scoring, and they didn't mention any additional comments on the construct validity, content validity, face validity, or any further suggestions or comments in the final new Functional Scale for trauma inpatients.

#### 4.3 C) Patient validation study

The principal researcher piloted the final new Functional Scale for trauma inpatients on a group of five trauma inpatients. The objectives of this pilot study were to ascertain if there were any difficulties in understanding the questions, scoring method and time to complete the final Functional Scale for trauma inpatients.

## 4.3.1 Study setting

The pilot study was conducted at the trauma wards, in RH, Dubai-UAE.

## 4.3.2 Sampling procedure and size

Convenience sampling was applied to collect data from a range of adult (17 years and above) trauma inpatients eligible for this study. Five patients were recruited according to the following four groups (Gabel et al 2006; Haley et al 2004):

- 1) Group A: inpatients with trauma to the lower extremity.
- 2) Group B: inpatients with trauma to lower extremity and upper extremity.
- 3) Group C: inpatients with trauma in pelvis.
- 4) Group D: inpatients with mixed injuries involving trauma to any combination of the above injuries.

## 4.3.3 Sample description

• Inclusion criteria

The following inclusion criteria were applied to the sample population

- 1. Male and/or female inpatients with the primary diagnosis of trauma (Chapter 2).
- 2. Adult (age 17 years and above) trauma inpatients (Chapter 2).
- 3. Inpatients who were able to understand English questions and respond verbally in Arabic or English.
- 4. Eligible inpatients that have been referred for physiotherapy intervention from trauma physicians (Chapter 2).
- Exclusion criteria

The following exclusion criteria were applied to the sample population:

- 1. Inpatients with head and/or spinal trauma (which would affect their ability to attain functional improvement) (Haley et al 2004).
- 2. Inpatients with upper extremity injury only (because it would not affect their ability of ambulation activities) (Gabel et al 2006).

## 4.3.4 Instrumentation and Procedures

The first five patients that complied with the inclusion criteria were invited to participate and written consent was obtained. This study took place between April 2008 and May 2008 The Functional Scale for trauma inpatients was attached with a checklist of questions and was conducted only once (see table 4.5). The trauma inpatients were asked to complete the checklist questions after they finished the Functional Scale for trauma inpatients questionnaire. The results of the pilot study regarding any changes suggested by the patients would be considered based on a minimum of three patients reporting difficulty of understanding any specific section of the Functional Scale for trauma inpatients.

Table 4.5

The pilot study checklist questions

1) Is the <u>duration of time</u> to complete the Functional Scale for
trauma inpatients acceptable?
2) Are the Functional Scale for trauma inpatients outcome
measure questions understandable and clear enough?
3) Did you understand the Functional Scale for trauma inpatients
scoring?
4) Does any of the questionnaire's content infringe on your
privacy?

The practical implementation of the Functional Scale for trauma inpatients was measured based on the changes of trauma inpatients functional activity during their acute period of stay in the hospital.

#### 4.4 Results

## • <u>Difficulty in understanding the Functional Scale for trauma inpatients</u> <u>questions</u>

The Functional Scale for trauma inpatients questions were understandable and clear enough for the trauma inpatients. All the five pilot study patients understood the Functional Scale for trauma inpatients questions (see table 4.6).

## • Functional Scale for trauma inpatients scoring method

No one of the trauma inpatients in the pilot study had any problem with understanding the scoring method which was used (see table 4.6).

#### • Time to complete the Functional Scale for trauma inpatients

Three out of the five patients reported that the time allocated to complete the Functional Scale for trauma inpatients questions was too long. The questionnaire could not be shortened as it was in the development phase (see table 4.6).

• Does any of the questionnaire's content infringe on patients privacy?

Questionnaire's content didn't infringe on the trauma inpatients' privacy (see table 4.6).

Patient's checklist questions	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
1) Is the <u>duration of time</u> to complete the Functional Scale for trauma inpatients acceptable?	NO	YES	YES	NO	NO
2) Are the Functional Scale for trauma inpatients outcome measure questions <u>understandable and clear</u> enough?	YES	YES	YES	YES	YES
3) Did you understand the Functional Scale for trauma inpatients <u>scoring</u> ?	YES	YES	YES	YES	YES
4) Does any of the questionnaire's content infringe on your privacy?	NO	NO	NO	NO	NO

Table 4.6The patient's checklist questions and answers

#### • The areas of functional difficulty

Functional Scale for trauma inpatients reflected areas that were important to patients who were unable to function, during the acute hospital care as Traumatic Neuro-Musculoskeletal Disorders (see table 4.7).

