PSYCHOMETRIC TESTING OF THE THERAPEUTIC SELF-CARE SCALE IN
HOME HEALTH CARE

by

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Psychometric Testing of the Therapeutic Self-care Scale in Home Health Care

Thesis directed by Professor Joyce A. Verran

ABSTRACT

Medicare-certified home health agencies (HHAs) receive reports on a number of quality indicators with national comparisons, based on Outcome and Assessment Information Set (OASIS) data. Currently-available measures for U.S. home health care (HHC) services do not fully evaluate HHA performance on improving a patient’s ability to manage his/her health condition at home. The Therapeutic Self-care Scale (TSCS) addresses aspects of self-management that are highly relevant to the goals of HHC educational and other interventions. The purpose of this project was to conduct psychometric analyses of the TSCS in an adult HHC population, a first step in the evaluation of its potential use as a generic self-management outcome measure for HHC services.

A descriptive design was used to assess reliability, validity and responsiveness of the TSCS. Fifty-nine patients were recruited from two HHAs in Colorado. Test-retest reliability was assessed through a comparison of TSCS responses from the admission visit to those from a telephone interview three days later. Convergent validity was tested by correlating the TSCS with data from OASIS and the General Symptom Distress Scale (GSDS). An exploratory factor analysis (EFA) was conducted to assess underlying dimensions. To evaluate responsiveness, TSCS change scores were calculated and correlated with a patient global rating of perception of change in self-management over the course of the HHC episode.
Cronbach’s alpha for the TSCS was .804 after the elimination of two items. The TSCS demonstrated strong test-retest reliability (ICC = 0.94; p<.001). Validity analysis was inconclusive due to a low sample size. Of particular interest, an EFA found two primary underlying dimensions. While the two dimensions explained only 51.5% of the variance, they were consistent with a theoretical difference between general self-care activities and more specific self-management activities. Responsiveness analysis indicated that the TSCS was not able to effectively measure change in self-management over the HHC episode. Overall, findings suggest that while the TSCS may be useful as a single-use tool to identify deficits in self-management for care-planning purposes, additional work is needed to refine and further test the scale in a U.S. adult HHC population.

The form and content of this abstract are approved. I recommend its publication.

Approved: Joyce A. Verran
This report, the culmination of over six years’ effort, is dedicated to my family:

Erik, Julia and Mason Richard and Frances and Arthur Arnold.
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CHAPTER I
INTRODUCTION

Evaluation of the effectiveness of health care is a central concern of health care providers, consumers, policymakers and others. Health care providers are concerned with evaluating clinical processes and quality improvement efforts. Regulators are interested in measuring outcomes to promote provider accountability. Payers and healthcare consumers consider outcomes for comparing providers and monitoring changes over time in provider performance. Researchers and policymakers use outcomes for tracking the effect of healthcare changes and evaluating potential cost containment measures (Bryant, Floersch, Richard, & Schlenker, 2004; Ingersoll, McIntosh, & Williams, 2000; Johnson & Maas, 1994; Jones & Burney, 2002; Jones, Jennings, Moritz & Moss, 1997; Lee, Chang, Pearson, Kahn, & Rubenstein, 1999; Oermann & Huber, 1999; Richard, Crisler, & Stearns, 2000).

As with other provider settings, major efforts have been made to develop quality indicators for home health care (HHC) in the United States over the past three decades (Rosati, 2009). In 1999, after significant investments in the development and testing of a system for collecting outcomes data for home health care, the Centers for Medicare & Medicaid Services (CMS) mandated collection of Outcome and Assessment Information Set (OASIS) data for all adult Medicare and Medicaid patients with the exception of those receiving services for pregnancy-related conditions. Medicare-certified home health agencies (HHAs) now have access to reports on a number of quality indicators with comparison to national data and the HHA’s own data from previous time periods (see Table 1). The quality indicators include several types of outcomes: hospitalization,
utilization of emergency department services, improvement and stabilization in selected physiological and psychological/emotional health status measures, functional status measures, and adverse events. Each of the outcome indicators is risk adjusted, using a unique logistic regression model that incorporates baseline patient characteristics, caregiver assistance, and home environmental elements to account for relevant differences between the agency and the comparison group. In 2010, a set of process-of-care measures were added to the array of quality indicators available for HHAs. A subset of these quality indicators have been endorsed by the National Quality Forum (NQF) and are publicly available for consumers on the CMS-maintained Home Health Compare website (Deitz, Dowell, Madigan, & Richard, 2010).

Table 1: **OASIS Outcome Indicators**

<table>
<thead>
<tr>
<th>Category</th>
<th>OASIS Outcome Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilization Outcomes</td>
<td>Acute Care Hospitalization</td>
</tr>
<tr>
<td></td>
<td>Discharged to Community</td>
</tr>
<tr>
<td></td>
<td>Emergency Department Use without Hospitalization</td>
</tr>
<tr>
<td></td>
<td>Emergency Department Use with Hospitalization</td>
</tr>
<tr>
<td>Clinical Status Improvement</td>
<td>Improvement in Anxiety Level</td>
</tr>
<tr>
<td></td>
<td>Improvement in Behavior Problem Frequency</td>
</tr>
<tr>
<td></td>
<td>Improvement in Bowel Incontinence</td>
</tr>
<tr>
<td></td>
<td>Improvement in Confusion Frequency</td>
</tr>
<tr>
<td></td>
<td>Improvement in Dyspnea</td>
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<tr>
<td></td>
<td>Improvement in Pain Interfering with Activity</td>
</tr>
<tr>
<td></td>
<td>Improvement in Speech and Language</td>
</tr>
<tr>
<td></td>
<td>Improvement in Status of Surgical Wounds</td>
</tr>
<tr>
<td></td>
<td>Improvement in Urinary Incontinence</td>
</tr>
<tr>
<td></td>
<td>Improvement in Urinary Tract Infection</td>
</tr>
<tr>
<td>Clinical Status Stabilization</td>
<td>Stabilization in Anxiety Level</td>
</tr>
<tr>
<td></td>
<td>Stabilization in Cognitive Functioning</td>
</tr>
<tr>
<td></td>
<td>Stabilization in Speech and Language</td>
</tr>
</tbody>
</table>
### Category | OASIS Outcome Indicator
---|---
Functional Status Improvement | Improvement in Ambulation/Locomotion  
| | Improvement in Bathing  
| | Improvement in Bed Transferring  
| | Improvement in Dressing – Lower Body  
| | Improvement in Dressing – Upper Body  
| | Improvement in Eating  
| | Improvement in Grooming  
| | Improvement in Management of Oral Medications  
| | Improvement in Light Meal Preparation  
| | Improvement in Phone Use  
| | Improvement in Toileting Hygiene  
| | Improvement in Toilet Transferring  

Functional Status Stabilization | Stabilization in Bathing  
| | Stabilization in Bed Transferring  
| | Stabilization in Grooming  
| | Stabilization in Light Meal Preparation  
| | Stabilization in Management of Oral Medications  
| | Stabilization in Phone Use  
| | Stabilization in Toileting Hygiene  
| | Stabilization in Toilet Transferring  

Adverse Event Outcomes | Emergent Care for Injury Cause by Fall  
| | Emergent Care for Wound Infections, Deteriorating Wound Status  
| | Emergent Care for Improper Med. Administration, Med. Side Effects  
| | Emergent Care for Hypo/hyperglycemia  
| | Development of Urinary Tract Infection  
| | Increase in Number of Pressure Ulcers  
| | Substantial Decline in 3 or more Activities of Daily Living  
| | Substantial Decline in Management of Oral Medication Management  
| | Discharged to the Community Needing Wound Care or Med. Assistance  
| | Discharged to the Community Needing Toileting Assistance  
| | Discharged to the Community with Behavioral Problems  
| | Discharged to the Community with an Unhealed Stage II Pressure Ulcer  

*Note.* Adapted from “Outcome-based Quality Improvement (OBQI) Manual” and “Outcome-based Quality Monitoring (OBQM) Manual” by Centers for Medicare and Medicaid Services, 2010

The availability of quality indicator reports for HHC represents significant progress for patients, providers and consumers. However, much work remains in the field of HHC quality measurement. Ongoing identification and testing of outcomes has been identified
as a top priority for HHC research by the Home Health Nurses Association Research Committee (Madigan & Vanderboom, 2005). Additional research should be undertaken to evaluate validity, reliability, sensitivity and responsiveness to clinical care as OASIS data items are revised. In addition, as the HHC patient population changes (e.g., increasing numbers of patients with chronic conditions), existing quality indicators should be re-evaluated to ensure they adequately reflect the most relevant outcomes and care processes for those patients (Kerr, Krein, Vjian, Hofer, & Hayward, 2001). Quality indicators used in other settings should be considered for general use in HHC, including quality of life outcomes, safety outcomes (e.g., infection rates), condition-specific outcomes and costs. These indicators may be particularly important for monitoring quality of care across settings. In addition to new quality indicators, there is room for improvement in current outcome risk models due to limited explanatory power (R-squares = .065 - .267) (CMS, n.d.; Murtaugh, Peng, Ayken, & Maduro, 2007), and researchers should consider inclusion of factors that may influence outcomes beyond those patient characteristics currently used, such as environmental and contextual factors.