	Bed activities	Out of bed activities	ADL activities
Patient 1	3, <b>6</b> ,7	15,17,25	<b>26</b> ,27,28
Patient 2	2,6	<b>17</b> ,20	<b>26</b> ,27
Patient 3	1,5, <b>6</b>	13,14,15	<b>26</b> ,28
Patient 4	1,2,3	8,9,10	<b>26</b> ,27,28
Patient 5	4, <b>6,</b> 7	<b>13</b> ,23, <b>25</b>	<b>26</b> ,27,28
Most difficult activity item	6	13, 15, 17, 25	26

 Table 4.7
 Most difficult functional activities

Item (6): Maintain sitting over edge of bed, item (26): Able to use toilet, item (13): Maintain standing position, item (15): Bend from standing to pick up something on the floor, item (17): Walk long distance (e.g. in corridor/ passage, between rooms), items (25): Get-up from the floor (e.g. if you fell).

The best total score in the pilot study was 34 out of total 87, and the worst score was 79 out of total 87, with a variety of trauma inpatients conditions, injuries, gender, age and with a different staying period of time in the hospital. In the 'bed' activities the best score was 1 for patient 2 and the worst score was 19 for patient 4. For 'Out of bed' activities the best score was 28 for patient 2 and the worst score was 52 for patient 4. But in the 'ADL' activities the best score was 3 for patient 5 and the worst score was 8 for patient 4 (see table 4.8).

Table 4.8 Pilot study scoring results

	Bed	OUT of bed	ADL	Best	Worst	TOTAL
	activities	activities	activities	score	score	= 87
Patient 1	8	34	4			46
Patient 2	1	28	5	N		34
Patient 3	7	39	4			50
Patient 4	19	52	8		N	79
Patient 5	11	41	3			55

#### 4.5 Chapter summary points

- A final number of 29 functional activity items were included in the new developed outcome measurement tool, the Functional Scale for trauma inpatients.
- Consensus was achieved from the expert panel members regarding the content and construct validity of the new outcome measurement tool, the Functional Scale for trauma inpatients.
- The pilot study results indicated that the Functional Scale for trauma inpatients was well understood by a sample of five trauma inpatients.
- Preliminary pilot study results, based on the patients' responses, showed that Functional Scale for trauma inpatients may able to detect change over time.

## **CHAPTER 5**

# VALIDATION OF THE NEW FUNCTIONAL SCALE FOR TRAUMA INPATIENTS

This chapter reports on the methodology and results to validate the Functional Scale for Trauma Inpatients.

#### 5.1 AIM

The aim of the validation study was to determine if the newly developed Functional Scale for Trauma Inpatients is valid and reliable for the trauma inpatients population in UAE.

## 5.2 STUDY OBJECTIVES

The specific objectives of the study were to determine:

- The internal consistency reliability of the Functional Scale for Trauma Inpatients.
- The validity (responsiveness to change and floor and ceiling effects) of the Functional Scale for Trauma Inpatients.

## 5.3 METHODOLOGY

#### 5.3.1 Study design

A validation study to measure the responsiveness to change and internal consistency reliability of Functional Scale for trauma inpatients.

#### Hypotheses

The following hypotheses were tested:

• The alternative hypotheses for Internal Consistency: The internal consistency between items will at least be 0.7 to be regarded as good (Gabel et al 2006; Jette et al 2005; Haley et al 2004 and Binkley et al 1999).

- The alternative hypothesis for Responsiveness to Change: There will be a significant difference in the average scores of Functional Scale for trauma patients over three repeated administrations during the inpatient period (Binkley et al 1999).
- The alternative hypothesis for Ceiling and Floor effects: No more than 20% of patient responses must be at the highest or lowest level of the scale over three repeated administrations of the Functional Scale for trauma inpatients (Jette et al 2005).

## 5.3.2 Setting

The same study setting was used in both the reliability and validity testing studies. Data collection took place in trauma wards at RH in Dubai, UAE. RH has the largest Trauma Inpatient Physiotherapy Department in Dubai (Government of Dubai's Copyright Act 2007). This study took place between May 2008 and July 2008

## 5.3.3 Sampling procedure and sample size

Consecutive sampling of new admissions to the trauma wards was applied. A sample size of 100 patients was selected according to the following four groups (Gabel et al 2006; Haley et al 2004):

- 5) Group A: inpatients with trauma to the lower extremity.
- 6) Group B: inpatients with trauma to lower extremity and upper extremity.
- 7) Group C: inpatients with trauma in pelvis.
- 8) Group D: inpatients with mixed injuries involving trauma to any combination of the above injuries.

## 5.3.4 Sample description

• Inclusion criteria

The following inclusion criteria were applied to the sample population:

- 5. Male and/or female inpatients with the primary diagnosis of trauma (Chapter 2).
- 6. Adult (age 17 years and above) trauma inpatients (Chapter 2).
- 7. Trauma inpatients who were able to understand English questions and respond verbally in Arabic or English (Chapter 2).
- Eligible trauma inpatients that were referred for physiotherapy intervention from trauma physicians (Chatman et al 1997; Dodds et al 1993).
- Exclusion criteria

The following exclusion criteria were applied to the sample population:

- Inpatients with head and/or spinal trauma (which would affect their ability to attain functional improvement) (Jette et al 2005).
- Inpatients with upper extremity injury only (because it would not affect their ambulation activity ability) (Gabel et al 2006).

## 5.3.5 Instrumentation

The Functional Scale for trauma inpatients (developed in Chapter 4) served as the primary instrument. The instructions on how to administer the scale and the scoring process is described in detail in Chapter 4.

## 5.3.6 Clinicians' responsibilities

The responsibilities of the therapists' were to identify eligible patients, obtain consent, administer the scale, and to record the assessment date.

## 5.3.7 Researcher's responsibilities

Responsibilities of the researcher were to coordinate the data collection procedure and to develop and provide the clinicians with colour-coded hard copies (white sheet for the initial evaluation, green colour sheets for the follow up and the rose colour sheets for the discharge). The researcher collected the completed Functional Scale for trauma inpatients forms, once the patients were discharged from hospital.

## 5.3.8 Data collection procedures

Data was collected between May and July 2008.

## • Clinician training

Physiotherapy clinicians working in the trauma unit acted as research assistants by administering the scales to eligible patients. Training was provided to these physiotherapists by the principle researcher to ensure that a standard protocol was followed in administering the scale. To simulate realistic clinical conditions and in light of ease and simplicity of administration, special training included reading the Functional Scale for trauma inpatients script and clarifying the process of data collection to the clinicians. The Functional Scale for trauma inpatients was completed by patients, and the clinicians only assisted when clarification was required.

## • Preparation of data collection forms

Numbered packets consisting of data collection forms were created. Each packet contained data collection guidelines, a consent form (Appendix-C), a demographic form, three copies of Functional Scale for trauma inpatients in three different colours (white colour for the initial assessment, green colour for follow up and rose colour for discharge note). Packets were distributed to the clinicians. The colour-coded data collection sheets helped the therapists to identify the target sheet and facilitate their follow-up and filing procedures easily.

## • <u>The initial assessment</u>

The Functional Scale for trauma inpatients was completed prior to physical examination. Clinicians explained the aim of this study and administered the Functional Scale for trauma inpatients. Patients were instructed to complete all sections. Patients took about five minutes to complete the Functional Scale for trauma inpatients.

A total score was determined by summing the responses. Trauma inpatients scored their ability to perform the functional activity as follows; 3= unable (completely can't do), 2= Major help (1 or 2 people, physical support), 1= Minor help (a little - somewhat verbal or physical support) and 0= independent

(Doesn't need help at all, but may use an aid—for example; stick, crutches etc.) Total sum of individual scores: Best score=0 and Worst score=87.

# • <u>The first follow-up</u>

Twenty-four to 48 hours after the first administration of the Functional Scale for trauma inpatients, the same clinician administered the Functional Scale for trauma inpatients to the same trauma inpatient. They enquired if there were any activities that the patients were unable to do or were having difficulty with because of their injuries. The Functional Scale for trauma inpatients was then administered in the same way as for the first evaluation.

# • <u>The second follow-up (Discharge)</u>

The same procedure of re-administering the Functional Scale for trauma inpatients was followed at discharge.

# 5.4 ETHICAL CONSIDERATIONS

This study was conducted according to internationally accepted ethical standards and guidelines. The approval of the Committee for Human Research at Stellenbosch University was obtained (Appendix-F).

- The study was conducted in the UAE: a letter was sent to Rashid hospital management seeking permission to conduct the study (Appendix-H). In addition, approval from the Health Sciences/Research Development in Dubai, UAE was sought (Appendix-I).
- Informed consent was obtained from each subject (Appendix-C).
- Subjects' names were replaced by coding numbers to keep subjects' information confidential.
- Results were handled confidentially and were only made available to specific subjects, referring medical practitioners and physiotherapists.
- Subjects were measured separately in order to maintain privacy.

#### 5.5 DATA ANALYSIS

All data was entered into MS Excel spreadsheet. Data analysis was conducted using Statistica version 7. Descriptive statistics were used to describe the study population in terms of demography, disease characteristics and score distributions.

**5.5.1 Internal consistency reliability** was investigated by evaluating the correlation between each item of the Functional Scale for trauma inpatients at baseline and the score of the whole Functional Scale for trauma inpatients using the Cronbach's  $\alpha$ . With this approach, the degree of homogeneity of the items in the Functional Scale for trauma inpatients' baseline was evaluated. A Cronbach alpha of 0.7 was deemed as an acceptable level of internal consistency (Haley et al 2004).