Statement of the Problem

The outcome measures currently reported for HHC were originally developed in the early 1990s, along with the data collection instrument called the Outcome and Assessment Information Set (OASIS). Outcome development work was based on a Donabedian structure-process-outcome conceptual framework (Shaughnessy et al., 2002). That framework posited a linear relationship between structures of care that support care delivery processes leading to outcomes (i.e., changes in health status attributable to antecedent care) (Donabedian, 1966/2005). In Donabedian’s model, patient
characteristics primarily enter the model as risk factors that affect the delivery of processes of care or the likelihood of achieving certain outcomes (Mitchell, Ferketich, Jenning, & the American Academy of Nursing [AAN] Expert Panel, 1998; Sidani, Doran, & Mitchell, 2004).

While Donabedian’s model is still used in health services research, it is based on a paradigm in which patients are viewed as passive recipients of health care services, rather than as active participants. The more contemporary view of patients as active members of the health care team began receiving greater interest in the latter half of the 20th century and has continued to gain traction into the new millennium (IOM, 2001). This viewpoint is incorporated into the goals of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). The U.S. Department of Health and Human Services’ National Quality Strategy, developed as directed by the Affordable Care Act, specifies the need to ensure that patients and families are engaged as partners in their own health care as one of six priority areas for U.S. healthcare (U.S. Department of Health and Human Services, 2011).

Several conceptual models of care delivery, particularly those for chronic health conditions, feature the notion of patient self-management as a central goal. For example, the Chronic Care Model (CCM) is focused on the idea that effective chronic illness management is based on productive interactions between care providers and patients, with patients being active, informed members of the health care team (Bodenheimer, Lorig, Holman, & Grumbach, 2002). Suter et al., (2008) proposed adapting the model to HHC delivery to maximize potential for successful outcomes for patients with chronic health conditions, using CCM constructs to identify four “pillars” of chronic disease care.
delivery in HHC: a) a high-touch delivery system, b) theory-based self-management support, c) specialist oversight, and d) use of health information technology to enhance coordination of services and provide decision support.

Currently-available HHC outcome measures have been criticized as not always within the provider’s control (CMS, 2010a; Deitz et al., 2010) and not directly related to the effects of HHC nursing interventions, such as patient education. In addition, OASIS has been criticized as not sensitive enough to detect some clinically discernible changes in patient outcomes (Schneider, Barkauskas, & Keenan, 2008). Madigan (2007) found that 13% of patients are discharged from HHAs after experiencing an adverse event and three-quarters of the adverse events were associated with discharge to the community requiring additional assistance. She suggested that HHAs may not be adequately considering self-management abilities and needs in terms of care planning, care delivery and assessment of quality of care services. When OASIS was created in the 1980s, lengths of stay in HHC typically were much longer, and OASIS creators identified the primary goal of HHC services as improvement in patient functional and physiological status. In contrast, due to payment changes made in the late 1990s, lengths of stay are typically shorter (Murkofsky, Phillips, McCarthy, Davis, & Hamel, 2003) and the primary goal is to move patient and family toward independence as quickly as possible. The longer term goals of improved functional status and some physiological changes such as wound healing may not be achieved during the HHC episode.

A few OASIS measures address elements of self-care, including activities of daily living (ADLs) and ability to manage oral and injectable medications (see Table 1). While these functional measures represent some aspects of self-management, none of the
currently-available measures for U.S. HHC services fully evaluate one of the primary reasons for delivering care: to improve the patient and family’s ability to manage his/her health condition at home (Dieckmann, 2010; Murkofsky & Alston, 2009; Rice, 2003), which includes identification and management of symptoms, effective performance of needed medical treatments (beyond administration of oral and injectable medications), identification of medical emergency and ability to access resources for daily needs and medical emergencies. A clear need exists to evaluate the feasibility and utility of additional outcome measures for HHC that are more sensitive to nursing care, more closely aligned with the primary goals for care delivery, and that acknowledge the increased patient/family autonomy that exists in home care environments.

A measure of self-management is currently being used as part of the Health Outcomes for Better Information and Care (HOBIC) project in Ontario, Canada. The Therapeutic Self-Care Scale (TSCS) includes 12 questions related to a person’s knowledge of medications, ability to take medications as prescribed, recognize and manage symptoms, perform prescribed treatments, access appropriate resources for medical emergencies, conduct activities of daily living, and manage changes in health condition (Doran et al., 2004; Ontario Ministry of Health and Long-term Care, 2010). While the title of the scale includes the term “self-care,” most of the questions are actually focused on a smaller set of activities specific to caring for one’s health care needs, which more closely fit the definition of self-management as “the ability to care for oneself and the performance of activities necessary to achieve, maintain, or promote optimal health (including activities specific to acute and chronic health conditions)” (Richard & Shea, 2011, p. 261). However, testing of the TSCS has been limited to a few
studies, primarily conducted in hospital settings. In one study, Chaboyer, Ringdal, Aitken, and Kendall (2012) reported psychometric properties of the TSCS in an Australian population of trauma patients post-hospital discharge, however there were no indications that patients were receiving HHC services. Reliability, validity and responsiveness testing have not been reported for a HHC setting (Doran, D.I., personal communication, 1/26/2011).

**Purpose and Rationale**

The purpose of this project is to conduct psychometric analyses of the TSCS in a U.S. adult HHC population, a first step in the evaluation of its potential use for a generic self-management outcome measure for HHC services. A self-management outcome measure for home care would be useful for evaluating clinical interventions designed to promote and support the patient and family’s role in taking primary responsibility for managing their own health. Further, such an outcome would support the stated vision of the National Quality Forum (NQF) National Priority Partner goal of patient and family engagement to “…envision healthcare that honors each individual patient and family, offering voice, control, choice, skills in self-care, and total transparency, and that can and does adapt readily to individual and family circumstances, and to differing cultures, languages, and social backgrounds” (NQF, 2009). Self-care was identified by an AAN Expert Panel on Outcomes as an outcome sensitive to nursing care (Mitchell et al., 1998; Mitchell & Lang, 2004), and may be broadly defined to incorporate human developmental needs, health promotion, and management of health deviations. Self-management is a more narrowly defined concept that is typically used when referring to management of chronic or acute illness (Richard & Shea, 2011). The TSCS measures
domains aspects of self-management not addressed by current outcome measures but that are highly relevant to the goals of HHC educational and other interventions.

**Research Aims**

Aim 1: Does the TSCS reliably measure the concept of self-management in an adult home health care population?

a. Does the scale reflect internal consistency with Cronbach’s alpha ≥ .70?

b. Do subscales (identified from factor analysis, #2.a. below) reflect internal consistency with Cronbach’s alpha ≥ .70?

c. Does the TSCS demonstrate test-retest reliability (r = .70 or higher)?

Aim 2: Is the TSCS a valid measure of self-management in an adult home health care population?

a. Does exploratory factor analysis indicate a single or multiple latent variables (factors with eigenvalues greater than 1; explaining at least 70% of the variance)?

b. Do TSCS scores demonstrate moderate correlations with the General Symptom Distress Scale (GSDS) scores (convergent validity)?

c. Do the TSCS scores demonstrate moderate correlations with the OASIS activities of daily living scores (convergent validity)?

Aim 3: Is the TSCS sensitive to changes in status?

a. In a subsample of adult home health care patients expected to change, do changes in TSCS scores correlate to on overall patient rating of changes in self-management abilities?

b. What is the minimum important clinical difference in TSCS scores, based on patient report?
Theoretical Framework

Over the past 40 years, Donabedian’s classic structure-process-outcome model has been adapted and expanded into several models specific to nursing, beginning with the Quality Health Outcomes Model (QHOM), developed by the AAN Expert Panel on Quality Health Care as a conceptual framework for quality and outcomes research in nursing (Mitchell et al., 1998), the Nursing Role Effectiveness Model (NREM) (Doran, Sidani, Keatings, & Doidge, 2002; Irvine, Sidani, & McGillis-Hall, 1998; Doran & Pringle, 2011) and the Systems Research Organizing Model (SROM) (Brewer, Verran, & Stichler, 2008; Effken et al., 2003). A common element of the adapted models was the view that patients or clients are active participants in the health delivery system. For example, the QHOM theorized that the relationship between interventions (processes) and outcomes was mediated by the concepts of system (structures) and clients (Mitchell et al., 1998).