**5.5.2** In this study, the **sensitivity to change validity** of Functional Scale for trauma inpatients was assessed using one-way analysis of variance. ANOVA was used to assess for significant (p=0.01) between the admission, follow-up and discharge mean scores.

**5.5.3 Ceiling and floor effects** for the Functional Scale for trauma inpatients' measurements at admission and discharge were not present if more than 20% of patient's measurements demonstrated ceiling or floor effects i.e. scores of at least 20% of the patients must be at the extreme low or high end of the Functional Scale for trauma inpatients at admission and discharge.

## 5.6 RESULTS

#### 5.6.1 Demographic Data Results

#### • Gender

88% of the total sample (n=100) trauma inpatients were male (see figure 5.1).



Fig 5.1 Percentage of the patients' gender

• Age

Of total 100 trauma inpatients sample, the range of age was between 17 years to 60 years old with mean age=34.75, median=32.0 and the standard deviation= 14.46 (see Figure5.2).



Fig 5.2 Patients' age

### • Groups of inclusion

63% of the total sample included Group A (1): inpatients with trauma to the lower extremity; 19% included Group B (2): inpatients with trauma to lower extremity and upper extremity; 10% included Group C (3): inpatients with trauma in pelvis and 8% included Group D (4): inpatients with mixed injuries involving trauma to any combination of the above injuries (see Figure 5.3).



Fig 5.3 Percentage of inclusion Groups

## • Duration of hospital stay

The duration of trauma inpatients stay in the hospital was between 4-14 days with mean=  $7.96\pm2.80$  (figure 5.4).



5.6.2 Internal Consistency Reliability

Cronbach's  $\alpha$  level ranged between 0.76-0.97, which is high internal consistency reliability (see table 5.1).

Table 5.1	Cronbach's a result
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Functional Scale for trauma inpatients activity domains	Admission	Follow up	Discharge
A) Bed activities (7 items)	α =0.89	α =0.87	α =0.78
B) OUT of bed activities (18 items)	α =0.97	α =0.96	α = <b>0.</b> 97
C) ADL (Personal care) activities (4 items)	α =0.80	α = 0.76	α =0.82

#### 5.6.3 Response to Change Validity

#### A) Bed activities

There was a significant difference in the mean scores over three administrations of the 'bed' activity items of the Functional Scale for trauma inpatients (p=0.0000), standard of error =0.37. The mean score of 'bed' activities at admission = 15.10 with 95% CI (14.36-15.83). Mean score of 'bed' activities at follow up = 4.0 with 95% CI (3.26-4.73). The mean score of 'bed' activities at discharge = 0.51 with 95% CI (-0.22-1.24) (see figure 5.5).



Fig 5.5 Bed activities mean scores

#### B) Out of bed activities

These findings illustrates the difference in the mean scores over three administrations of the 'out of bed' activity items of the Functional Scale for trauma inpatients (p=0.0000), standard error=1.36. Mean score for 'out of bed' activities at admission = 50.10 with 95 % CI (47.40- 52.79). Mean score for out of bed activities at follow up = 29.67, with 95 % CI (26.97-32.36). Mean score for 'out of bed' activities at discharge = 14.99 with 95 % CI (12.29-17.68) (see figure 5.6).



Fig 5.6 Out of bed activities mean scores

#### C) ADL activities

Figure 5.7 illustrates that there was a significant difference in the mean scores over three administrations of 'ADL' activity items of the Functional Scale for trauma inpatients (p=0.0000), standard error =0.19. Mean score for 'ADL' activities at admission = 7.12 with 95% CI (6.73- 7.50). Mean score for 'ADL' activities at follow up = 2.98 with 95% CI (2.59-3.36). Mean score for 'ADL' activities at discharge = 0.80 with 95% CI (0.4-1.18).



Fig 5.7 ADL activities mean scores

## 5.6.4 Ceiling and Floor effects

Table 5.2 summarizes the floor and ceiling effect results. There was a floor effect noted at discharge for 'bed' activities and 'ADL' activities, but there was a ceiling effect only noted at admission for 'out of bed' activities.

Activity domains		Floor effect	Ceiling effect
Bed Activity	Admission	NO	NO
	Discharge	YES	NO
Out of bed	Admission	NO	YES
Activity	Discharge	NO	NO
ADL Activity	Admission	NO	NO
	Discharge	YES	NO

Table 5.2	The floor and ceiling effect results summary
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#### Bed activities (At admission)

Figure 5.8 illustrates that no floor and ceiling effect was noted at admission for 'bed' activities as only 1% of patients' scores were at the lowest end of the scale and 12% of the scores were at the upper end of the scale.



Fig 5.8 Percentage of patients' activity scores at 'Admission'

#### Bed activities (At discharge)

Figure 5.9 illustrates that there was a high floor effect was noted at discharge for 'bed' activities, as 84% of patients' scores were at the lowest end of the

scale. There was no ceiling effect noted at discharge for 'bed' activities as 1% of the patients' scores were at the upper end of the scale.