The SROM, based on the QHOM, was developed to guide systems-level research on health care and outcomes. The SROM allows for the viewpoint of the system as a whole, a complex structure with interrelated components. While the SROM can be applied in a variety of disciplines, it has been used as the basis of several studies specific to nursing (Brewer et al., 2008), and can serve as the theoretical foundation for HHC quality research. The SROM focuses on four constructs (client, context, action focus, and outcomes), each of which interacts in reciprocal relationships with all other constructs. Figure 1 depicts the Home Health Outcomes Research Organizing Model, an adaptation of the SROM that can be used to guide HHC research. The construct of client drives the
model, and may include characteristics of individual patients and informal caregivers, which may include family and helping friends.

Figure 1. Home Health Outcomes Research Organizing Model

The construct of context is the environment of care. HHC environmental context may consist of the HHA characteristics (e.g., proprietary vs. nonprofit; organizational culture, staffing and skill mix, etc.) or characteristics of the care delivery setting, the patient’s home. For HHC patients, OASIS data include information on home environment, particularly environmental characteristics that may influence patient safety such as sanitation (i.e., presence of running water, etc.) and other environmental hazards (i.e., throw rugs on floors, etc.).

The SROM concept of action focus is dependent on the research question and includes measures that the researcher intends to manipulate. As adapted for HHC research, the action focus may be conceptualized as the care delivery process. Examples
of potential action foci in HHC research are introduction/implementation of use of best practices, changes in staffing patterns, and implementation of electronic health records. Currently, OASIS data are collected on selected best practices for HHC related to assessment/screening, care planning, and clinical interventions (e.g., falls risk assessment, care planning related to diabetic foot care, etc.).

Outcomes are defined as “the result of actions taken, interventions, or changes that occurred within a system” (Brewer et al., 2008, p. 14). While they reflect the result of care, they also influence the constructs of client, context, and action focus. For example, an outcome that does not meet expectations may result in changes (action focus) in efforts to improve the outcome. The complete list of OASIS outcomes available for Medicare-certified HHAs is in Table 1. HHAs are encouraged to use the OASIS outcomes to target areas for quality improvement activities (CMS, 2010b; CMS 2010c; Richard et al., 2000).

Table 2 provides a detailed list of variables identified through literature review (see Chapter II) for each of the four constructs. Client characteristics that have been found to influence care provider actions, context, and outcomes include demographic and social characteristics, diagnoses/comorbidities, health status, cognitive status, frailty, functional status, health status, cultural values, psychological health status/depression, family/caregiver willingness and ability to provide assistance, self-management skills, self-efficacy and patient activation (Armstrong, Stole, Hirdes, & Poss, 2010; Hibbard, Stockard, Mahoney, & Tusler, 2004; Murtaugh et al., 2009; Richard & Shea, 2011; Sidani, 2011; Sidani et al., 2004). Currently, HHAs collect data on patient demographics (age, sex, race, payer source), diagnoses/comorbidities, frailty, selected health status
measures (pain, dyspnea, wounds, etc.), functional status on 13 ADLs, and family/caregiver assistance.

Table 2: Patient and Contextual Factors Influencing U.S. Home Health Care Outcomes

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Context</th>
<th>Action Focus</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Demographics (age, sex, race/ethnicity, marital status, educational level, payment source)</td>
<td>• Patient home environment: sanitation, safety</td>
<td>• Total volume of services provided</td>
<td>• Physiologic/symptom management (generic and condition-specific)</td>
</tr>
<tr>
<td>• Diagnoses</td>
<td>• Community characteristics: urban/rural location socioeconomic; market factors (e.g., numbers of HHAs, etc.)</td>
<td>• Service mix</td>
<td>• Symptom frequency/severity</td>
</tr>
<tr>
<td>• Multiple comorbidities</td>
<td>• HHA provider ownership (e.g., for-profit, hospital-based, etc.)</td>
<td>• Presence of a care plan</td>
<td>• Functional (ADLs and IADLs)</td>
</tr>
<tr>
<td>• Recent hospital discharge and history of prior hospitalization</td>
<td>• Nurse characteristics: education, length of experience; employment status; caseload</td>
<td>• “Front-loading” visits</td>
<td>• Use of services (e.g., ER use, rehospitalization)</td>
</tr>
<tr>
<td>• Equipment (e.g., urinary catheters, vascular access devices);</td>
<td></td>
<td>• Number of nursing interventions provided during home visit</td>
<td>• Adverse events (use of services above, medication errors, falls, infections, IV-therapy complications)</td>
</tr>
<tr>
<td>• Complexity of medical condition/treatment</td>
<td></td>
<td></td>
<td>• Self-management</td>
</tr>
<tr>
<td>• Frailty</td>
<td></td>
<td></td>
<td>• Knowledge</td>
</tr>
<tr>
<td>• Guarded rehabilitation prognosis</td>
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<td></td>
<td>• Behaviors</td>
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<tr>
<td>• Baseline and prior health and functional status</td>
<td></td>
<td></td>
<td>• Costs</td>
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<td>• History of falls</td>
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<td></td>
<td>• Satisfaction</td>
</tr>
<tr>
<td>• Polypharmacy</td>
<td></td>
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<td>• Quality of life</td>
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<tr>
<td>• Receipt of anxiolytic or anti-depression medications</td>
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<tr>
<td>• Multiple comorbidities</td>
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<tr>
<td>• Depression</td>
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<td></td>
<td></td>
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<tr>
<td>• Social functioning</td>
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<td></td>
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<tr>
<td>• Cognitive functioning</td>
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<td></td>
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<tr>
<td>• Sociocultural factors</td>
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<tr>
<td>• Caregiver relationships</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Social support</td>
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<td></td>
<td></td>
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<tr>
<td>• Health-related behaviors and activities</td>
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</table>
The Home Health Outcomes Research Organizing Model can be used to guide programs of research in HHC, including identification of quality indicators, development of risk models, and testing of clinical interventions. If the psychometric testing of the TSCS as proposed in this study supports the validity and reliability of the scale for a U.S. HHC population, the model will be used to guide the development of a self-management outcome and identification of patient and system factors that influence the outcome.

**Summary**

While a great deal of work must occur to fully understand the relationships between the clients, context, action focus and outcomes in home health care, in order to do so, one must ensure the validity, reliability and responsiveness of instruments to measure concepts for further outcome development. This study will address the measurement of the concept of self-management using the TSCS. While the TSCS questions address important aspects of self-management relevant to HHC providers, its performance with a HHC population has not been established. If the psychometric properties of the instrument are acceptable for its use in the HHC setting, then additional research can be pursued to develop a self-management outcome measure and evaluate patient, contextual, and action focus strategies that influence self-management.
CHAPTER II

REVIEW OF THE LITERATURE

A review of the literature was completed using OVID Medline, CINAHL, and Google Scholar databases. Keywords included “nursing outcomes,” “home health care” and “home health services” individually and in combination with “outcomes,” “self-care,” “self-management,” and “self-efficacy.” Several hundred articles were identified with the database searches. Article abstracts were examined to ensure relevance to adult patients receiving nursing or therapy visits in the home provided through a home health agency (HHA), and excluded if they focused on pediatric care, telemedicine, or inpatient settings. Literature primarily focused on articles published between 1999 and 2013, although earlier classic articles were examined also. The evaluation is structured to provide an overview of home health care (HHC) delivery in the U.S., then a broad review of nursing outcomes literature followed by a summary of HHC outcomes research. Because the literature on nursing outcomes was vast, the literature review was constrained to articles that provided information on the state of the science of in this area. In addition, literature for four concepts: self-care, self-management, self-efficacy and patient activation relevant to the research question were then reviewed and differentiated. This concept delineation provides context and conceptual clarity for the study.

Home Health Care in the U.S.

Formal HHC services represent a small but growing component of the health care continuum of care services. There are currently 12,200 HHAs in the U.S. providing home health and hospice (combined) services, and 10,800 agencies providing HHC only (Park-Lee & Decker, 2010). Medicare is the largest payer for HHC services in the U.S., and
HHAs providing care to Medicare patients must be certified and periodically surveyed for compliance with the Medicare Conditions of Participation, a set of standards designed to assure a minimum level of quality in the delivery services (Dieckmann, 2010; National Association for Home Care and Hospice [NAHC], 2010). Almost all of the agencies providing both home care and hospice services (97.6%) are Medicare-certified and 79.5% of agencies providing home health services only are Medicare-certified (Park-Lee & Decker, 2010).