Fig 5.9 Percentage of patients' activity scores at 'Discharge'

## Out of bed activities (At admission)

Figure 5.10 illustrates that there was no floor effect noted at admission for 'out of bed' activities as 1% of patients' scores were at the lowest end of the scale. There was a high ceiling effect noted as admission for 'out of bed' activities as 78% of the patients' scores were at the upper end of the scale.



Fig 5.10 Percentage of patients' activity scores at 'Admission'

#### Out of bed activities (At discharge)

Figure 5.11 illustrates that no floor and ceiling effect was noted at discharge for 'out of bed' activities as 15% of patients' scores were at the lowest end of the scale and only 1% of the scores were at the upper end of the scale.



Fig 5.11 Percentage of patients' activity scores at 'Discharge'

#### ADL activities (At admission)

Figure 5.12 illustrates that no floor and ceiling effect was noted at admission for 'ADL' activities as only 2% of patients' scores were at the lowest end of the scale and 5% of the scores were at the upper end of the scale.



Fig 5.12 Percentage of patients' activity scores at 'Admission'

## ADL activities (At discharge)

Figure 5.13 illustrates that a high floor effect was noted at discharge for 'ADL' activities as 57% of patients' scores were at the lowest end of the scale and there was no ceiling effect noted at discharge for 'ADL' activities as only 1% of the scores were at the upper end of the scale.



Fig 5.13 Percentage of patients' activity scores at 'Discharge'

## 5.7 Chapter summary points

- A Cronbach's alpha ranged between 0.76 and 0.97.
- The lowest alpha result was for the 'ADL' activities at follow-up (0.76).
- The highest alpha result was for 'out of bed' activity at admission and discharge (0.97).
- The response to change of the Functional Scale for trauma inpatients over time results illustrates that there was a significant difference in the mean scores over three administrations of 'Bed', 'Out of bed' and 'ADL' activity items of the Functional Scale for trauma inpatients (p=0.0000).
- In general, there was no significant floor and ceiling effect at admission or discharge for 'bed', 'out of bed' and 'ADL' activities.
- However, there was a floor effect noted at discharge for 'bed' activities and 'ADL' activities, and a ceiling effect noted at admission for 'out of bed activities' only.

#### **CHAPTER 6**

#### DISCUSSION

The overall aim of this research project was contribute towards the current knowledge base regarding functional outcome measurement in orthopaedic trauma inpatients. The majority of outcome measurement scales were developed for outpatient populations (Binkley et al 1999). The specific objectives of this project were thus to develop an outcome measurement tool for trauma inpatients and to assess selected psychometric properties of this newly developed outcome measure.

The findings of the systematic review (Chapter 2) indicated that an appropriate functional outcome measure for trauma inpatients has not been published. The majority of the outcome measurement tools reviewed in Chapter 2 were not tested or evaluated in orthopedic trauma inpatients during the acute hospital period, which is usually a relatively short period compared to outpatient rehabilitation periods (Binkley et al 1999). Five out of the eight outcome measures reviewed (Chapter 2) were applied in an inpatient setting (Gabel et al 2006, Jette et al 2005, Haley et al 2004, Hobart and Thompson 2001, Dodds et al 1993). However, these outcome measures were administered to patients with central nervous system dysfunction in rehabilitation settings and the inpatient phase is usually longer compared with the inpatient phase of orthopaedic trauma patients (Chapter 2). Consequently, the type of functional items and scoring methods used in the outcome measures applied in rehabilitation settings may not be appropriate for orthopaedic trauma inpatients (Guermazi et al 2004). Development of a new functional outcome measure for orthopaedic trauma inpatients was thus warranted to assess and monitor the progress of the functional status of orthopaedic trauma inpatients (Haley et al 2004).

The first step towards the development of a new outcome measure was to generate items to be included in the scale. A large range of functional

activities relevant to orthpaedic trauma inpatients were generated in the qualitative study (Chapter 3) and systematic review (Chapter 2). However, many of functional activities identified in the systematic review (Chapter 2) were not appropriate to the needs of trauma inpatients. For instance, the 'Lower Extremity Functional Scale' (Binkley et al 1999) was administered to outpatients with lower extremity musculoskeletal dysfunction, but most of the functional activities such as "squatting" listed in this outcome measure are inappropriate for trauma inpatients. Another example of the reviewed instruments in Chapter 2, the 'Functional Independence Measure' (Jette et al 2005) was administered in skilled nursing facilities and comprised comprehensive assessment of functional independence (e.g. sphincter management, executive function). Consequently, many of these items were also inappropriate for orthopaedic trauma inpatients. The findings of the qualitative study (Chapter 3) illustrated that trauma inpatients nominated functional activities such as ADL, mobility and ambulation functional activities as their most impaired functional activities during the inpatient period (Chapter 4). Thus, according to the ICF, these activities are mostly limited to activity impairments (World Health Organization 2001).

A clinically useful outcome measure should be acceptable to patients and thus involve a representative sample of the target population (Gabel et al 2006). The range of functional activities generated in Chapter 2 and 3 generated was reduced to the 29 functional activity items (Chapter 4) deemed most relevant for orthopaedic trauma inpatients. This list of 29 functional items (Chapter 3) is relatively longer than the list of items in most of the outcome measures reviewed in Chapter 2. The range of functional items ranged between 5 (Hobart and Thompson 2001) and 41 items (Haley et al 2004), but only one of the reviewed scales listed more than 20 items (Gabel et al 2006). Therefore further research incorporating statistical methods such as factor analysis may be required to reduce the list of items to the core items only. Reducing the list of functional items may have important clinical utility implications in terms of administrative burdens as the time required to administer and complete the outcome measure will be reduced.

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The type of functional items nominated by patients in this study sample may also have been influenced by the demographics of this sample recruited for this study (Chapter 3). The majority the subjects were male labourers (88%) who sustained a traumatic injury to the lower extremity (63%). The mean age of the sample was 34.75 and the hospital inpatient phase was relatively short (mean days= 7.96±2.80). Although this sample was recruited from the largest trauma hospital in the UAE and included a multi-national group of subjects, the new outcome measure may be applied in other similar contexts. However, further development of this outcome measure should include wider range age groups (e.g. geriatric patients) and occupations to improve applicability to other populations and therefore enhance wide-scale application of this new outcome measure (Haley et al 2004).

Scoring methods of generic tools such as the numerical rating scoring methods (0 = can't do any activity to 10 = can do activity as normal as beforeinjury) used in the 'Patient Specific Functional Scale' (Stratford et al 1995) was not an appropriate method to score the functional activities of trauma inpatients, because the patients would be discharged from the hospital at an ambulatory level of function, and not at a normal level of function as before their injury (Stratford et al 1995). While the AM-PAC (Haley et al 2004) quantifies changes as being slight, moderate, and severe, one difficulty associated with a transitional scale is determining where on the activity specific continuum a patient is functioning at any given point in time (Stratford et al 1995). In attempting to minimize this deficiency, a 4-point numerical and transitional rating scale (0= independent-does need help at all, but may use an aid—for example; stick, crutches and 3=unable-completely can't do) adapted from the previous work of Hobart and Thompson 2001 in the 'Barthel Index outcome measure' was incorporated into the new outcome measure (Chapter 4). The short duration of the inpatient hospital period, the relatively fast progression to perform inpatient appropriate functional activities as well as the assistance required to perform functional activities were the main factors considered when a scoring method of the new scale was selected (Chapter 4-table 4.3). The findings of the pilot patient study (Chapter 4) also indicated that the patients understood the selected scoring method.

Therefore, the Functional Scale for trauma inpatients scoring method may be acceptable for this patient population (chapter 4-table 4.6).

#### 6.1 Psychometric property testing

A basic requirement of any outcome measurement is that it is reliable and valid (Donnelly and Carswell 2002) for the target population. Adequate psychometric testing for the outcome measure is necessary to demonstrate the scale's usefulness in both clinical practice and research (Binkley et al 1999).

The testing of the psychometric properties of existing published functional outcome measures was limited, because none of the eight published outcome measures yielded satisfactory results when the psychometric properties of the outcome measures were appraised (Chapter 2). Overall, the outcome measures reported by Gabel et al 2006 and Binkley et al 1999 received the highest scores for evidence of psychometric properties reported (6.0 out of 7.0). The 'Upper Limb Functional Index' (Gabel et al 2006) (included 25 activity items) received a moderate quality score, but the tool was easy and quick to administer (chapter 2-table 2.2). No information found about clinical utility was reported about the 'Lower Extremity Functional Scale' (Binkley et al 1999 chapter 2- table 2.2). Clinical utility is important as shorter administration time may be more practical and will facilitate the use of outcome measures in clinical practice (Williams et al 2007). Therefore, further studies to determine the psychometric properties of functional outcome measures for trauma inpatients must be addressed in future studies (Terwee et al 2007 and Williams et al 2007). Findings of published systematic reviews (Donnelly and Carswell 2002 and Williams et al 2007) also illustrated that the psychometric properties of identified outcome measures have not been adequately evaluated. Furthermore, many of the outcome measures that were examined in these reviews were tested among outpatients (Donnelly and Carswell 2002and Williams et al 2007). Therefore, the systematic review (Chapter 2) highlighted the shortcoming in the psychometric properties of outcome measures and further supported the development an outcome measurement tool for trauma inpatients.