HHC in the United States is provided to patients recuperating from an acute illness or surgery, and/or chronic condition(s) that limit the ability to function independently in the home. Patients requiring long-term HHC, including assistance with personal care, housekeeping, and other activities, may be eligible for HHC services through Medicaid waiver programs such as Home and Community-based Services (HCBS), Program for All-inclusive Care for the Elderly (PACE) programs, private pay, or insurance arrangements. Eligibility for these services is determined by caseworkers (frequently social workers), and the goals of such services are to provide long-term assistance with functional needs and household maintenance to postpone or eliminate the need for the patient to be placed in a skilled nursing facility (Dieckmann, 2010; Madigan, Tullai-McGuinness, & Neff, 2002).

In contrast, HHC services provided through the Medicare benefit are intended to meet acute health needs and to facilitate the eventual ability of the patient and family to independently manage longer-term health care needs. Formal HHC typically substitutes for extended inpatient hospital or rehabilitation facility care, and has been referred to informally as a “hospital at home” (Dieckmann, 2010; Madigan, Schott, & Matthews,
Eligibility for these services is determined by the HHC provider and the physician, and requires that the patient meet the definition of “homebound,” defined as requiring considerable and taxing effort to leave the home (Dieckmann, 2010; Madigan, 2007). The majority of patients admitted to Medicare-certified HHAs were discharged from hospitals or acute rehabilitation facilities, although patients may be referred to HHAs from primary care physicians, nursing homes, outpatient providers, and patient/family (Brega, Jordan, & Schlenker, 2003; Madigan et al., 2002; Park-Lee & Decker, 2010). The five most frequently-seen diagnoses for HHC patients are chronic conditions including diabetes, hypertension, heart failure, chronic skin ulcers and osteoarthritis (NAHC, 2010), however, it is common for HHC patients to have multiple co-morbid health conditions (Boling, 2009). While rehabilitative services frequently are provided, the bulk of HHC services are managed and delivered by nurses (Irvine et al., 2000; Madigan et al., 2002). Physician involvement varies, but frequently is limited to general oversight vs. an integral role in the coordination of care delivery (Dieckmann, 2010; Office of Inspector General [OIG], 2001). If patients are not rehospitalized or moved to other inpatient facilities, they are typically discharged when goals are met or when the approved reimbursement services have been exhausted (Dieckmann, 2010).

The use of HHC services has increased dramatically since formalized by Medicare in 1965, despite several changes in the Medicare payment benefit designed to limit growth of Medicare HHC expenditures (NAHC, 2010). There are multiple reasons for the increase. Research has shown that cost savings can be realized by reducing or eliminating the use of inpatient facility care (Boult, Kane, & Brown, 2000; Hughes et al., 1997;
NAHC, 2010). Changes in reimbursement for hospitalization have resulted in patients being discharged home with ongoing health needs, and HHAs may provide a “safety net” for patients who need additional nursing and rehabilitative services (Bowles et al., 2002). Improved technology has resulted in an increase in the types of care that can be provided in the home setting. In addition, employment, economic, and social needs tend to disperse families geographically, and with the increase in dual-income families, fewer family resources may be available to provide assistance when a family member becomes ill or functionally impaired. In the home, the role of the family and other informal caregivers is central. Patients (in conjunction with those caregivers) take an active role in directing and managing their care. This is attractive to many patients and families, who frequently voice a preference for receiving care in their homes (DePalma, 2002; Dieckmann, 2010; Murkofsky & Alston, 2009). The aging U.S. demographic, and along with it, the increased prevalence of chronic diseases, is projected to increase the need for HHC services (Bowles, Naylor, & Foust, 2002).

The median length of a Medicare HHC episode is 44 days (Murkofsky et al., 2003), although some patients may stay on service for months or years. Medicare reimbursement for HHC services is paid prospectively for a 60-day episode, based on a case mix weight assigned based on OASIS data on clinical characteristics identified on the admission visit. This reimbursement mechanism provides HHAs with an incentive to deliver care efficiently and move patients toward independence as quickly as possible. The primary goals of HHC service delivery are to provide direct care as well as educational and supportive care to promote the patient’s ability to manage his/her own health care needs (Dieckman, 2010).
Nursing Outcomes

Interest in assessing effectiveness of nursing care has long been a focus of the discipline (Brooten & Naylor, 1995; Doran & Pringle, 2011; Lang & Marek, 1990; Martin, 1994; Mitchell, 1993; Naylor, Munro, & Brooten, 1991; Marek, 1989) asserted that Florence Nightingale was the first proponent of assessing outcomes of care. Lang and Marek (1990) developed a classification of nurse outcomes that included the following domains: physiological, psychosocial, functional, behavioral, knowledge, symptom control, home maintenance, well-being, goal attainment, patient satisfaction, safety, cost and rehospitalization. Hegyvary (1991) categorized four areas of outcomes sensitive to nursing: clinical, functional, financial, and perceptual. Quality indicators used to assess nursing care have traditionally been either sentinel event (measures of undesirable occurrences) or rate-based indicators for which aggregate data are available. The latter type can be useful for monitoring trends and making comparisons to other groups. Selection of quality indicators for quality improvement or research is dictated by aspects of care, clinical diagnosis, or sample size (Idvall, Rooke, & Hamrin, 1997).

When the American Academy of Nursing (AAN) Expert Panel proposed the Quality Health Outcomes Model to guide outcomes research in nursing, they identified five outcomes sensitive to nursing care: achievement of appropriate self-care, demonstration of health-promoting behaviors, health-related quality of life, perception of being well-cared for, and symptom management (Mitchell et al., 1998; Mitchell & Lang, 2004). These outcomes reflected the positive impact of nursing care beyond traditional health outcomes measurement of the 5 “Ds” of death, disease, disability, discomfort, and dissatisfaction (Lohr, 1988) and were identified as applicable across the continuum of
care. Irvine and colleagues identified outcomes of nursing consistent with Hegyvary’s (1991) classification: clinical (iatrogenic complications and symptom level), functional (self-care, knowledge, and cognitive, psychological, functioning, social and role functioning), patient satisfaction, and costs (Doran et al., 2002; Irvine et al., 1998; Megivern, Halm, & Jones, 1992).

In a seminal study on nursing outcomes, Aiken, Smith and Lake (1994) studied outcomes in magnet hospitals (those that embody attributes that nurses find desirable) vs. hospitals without magnet designation, finding that patient mortality rates were lower in magnet-designated hospitals. Subsequently, many studies have addressed the influence on nurse staffing in hospitals on patient outcomes. Nurse staffing studies use several different methods of calculating nurse staffing (i.e., hours of care per patient day, staff mix, nurse:patient ratio) (Lankshear, Sheldon, & Maynard, 2005). Increased hours of care per patient day has been associated with reductions in falls, medication errors, pneumonia, unplanned extubation, respiratory failure and cardiac arrest (Blegen, Goode, & Reed, 1998; Cho, Ketefian, Barkauskas, & Smith, 2003; Kane, Shamliyan, Mueller, Duval, & Wilt, 2007). Aiken, Clarke, Sloane, Sochalski, and Silber (2002) found that higher nurse to patient ratios resulted in lower odds of patient mortality and failure-to-rescue outcomes. A higher proportion of professional nursing staff has been associated with lower rates of medication errors, wound infections, and 30-day mortality (Hall, Doran & Pink, 2004; Tourangeau et al., 2006) as well as better functional scores and better social function at discharge (Hall et al., 2003). Higher proportions of baccalaureate-prepared nurses have been associated with lower odds of mortality and failure-to-rescue in surgical units (Aiken, Clarke, Cheung, Sloan, & Silber, 2003). Van
den Heede, Clark, Sermeus, Vleugels, and Aiken (2007) used a Delphi technique to assess researcher and nurse administrator feedback on outcomes that should be most closely influenced by nurse staffing and skill mix, identifying outcomes of nurse-perceived quality of care, patient satisfaction, and pain. Renal failure, cardiac failure, and central nervous system complications were outcomes that were rated least likely to be sensitive to nurse staffing.

The identification and measurement of outcomes for advance practice nurses (APNs) has received considerable attention (Newhouse et al., 2011). In 2000, Ingersoll et al. analyzed feedback from APNs to identify outcome indicators for advanced practice nursing care: 1) satisfaction with care delivery; 2) symptom resolution/reduction; 3) perception of being well cared for; 4) compliance/adherence with treatment plan; 5) knowledge of patients and families; 6) trust of care provider; 7) collaboration among care providers; 8) frequency and type of procedures ordered; and 9) quality of life. Several studies on the effect of nurse specialist care to ease care transitions have found improvements in hospital lengths of stay, use of health care services after hospital discharge, costs, and patient satisfaction (Brooten et al., 1995; Naylor et al., 1999). Naylor et al. (2007) found that a community-based advanced practice nurse intervention resulted in statistically significant improvements in functional status, symptom management, and quality of life, along with non-significant trends of reduction in hospitalization and increased primary care physician visits.