An instrument's responsiveness to change over time is critical in outcome measurement research and program evaluation (Dodds et al 1993). Since there is no gold standard for assessing functional status (Haley et al 2004), the validation of outcome measurement tool designed to assess functional status is an ongoing and important process (Gabel et al 2006). This study's results found that there was a significant difference in the average mean scores of the 'Bed', 'Out of bed' and 'ADL' activity items of the Functional Scale for trauma patients over three repeated administrations during the inpatient period (Chapter 5- figures 5.5, 5.6 and 5.7). The significant improvement between admission and discharge was superior to the results illustrated by Dodds et al 1993. Although this was an expected finding, as patients should improved over time, the interpretation of this temporal change is unclear. Although score improvement may be due to natural recovery or treatment, it could also reflect unintentional scoring biases if the evaluators underscore admission and inflate the discharge outcome measure scores (Dodds et al 1993). Further investigation of the responsiveness of the Functional Scale for trauma inpatients is thus recommended.

The 'bed' activities and 'ADL' activities domains showed floor effects in this sample of trauma inpatients. There was a floor effect noted at discharge for 'bed' activities and 'ADL' activities, and there was a ceiling effect only noted at admission for 'out of bed' activities (Chapter 5). This illustrates that the new functional scale for trauma inpatients was able to detect change functional ability over time. Since this is the expected pattern of functional improvement during the inpatient phase, it supports these findings with respect to the observed floor and ceiling effects (Chapter 5) for these domains (Jette et al 2005).

The 'out of bed' activity domain showed substantial ceiling effects at admission. This finding may indicate that when the trauma inpatients were admitted to hospital, they had significant deficiency in 'out of bed' activities (Chapter 5). This finding also suggests that the 'Out of bed' activity items might be redefined to improve discrimination between patients' ability to

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perform "out of bed activities". Further development of this section may thus reduce the ceiling effect of items listed in this domain.

Floor or ceiling effects were considered to be present if more than 20% of the respondents achieved the lowest or highest possible score, respectively (Costa et al 2007). If floor or ceiling effects are present, it is likely that the extreme items are missing in the lower or upper end of an outcome measure and this imply that further development to assure content validity may be required (Terwee et al 2007). As a consequence, patients with the lowest or highest possible score cannot be distinguished from each other, thus reliability may also be implicated (Terwee et al 2007). Furthermore, the responsiveness is limited because changes cannot be measured in these patients (Terwee et al 2007). However, since floor effect was only noted in two of the three domains ('Bed' and 'ADL' activities) and ceiling effects noted only in one of the three domains ('Out of bed' activities), it implies that reasonable content validity and responsiveness of the new scale for trauma inpatients has been achieved (Chapter 5- table 5.2).

A Cronbach's alpha ( $\alpha$ ) of the Functional Scale was calculated at 0.76 to 0.97, which is indicative of a good internal consistency (Chapter 5; Jette et al 2005). The high Cronbach's  $\alpha$  demonstrates that the Functional Scale there is good consistency between the items listed in the scale. Thus, for instance, if a score of one or zero is achieved on one 'Out of bed' activity item, the likelihood is high that the same score will be achieved on another item in the same domain. The high Cronbach's  $\alpha$  also suggests that the number of items in the Functional Scale could possibly be further reduced. Cronbach's  $\alpha$  values tend to decrease when there are fewer scale items (Dodds et al 1993), and this may explain why it was relatively lower in the ADL domain (Cronbach's  $\alpha$  of at least 0.90 is required to successfully apply scores to make decisions about an individual and that a Cronbach's  $\alpha$  of at least 0.70 is required for comparing groups (Jette et al 2005). To improve the internal consistency of the ADL activity items, one could either add more items that

assess ADL-related disability or create separate subscales for ADL activity domains.

The new Functional Scale for trauma inpatients appears to be a good choice for documenting trauma inpatients' function. It has been shown to be internally consistent and appears to be valid with respect to response to change in this sample of trauma inpatients. The results of this study thus suggest that the Functional Scale for trauma inpatients may be an appropriate tool when the goal is the assessment of change in disability functions, although further psychometric testing may be required.

## 6.2 Clinical implications

The Functional Scale for trauma inpatients was developed to determine if it can be used to derive an expression of functional independence that is meaningful in terms of making a prognosis and determining appropriate interventions for trauma inpatients (Jette et al 2005). As the Functional Scale for trauma inpatients measures physical function activity, but not overall health, a generic health status measure such as the FIM should also be used when the goal is to measure the overall health status of trauma inpatients (Binkley et al 1999).