A variety of methodological issues in nurse outcome measurement have been identified. These include defining the “patient” (e.g., individual, family, group or community) (Feetham, 1992; Johnson & Maas, 1994) and operationalizing the concept of
nurse “dose” for research studies. Nurse dose includes consideration of a) nurse education, expertise, and experience; b) staffing (number of nurse FTEs); c) frequency of contacts (hours per patient day or nurse-patient ratio); and d) duration (length of stay) (Blegen, Vaughn, & Goode, 2001; Bolton, Donaldson, Rutledge, Bennett, & Brown, 2007; Brooten & Youngblut, 2006; Manojlovich & Sidani, 2008). Another challenge is attribution of outcomes to nursing care because of the interdisciplinary nature of health care services (Jones & Burney, 2002; Needleman, Kurtzman, & Kizer, 2007).

Measurement issues include a) selection of appropriate time intervals for measurement (Hegyvary, 1991; Kosel, Gelinas, & Paxson, 2007); b) consideration of the burden and feasibility of data collection (Needleman et al., 2007); c) ensuring adequate psychometric properties (i.e., reliability, validity, sensitivity and responsiveness) of research instruments (Schneider et al., 2008; Strickland, 1992); d) identification of factors that may influence outcomes such as patient, environmental and organizational characteristics (Brooten & Naylor, 1995; Effken et al., 2004; Mark, Sayler, & Smith, 1996; Sidani & Epstein, 2003); e) identification of the appropriate methods for measuring and analyzing outcomes for complex health systems (Effken et al., 2003; Ferketich & Verran, 1992; Mitchell, 1993); and f) selection and application of statistical techniques appropriate for the level of measurement (Ferketich & Verran, 1992; Fox, Brathwaite, & Sidani, 2004).

Since the early 2000s, several mechanisms to assess and benchmark nursing outcomes have been developed. These include the Nursing Outcomes Classification (NOC) taxonomy (with its counterpart, the Nursing Interventions Classification [NIC]) that integrates standardized Nursing Minimum Dataset (NMDS) data (Head et al., 2004; Head, Maas, & Johnson, 2003; Maas & Delaney, 2004). The NOC and NIC have not yet
been incorporated into many electronic health records systems, limiting their usefulness for outcomes measurement (Needleman et al., 2007). The National Database of Nursing Quality Indicators (NDNQI) is a proprietary database of the ANA. Hospitals subscribe to the NDNQI services and submit data on selected indicators, in return receiving quarterly outcome reports and benchmarking data (ANA National Center for Data Quality, n.d.; Furukawa, Raghu, & Shao, 2011; NDNQI, n.d.). The Collaborative Alliance for Nursing Outcomes (CalNOC) is a group of member hospitals which submit data and receive benchmarked reports on nurse staffing and nursing outcomes, including the NDNQI measures (Aydin et al., 2004). CalNOC has been the model for other databases including the Military Nursing Outcomes Database (MilNOD) and the U.S. Department of Veterans Affairs Nursing Outcomes Database (VANOD) (Alexander, 2007; Aydin et al., 2004; Needleman et al., 2007; Patrician, Loan, McCarthy, Brosch, & Davey, 2010).

Large national databases maintained by the Centers for Medicare & Medicaid Services (CMS) include standardized outcome data for post-acute care settings including nursing homes and HHAs (Rantz & Connolly, 2004).

The substantial developmental work in nurse outcomes research, coupled with concerns about an aging U.S. population and potential nursing workforce shortage has drawn national attention to the need to assess and improve quality of nursing care in hospitals and other settings. With support from the Robert Wood Johnson Foundation, NQF used their Consensus Development Process to endorse a set of 15 nursing-sensitive outcome measures in 2003. The endorsement of these measures (see Table 3) represented a vehicle for capturing the contributions of nursing and should be considered a starting point for ongoing work to develop additional outcome measures for nursing (Melichar,
2007; Naylor, 2007; Needleman et al., 2007; NQF, 2004). Despite methodological challenges, nursing leaders have noted that as nursing’s role in the U.S. health care system continues to expand, it is imperative that nurses continue to identify and measure outcomes to demonstrate value and develop a sound basis for practice (Doran & Pringle, 2011; Needleman et al., 2007; Oermann & Huber, 1999; Sidani & Epstein, 2003).

Table 3: The NQF 15 Nursing-Sensitive Outcome Measures

<table>
<thead>
<tr>
<th>NQF Framework Category</th>
<th>Measures</th>
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<tr>
<td>Patient-centered outcome measures</td>
<td>1. Death among surgical inpatients with treatable serious complications (failure to rescue)</td>
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<td></td>
<td>2. Pressure ulcer prevalence</td>
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<td></td>
<td>3. Falls prevalence</td>
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<td>4. Falls with injury</td>
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<td>5. Restraint prevalence (vest and limb only)</td>
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<td></td>
<td>6. Urinary catheter-associated urinary tract infection (UTI) for intensive care unit (ICU) patients</td>
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<td></td>
<td>7. Central line catheter-associated blood stream infection for ICU and high-risk nursery (HRN) patients</td>
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<td></td>
<td>8. Ventilator-associated pneumonia for ICU and HRN patients</td>
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<tr>
<td>Nursing-centered intervention measures</td>
<td>9. Smoking cessation counseling for acute myocardial infarction (AMI)</td>
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<tr>
<td></td>
<td>10. Smoking cessation counseling for heart failure (HF)</td>
</tr>
<tr>
<td></td>
<td>11. Smoking cessation counseling for pneumonia</td>
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<tr>
<td>System-centered measures</td>
<td>12. Skill mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)</td>
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<td></td>
<td>13. Nursing care hours per patient day (RN, LVN/LPN, and UAP)</td>
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<td></td>
<td>14. Practice Environment Scale – Nursing Work Index (PES-NWI) (composite and five subscales)</td>
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<td></td>
<td>15. Voluntary turnover</td>
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Home Health Care Outcomes

HHA and community health providers, researchers, and policymakers were early supporters of the concept of outcome measurements that incorporated positive contributions of HHC providers. By the 1980s several efforts were underway to support wide-scale outcome measurement for HHC and community health services. Daubert (1979) identified five patient groups along with their expected outcomes: 1) acute, 2) chronic but expected to return to pre-episodic level of function; 3) chronic and expected to improve but not to pre-episodic levels; 4) chronic and cannot be maintained at home without assistance; and 5) terminal end-stage. In the early 1980s, Lalonde and the Home Care Association of Washington received federal funding to develop outcome measures for HHC patients. Scales for outcomes in several domains were developed, including general symptom distress, discharge status, and taking medications as prescribed (Lalonde, 1987a, 1987b). These early efforts informed additional work in HHC research, including development of the Omaha System and the Outcome and Assessment Information Set (OASIS).

Omaha System

In the 1980s, the Omaha System taxonomy of nursing problems, interventions, and outcome measures was developed by the Visiting Nurses Association of Omaha. The taxonomy, recognized by the ANA, was designed to allow for the collection and organization of clinical data in community health settings. In addition to HHAs the system has been used in public health agencies and other community settings (Barrera, Machanga, Connolly, & Yoder, 2003; Barton, Clark, & Baramee, 2004; O’Brien-Pallas et al., 2002) and its application to acute care has been explored (Bowles, 2000). The Omaha
Problem Classification Scheme consists of 40 nursing diagnoses and patient health concerns in four domains: environmental, psychosocial, physiological and health-related behaviors. The problem rating scale for outcomes focuses on knowledge, behavior, and health status changes. For each identified problem, the outcomes are rated by nurses on a five-point Likert scale at admission, regular time intervals during the episode and discharge. The intervention taxonomy is comprised of over 60 objects of nursing actions for four broad categories: health teaching, guidance and counseling; treatments and procedures; case management and surveillance (Martin, Leak, & Aden, 1992; Martin, Scheet, & Stegman, 1993) and incorporates NMDS interventions (Barton et al., 2004).