The Functional Scale for trauma inpatients can be used by clinicians as a measure of patients' initial function, ongoing progress, and outcome, as well as to set functional goals. For an inpatient orthopedic trauma population, for example, initial and weekly follow-up (7 days  $\pm 2$ ) administration may be considered appropriate. In order to set short- and long-term goals based on a self-report functional scale such as the Functional Scale for trauma inpatients, the clinician should synthesize the patient's clinical history and findings, as well the measurement properties of the scale.

The Functional Scale for trauma inpatients outcome measure can serve as a guide in the education of undergraduate students as well as to clinicians working in orthopedic trauma wards. The present results provide clinical

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evidence that the three meaningful domains of the Functional Scale can be used to describe the functional status of this patient population (Chapter 5).

The Functional Scale for trauma inpatients is easy to administer and score, and may be applicable for research purposes and clinical decision-making for individual patients. The Functional Scale for trauma inpatients may also be useful in predicting the discharge needs of the trauma inpatients and may also assist clinicians in planning treatment and making decisions on continuation of treatment.

## 6.3 Summary of study limitations

- A modified version of the checklist developed by Williams et al 2007 to evaluate the quality of the psychometric properties of published self-reported outcome measures for traumatic neuromusculoskeletal disorders was used, as there are no standardized criteria to evaluate the quality of functional outcome measurements tools. Guidelines are needed to set standards and define the criteria by which functional outcome measures should be assessed.
- Bias in choosing articles to be evaluated may be a problem in systematic reviews (Terwee et al 2007). This review only included English and Arabic papers and this could have introduced bias (Chapter 2).
- Randomization of this study sample selection was not applied and may have influenced (bias) the generation of the functional activity items.
- The conclusions from this study cannot be directly considered to have global implications due to sample diversity from the subjects and geographical contexts.
- This study did not evaluate validity for different levels of work status, personal activity, or symptom duration.
- Clinical utility refers to the ease of administration of an outcome measure. This aspect was not evaluated in this study.

• Reliability indicates the stability of a measure and is commonly assessed by conducting test-retest reliability and internal consistency (Williams et al 2007). In this study, test-retest reliability remained unaddressed because of the memory effect and short inpatient period. Moreover, internal consistency is recognized to be the most important type of reliability for multi-item measures (Haley et al 2004).

#### **CHAPTER 7**

## **RECOMMENDATIONS and CONCLUSION**

#### 7.1 Recommendations for further research

This thesis reports on the development of a new outcome measure tool, the *Functional Scale for orthopaedic trauma inpatients*. Further studies are recommended to test the clinical utility of this newly developed Functional Scale for trauma inpatients and its ability to detect deterioration. Further investigation is also needed to document the measurement properties of the Functional Scale for trauma inpatients in other settings, and to examine if other domains of the ICF should be included. The Functional Scale for trauma inpatients needs further examination and comparison with competing scales to assess convergent and divergent validity. Clinical studies to determine if the scale is efficient in assessing the effectiveness of an intervention should be conducted.

Research into the clinical application of the tool and methods to facilitate the use of outcome measurement in this patient population should be addressed. This may include application of the tool in computerized systems to reduce administrative burden and build a data bank to describe the profile and progress of orthopaedic trauma inpatients.

#### 7.2 CONCLUSION

This study presents the first steps in the development of an outcome measurement tool for trauma inpatients, as the systematic review findings indicate that there is currently no published outcome measurement tool for orthopedic trauma inpatients. A total of 136 functional items were generated and reduced to 29 items, deemed to be appropriate by an physiotherapy experts' and patients' panel. These activity domains can provide a framework for the development of future outcome measurement tools and item banking for the instruments which could be used with trauma inpatients populations.

The pilot study results indicated that the Functional Scale for trauma inpatients was well understood by a sample of five trauma inpatients. Preliminary pilot study results based on patients' responses showed that the Functional Scale for trauma inpatients may be able to detect change over time. The response to change of the Functional Scale for trauma inpatients over time results illustrates that there was a significant difference in the mean scores over three administrations of 'Bed', 'Out of bed' and 'ADL' activity items (p=0.0000). In general, there was no significant floor and ceiling effects at admission or discharge for 'bed', 'out of bed' and 'ADL' activities, except there was a floor effect noted as discharge for bed activities and 'ADL' activities' only.

The Functional Scale for trauma inpatients may be useful to clinicians working in trauma orthopedic wards in the hospitals. The use of the Functional Scale for trauma inpatients may provide valuable information about an individual's independence and reflect areas that are important to patients who are unable to function during the acute hospital stay because of traumatic neuromusculoskeletal disorders. Further work in this area is needed to continue to validate these measures and to make them more meaningful for patients and clinicians.

The availability of a valid and reliable tool to measure functional status of inpatients in conjunction with a structured outcome measurement plan will

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empower physiotherapists to contribute towards discharge planning, an important aspect considering the global increase in the economic cost of hospital care. Further research to improve the psychometric properties of the Functional scale for trauma inpatients is also advocated.

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