The Omaha system is the most widely used classification system for nursing care in HHAs (Martin & Correll, 2010; Schumacher & Marren, 2004) and has been used in research studies. O’Brien-Pallas et al. (2002) reported that the Omaha system outcomes of improvement in knowledge and improvement in behavior were associated positively with increased educational preparation of nurses. Patient characteristics negatively impacting outcomes were increased age, mental health problems, increased number of nursing diagnoses, and patients in need of duration visits. Westra, Solomon and Ashley (2006) used a case study to illustrate how OASIS and Omaha System data can work in a complementary fashion to improve patient care. Using Omaha System data in 15 HHAs, Westra et al. (2011) identified several interventions associated with improvements in bowel incontinence.

**OASIS**

In the mid-1990s, the Center for Medicare and Medicaid Services (CMS) contracted with the University of Colorado to develop a set of outcome measures for the purposes of
quality improvement. The researchers developed OASIS, which consisted of approximately 100 data items to assess and risk-adjust outcomes of care. The OASIS outcomes were intended to be “discipline-neutral” or allow for the assessment of clinical outcomes regardless of the discipline of the HHC provider (e.g., nurses, therapists, etc.) (Krafft, 2009). Beginning in 1999, CMS implemented regulations requiring OASIS data collection for all Medicare and Medicaid patients at admission and every 60 days up to and including discharge. In return CMS began providing Medicare-certified HHAs with reports on outcomes. These outcomes included rates of improvement and/or stabilization (nonworsening) calculated as change from admission to discharge for several physiologic, neurological/emotional/behavioral, and functional indicators, as well as rates of use of emergency care and hospitalization. Comparison data were provided based on a national sample and from the agency’s previous OASIS data. Agency-level outcomes were computed by aggregating individual patient-level outcomes and adjusted for the agency’s aggregated patient characteristic data (from admission OASIS) using logistic regression techniques.

Shaughnessy et al. (2002) conducted two separate demonstration studies, one consisting of 50 HHAs nationally and one with 19 HHAs in New York State to test whether the HHAs receiving outcome reports and implementing targeted quality improvement efforts could improve outcomes of care. They found statistically significant decreases in rates of hospitalization one year after the initial outcome report and a greater rate of improvement of other outcomes compared to a control group. OASIS has been revised several times and is now used for purposes other than quality improvement including payment, public reporting, survey and surveillance (Anderson, Madigan, &
Helms, 2001; Deitz et al., 2010). Research uses of OASIS include studies to predict hospitalization (Fortinsky, Madigan, Sheehan, Tullai-McGuinness, & Fenster, 2006; Rosati & Huang, 2007), refine definitions of adverse events (Scharpf et al., 2006); evaluate outcomes for subpopulations (Madigan, 2008); assess the impact of payment changes on HHC (Eaton, 2005); and to assess effectiveness of clinical interventions including a nurse care coordination program (Marek, Popejoy, Petroski, & Rantz, 2006) and a restorative care program (Tinetti et al., 2002).

Criticism of OASIS has been multifaceted. One concern is a lack of responsiveness to nursing interventions and insufficient sensitivity or ability to detect clinically meaningful differences in status (Schneider et al., 2008). OASIS may lack sensitivity for specific conditions because it was intended to be generic for all adult HHC patients (Kane & Kane, 2000; Schneider et al., 2008). Other criticisms of OASIS are related to its exclusive focus on outcomes in an environment where the home care clinician may have less control and the burden associated with data collection and management of OASIS data. Mor (2006) noted that consumer groups have expressed concerns that OASIS outcomes do not capture improvements associated with educational interventions. Fortinsky and Madigan (2004) discussed OASIS outcome shortcomings in addressing nursing interventions designed to improve patient knowledge about disease processes, medications, and self-management. In addition, concerns have been voiced repeatedly about reliability and validity of certain items, in part due to some confusing wording in the scale responses (Mor 2006; Sangl, Saliba, Gifford, & Hittle, 2005). Fortinsky, Garcia, Sheehan, Madigan, and Tullai-McGuinness (2003) used a Rasch modeling approach for assessing OASIS scale linearity and found that two items: bathing and telephone use had
nonlinear response options. Several published findings have indicated acceptable validity and reliability for most items (Deitz et al., 2010; Hittle et al., 2003; Madigan & Fortinsky, 2000, 2004; Tullai-McGuinness, Madigan & Fortinsky, 2009). However, other studies have reported issues with inter-rater reliability (Kinatukara, Rosati, & Huang, 2005). Madigan, Tullai-McGuinness, and Fortinsky (2003) found that when comparing nurse and therapist ratings to “correct ratings” for videotaped simulation patients, many discrepancies existed. Other studies have illuminated concerns about convergent validity of the OASIS depression items and sensitivity for detection of depression (Brown et al., 2004; Tullai-McGuinness et al., 2009). The current iteration of OASIS (OASIS-C), implemented in 2010, includes revisions designed to address HHC provider concerns about specific data items with confusing wording, update scales to allow the measurement of improvements for a few items, harmonize several items with corresponding items from the nursing home minimum data set (MDS) and include additional items designed to assess HHA use of specific evidenced-based care processes (Deitz et al., 2010).

**Additional Home Health Care Outcomes Research**

The developers of the Minimum Data Set (MDS) for nursing homes developed a version of the tool for HHC services (Kane & Kane, 2000; Hirdes et al., 2004). Noting distinct differences in nursing facility-based care and HHC, the MDS-Home Care (MDS-HC, now known as the Resident Assessment Instrument-Home Care [RAI-HC]) was developed with the intention of measuring patient outcomes across care settings. The developers noted that “MDS differs from OASIS in that it is designed to serve multiple functions including care planning, eligibility screening, case mix outcome measurement,
and quality indicators” (Hirdes et al., 2004, p. 666), although OASIS was intended to enhance care planning, outcome measurement, risk adjustment and quality improvement efforts (Richard et al., 2000). The RAI-HC has undergone rigorous reliability and validity analyses (Landi et al., 2000; Morris et al., 1997; Morris, Jones, Fries, & Hirdes, 2004). Marek et al. (2006) used selected RAI-HC outcomes to evaluate the Missouri Care Options Nurse Coordination Program for patients on Medicaid Home and Community-based Services Waivers, finding improved ADL outcomes for patients on the program compared to standard care delivery. The RAI-HC is in use in the U.S. and Canada, and translated versions are in use internationally including countries in Europe and Asia (interRAI-HC, n.d.).

In Ontario, Canada, a set of outcome measures was tested in acute care, long-term care facilities, continuing complex care (inpatient care for patients with complex chronic conditions who cannot be care for in long-term care facilities or at home) and HHC for the Nursing and Health Outcomes Feasibility Project. The measures included functional status (from RAI-HC data items), symptom frequency and severity, and therapeutic self-care. Symptom frequency and severity were measured using scales the authors developed for bladder continence, pain, fatigue, dyspnea and nausea, falls risk, and pressure ulcers. Therapeutic self-care, defined as “the patient’s knowledge of the prescribed medications and treatment, ability to recognize signs and symptoms, ability to carry out treatments as prescribed, and knowledge of what to do in case of emergency” (Doran et al., 2002, p. 34) was assessed by interviewing the patient using the Therapeutic Self-Care Scale (TSCS), developed by Sidani and Irvine based on literature review and used for several studies in acute and post-acute care settings (Doran et al., 2006a, 2006b; Doran et al.,
2002; Sidani, 2011; Sidani, 2008). The intent of the project was to evaluate the feasibility of collecting standardized data for nurse-sensitive outcomes across care settings, identify appropriate time intervals for collecting symptom data, assess validity and reliability of measures, and determine learning needs for implementation of the measures across the province of Ontario. Project findings included a positive assessment of feasibility of data collection, which laid the groundwork for a full-scale rollout. Recommended time intervals for data collection were start of care and discharge for inpatient and HHC, monthly for long-term HHC patients and quarterly for long-term care and complex continuing care settings (Doran et al., 2004). Following the feasibility study, the Ontario Ministry of Health and Long Term Care began implementing use of the nurse-sensitive outcome measures in hospitals, complex continuing care settings, long-term care and HHC as part of the HOBIC initiative. The roll-out plan calls for the eventual expansion of HOBIC to include outcomes for other allied health disciplines and practice settings (Ontario Ministry of Health and Long-term Care, 2010).

Saba developed the Home Health Care Classification (HHCC), primarily a taxonomy of nursing diagnoses and interventions, but inclusive of an outcome rating scale to accompany each diagnosis (improved, stabilized, deteriorated) (Saba, 1997; Saba, 2002). No research publications using HHCC data were identified during this literature search. However, other HHC outcome studies have used various other instruments. The SF-36, a generic health outcomes instrument used to evaluate general health status, functional status, and quality of life has been used in several home health studies. Alexy, Benjamin-Coleman, and Brown (2001) examined hospital readmission among 160 Medicare HHC patients serviced by three HHAs using retrospective record review and prospectively
collected outcome and quality of life data using the SF-36 for 17 patients. While tests of mean differences between SF-36 scores on admission and 30 days showed no significant differences, the small sample may have hindered their ability to detect effects. O’Brien-Pallas et al. (2002) evaluated outcomes of community home nursing services in Ontario using the SF-36 and Omaha knowledge and behavior scores. Omaha data were collected for 372 patients and SF-36 was collected for a subsample (n = 50) at admission and discharge from HHC services. The authors found that clients cared for by baccalaureate-prepared nurses demonstrated greater improvements in knowledge and behaviors related to their nursing diagnoses. Time on program was positively associated with improved outcomes; case complexity and age were negatively related. Only two SF-36 scales (social functioning and vitality) showed significant differences between admission and discharge for a small subsample of patients (n = 50). Todero, LaFramboise, and Zimmerman (2002) used the SF-36 and the Cardiac Symptom Survey to assess outcomes of a home-based disease management program for patients recently rehospitalized for exacerbation of chronic heart failure (n = 87). The intervention included use of telehealth, nursing visits, and education with reinforcement. Intervention effects after two months included statistically significant reductions in symptoms and improvements in SF-36 subscale outcomes for role physical, body pain, mental, and vitality domains. Non-significant trends were shown in SF-36 subscales for physical and general health status. Irvine et al. (2000) evaluated the SF-36 and the Quality of Life Profile: Senior Version (QOLPSV) to assess their utility in measuring HHC nursing services. They found that the SF-36 was more sensitive to change over time than the QOLPSV in general, and that SF-36 subscales were more sensitive to nursing variables (e.g., skill mix) than the QOLPSV.
The Older Americans Resources and Services Multidimensional Functional Assessment Questionnaire (OMFAQ) was used by O’Halloran, El-Masri, and Fox-Wasylyshyn (2008) to evaluate factors related to home intravenous (IV) therapy that affected ability to perform self-care activities of daily living. They found that IV delivery method, placement of the venous catheter in the dominant hand, and types of dressing and solutions predicted self-care activities of daily living scores. Delaney and Apostolidis (2010) pilot-tested a self-management intervention using the Minnesota Living with Heart Failure Questionnaire and the PHQ-9 with an intervention group (n = 12) and a control group (n = 12). The intervention group showed significant improvements in quality of life and depressive symptoms, and non-significant trends in the 90-day hospitalization rates. Naylor et al. (2007) tested changes in patient status for APNs delivering community-based care using the Enforced Social Dependency Scale, the Symptom Bother Scale, the Center for Epidemiologic Studies Depression Scale (CES-D), and the Ferran Quality of Life Index Generic Version III. Outcomes derived from these instruments include changes in general health status, physiologic health, mental health, depression, function, self-care (instrumental activities of daily living) coping, patient knowledge, treatment behavior, and quality of life. Findings included improvements in functional status, decreased acute care visits to physicians, and decreases in HHC aide and physical therapy visits. There was a non-significant trend toward reductions in hospitalization and emergency department use. Naylor et al. (1999) used outcomes of hospital readmission, costs, functional status (using the Enforced Social Dependency Scale), depression (measured using the CES-D) and patient satisfaction in their seminal study demonstrating that an intervention in which advance practice nurses followed
elderly patients from the hospital to HHC resulted in reductions in hospital readmissions and costs.

Lengths of stay, use of resources, and costs have been used in descriptive and outcome studies in HHC. Murtaugh et al. (2009) used 2004 – 2005 OASIS data to describe the clinical complexity of patients admitted to HHC (n = 5,585,931), finding longer lengths of stay for patients with cognitive impairment and multiple chronic conditions. Madigan (2008) described HHC patients with heart failure, using the 2003 National OASIS database, reporting an average length stay of 44 days. In a data-mining project of 2000 National Home and Hospice Care Survey data, Madigan and Curet (2006) used a Classification and Regression Tree approach and found that patient age of 85 or older was a primary factor influencing discharge destination and length of stay for patients with chronic obstructive pulmonary disease, heart failure, or hip replacement. Fortinsky and Madigan (1997) found similar service volume and costs among HHC patients who were hospitalized vs. those who were discharged to home, although hospitalized patients used the resources in a shorter period of time. Eaton (2005) compared ulcer healing in elderly HHC patients with Stage III or IV decubitus ulcers prior to and following the implementation of prospective payment. After controlling for comorbid conditions, she found statistically significant longer lengths of stay under prospective payment along with reductions in ulcer healing. Tinetti et al. (2002) evaluated a restorative care intervention in a sample of 691 elderly Medicare HHC patients. The control group was a matched sample receiving usual care. Patients receiving the intervention, which included multidisciplinary care provided based on geriatric medicine, nursing, and rehabilitation principles had a greater likelihood of remaining at
home, reduced likelihood of emergency department use, shorter HHC length of stay, and improved OASIS functional outcomes.

A few HHC studies have incorporated the notion of self-management outcomes. Feldman, Murtaugh, Pezzine, McDonald, and Peng (2005) found improved outcomes with an intervention consisting of “just-in-time” email reminders to heart failure patients to remind them to take medications and perform other self-management measures. In addition to OASIS outcomes, Feldman and colleagues assessed condition-specific functional and clinical outcomes using the Kansas City Cardiomyopathy Questionnaire, depression with the Geriatric Depression Scale (GDS); quality of life using the EuroQoL, costs, self-management using interview questions derived for the study, and costs. Kline, Scott, and Britton (2007) adapted a self-efficacy scale from Lorig and colleagues to assess the effectiveness of nursing approaches designed to improve self-management in HHC patients with heart failure. Several non-research articles were found discussing the use of clinical nursing interventions to promote self-management (Bowles & Dansky, 2002; Huffman, 2007; Suter et al., 2008; Suter & Suter, 2008; Wolf, 2006).

**Adverse Event and Patient Safety Outcomes**

Masotti, McColl, and Green (2010) conducted an extensive literature review of adverse events in HHC and identified eight categories: a) adverse drug events, b) central lines, c) technology, d) infections and urinary catheter-related, e) wounds, f) falls, g) other, and h) multiple events. Patient characteristics associated with increased risk of adverse events include advanced age, more comorbidities, female gender, increased depression, cognitive impairments, functional impairments, poor patient compliance/adherence, and living alone/no caregiver. Doran et al., (2009) assessed
adverse events for Canadian home care patients including new falls, unintended weight loss, emergency room visits, and new hospitalizations. An incident rate of adverse events was reported to be 13.2 per 100 patients in a sample of 430 receiving publicly funded HHC in Ontario in 2004 and 2005 (Sears, Baker, Barnsley, & Shortt, 2013). Adverse event reports based on OASIS data are currently reported to agencies through the CMS HHC reporting system (CMS, 2010b). Madigan (2007) found that 13% of Medicare and Medicaid patients are discharged from HHA services after experiencing an (OASIS-defined) adverse event and 75% of adverse events reported are associated with discharge to community requiring additional assistance. She noted that female patients had a slightly lower relative risk for experiencing adverse events, while patients from minority race groups had a slightly higher relative risk. Other patient characteristics associated with adverse events included depressive symptoms, behavioral problems and functional impairment. Moureau, Poole, Murdock, Gray, and Semba (2002) identified additional adverse outcomes for patients receiving intravenous therapy at home: catheter dysfunction (loss of patency), site infections, and bloodstream infections.

**Satisfaction Outcomes**

Patient satisfaction outcomes are frequently used by HHAs to evaluate their own services, often using outside vendor products and analytic services (e.g., Press-Ganey) (Qualidigm, 2003; Rosati, 2009). Riccio (2001) noted that in a competitive health care environment, the need to assess consumer satisfaction is critical. Recently in the U.S., a standardized satisfaction instrument, the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) has been implemented for Medicare and Medicaid patients (HHCAHPS survey, n.d.). HHAs contract with specific vendors to
collect and analyze HHCAHPS data for use in their quality improvement programs.

Mager and Ross (2013) used HHCAHPS to evaluate an intervention to improve nurse medication management skills, finding an improvement in patient satisfaction following the intervention.

**Factors Influencing Home Health Care Outcomes**

Beyond nursing and allied health provider intervention, there are many factors that may influence patient outcomes. These include patient-level and contextual factors. Patient characteristics thought to impact HHC outcomes include demographics (i.e., age, sex, race/ethnicity, marital status, educational level, payment source), diagnosis, recent hospital discharge and history of prior hospitalization, equipment (e.g., urinary catheters, vascular access devices), complexity of medical condition/treatment, frailty, guarded rehabilitation prognosis, baseline and prior health and functional status, history of falls, polypharmacy, receipt of anxiolytic or antidepressant medications, multiple comorbidities, depression, social and cognitive functioning, caregiver relationships, social support, and health-related behaviors and activities (Adams, Moore, & Michel, 2000; Anderson et al., 2001; Armstrong, Stole, Hirdes, & Poss, 2010; Doran et al., 2009; Feldman et al., 2005; Fortinsky et al., 2006; Madigan, 2007; Madigan & Curet, 2006; Madigan et al., 2001; Murtaugh et al., 2009; Murtaugh et al., 2007; Nuccio & Richard, 2010; O’Brien-Pallas et al., 2002; O’Halloran et al., 2008; Rosati, 2009; Rosati & Huang, 2007; Shaughnessy, Crisler, Schlenker, & Arnold, 1997; Tinetti et al., 2002). Sorenson, Stokes, Purdie, Woodward, and Roberts (2005) reported polypharmacy to be a risk factor for poor outcomes in community-dwelling elders in Australia, although these were not patients receiving HHC services. Environmental factors thought to be associated with
HHC outcomes include sanitation and other aspects of the home environment (Shaughnessy et al., 1997) and community characteristics (rural/urban location; low-income community; market factors) (Brega et al., 2003; Fortinsky, Madigan, & Tullai-McGuinness, 2000; Schlenker, Powell, & Goodrich, 2002). Adams, Corbett, and Michel (2000) did not find significant differences in outcomes between rural and urban HHAs, only differences in the number of visits provided. Vanderboom and Madigan (2008) found only an indirect effect of rurality on the outcome of acute care hospitalization through service use.

System/context level factors studied in relation to HHA outcomes include provider ownership (for-profit vs. nonprofit, hospital-based) (Fortinsky et al., 2006; Grabowski, Huskamp, Stevenson, & Keating, 2009; Madigan & Curet, 2006). Grabowski et al. did not find significant differences in outcomes for for-profit vs. nonprofit HHAs. O’Brien-Pallas et al. (2002) found that nurse characteristics were associated with improved clinical outcomes. In their study of 751 patients receiving home health care in Ontario, Canada, patients cared for by nurses with higher levels of education demonstrated improved knowledge and behavior health outcomes. Patient knowledge outcomes improved at a greater rate when they were cared for by nurses with more experience in community health.

Action focus processes considered in evaluation of outcomes include total volume of services provided, although the effect of the number of visits on outcomes has been mixed (Adams et al., 2000; Fortinsky & Madigan, 1997; Rosati & Huang, 2007). Nuccio and Richard (2010) found that the length of time between referral and initiation of services impacted outcomes. Patients receiving within the same day as hospital referral
were more likely to be rehospitalized, although for patients not hospitalized, timely
initiation of services was associated with improved on certain functional and
physiological outcomes than those seen three days after the referral for care. Authors
hypothesized that the higher rehospitalization rates were likely for patients who were less
medically stable at hospital discharge. Other action focus processes that have been
studied include “front-loading” visits early in the HHC episode (Rogers, Perlic &
Madigan, 2007), presence of a care plan (Van Houdt & De Lepelieire, 2010),
consideration of service mix (RN visits vs. other staff) and number of NIC interventions
performed (Schneider et al., 2008), and use of e-mail reminders to augment visits
(Feldman et al., 2005).

Home Health Care Outcomes Summary

A great deal of work has been conducted in the area of HHC outcomes. While a
variety of concepts and instruments have been used for research, the Omaha system and
OASIS are the two outcome systems most frequently used in practice to assess U.S. HHC
outcomes. The largest payer of HHC services, CMS, requires OASIS data collection for
Medicare and Medicaid patients and in turn, produces outcome reports for Medicare-
certified HHAs. The OASIS outcomes, while addressing some elements of self-care/self-
management (i.e., ADLs, oral medication management), do not assess patient perception
of ability to manage health conditions, including symptom management and knowledge
and ability of how to handle emergencies. In Canada, the RAI-HC and the TSCS are used
to assess outcomes across inpatient and post-acute care settings. The TSCS was designed
to capture a elements of self-management and self-care as discussed below.
Self-care and Self-management

Self-care and self-management are considered to be sensitive to nursing care, particularly those nursing interventions involving self-help education and support of patients and families (Cebeci & Senol, 2007; Kreulen & Braden, 2004; Sidani, 2011). The concepts have been extensively addressed in nursing and related literature and defined and delineated by Richard and Shea (2011). However, a summary discussion of the concepts is included in this section to clarify the primary aims of the proposed study.

Both self-care and self-management consist of two primary dimensions: the ability to care for oneself and the performance of activities necessary to achieve, maintain, or promote optimal health. Self-care is a broad construct that incorporates a view of health that includes needs and activities related to promotion and maintenance of health, human development, and general well-being as well as activities specific to particular acute or chronic health conditions (Orem, 1995). Lipson and Steiger (1996) expanded the definition of self-care beyond the notion of the individual by stating that self-care involves “activities performed by individuals or communities to achieve, maintain, or promote maximum health” (p. 16). Gantz (1990) noted that while the term is used across health care disciplines, common definitional elements are recognition that self-care is situation-specific and culturally influenced, involves abilities for decision-making and action performance for those activities under the individual’s control, and is influenced by individual characteristics including self-efficacy, locus of control, knowledge, skills, and values. Much of the nursing research on self-care is framed by Orem’s self-care deficit theory, which posited that therapeutic self-care demand that exceeds self-care agency results in self-care deficits, and that nursing care addresses those self-care deficits.
in a variety of ways (e.g., doing for, teaching, guiding, supporting, manipulating the environment, etc.) (Denyes, Orem, & Bekel, 2001; Gast et al., 1989; Henry & Holzemer, 1997; Orem, 1995). In the past 25 years, a variety of instruments have been developed and tested to measure self-care. Self-care tools include the Self-as-Carer Inventory, the Exercise of Self-Care Agency, the Denyes Self-Care Agency Scale, the Perception of Self-Care Agency Questionnaire, and the Appraisal of Self-Care Agency Scale (Gast et al., 1989; Geden & Taylor, 1991; Henry & Holzemer, 1997; McBride, 1987; McBride, 1991; Sousa, Zauszniewski, Zeller, & Neese, 2008).

Self-management is a more circumscribed aspect of self-care, most frequently focused on patient/family management of health care conditions such as chronic diseases (Barlow et al., 2002; Jerant, von Friederichs-Fitzwater, & Moore, 2005; Lorig & Holman, 2003; Novak, Costantini, Schneider, & Beanlands, 2013; Wagner, Davis, Shafer, Von Korff, & Austin, 2002; Wilde & Garvin, 2007; Wilkinson & Whitehead, 2009). Self-management has been defined as the ability and performance for managing chronic disease symptoms, treatments and psychosocial and lifestyle consequences (Clark et al., 1991; Paradis, Cossette, Frasure-Smith, Heppell, & Guertin, 2010; Riegel & Dickson, 2008; Thorne, Paterson, & Russell, 2003, Unger & Buelow, 2009; Wilkinson & Whitehead, 2009). In a qualitative metasynthesis of 101 studies on self-management, Schulman-Green et al. (2012) found three categories of self-management processes: a) focusing on illness needs; b) activating resources; and c) living with a chronic illness. Chronic disease self-management programs have been developed to improve self-care generically and for specific conditions. Interventions may include feedback, teaching, role playing, contracting, psychological support, medical care, use of decision support
guidelines/tools, and information technology (Barlow et al., 2002; Chodosh et al., 2005; Wagner et al., 2002). Kreulen and Braden (2004) tested a nursing intervention to improve self-care outcomes for breast cancer patients. Using path analysis, they found that nursing interventions had a direct impact on self-care behaviors and that self-care practices were associated with less morbidity. In HHC, nursing strategies to promote self-management have been identified as supportive-educative strategies and mutual goal-setting (Kline et al., 2007); health coaching (Huffman, 2007); use of “just-in-time” email reminders (Feldman et al., 2005); use of evidence-based principles of learning such as feedback, integration with pre-existing knowledge, and hands-on activities (Suter & Suter, 2008); and telehealth interventions (Bowles & Dansky, 2002).

A major factor influencing self-care and self-management outcomes has been identified as perceived self-care agency or self-efficacy, which is the belief that one can accomplish certain activities (Bandura, 1997; Lenz & Shortridge-Baggett, 2002). The concept of patient activation, based on tenets of the Chronic Illness Model in which patients and families play an integral role in the care team has been associated with improved self-management behaviors and processes (Hibbard, Mahoney, Stock, & Tusler, 2007; Hibbard & Tusler, 2007; Hibbard et al., 2004; Mosen et al., 2007; Remmers et al., 2009; Wagner et al., 2001). Patient activation encompasses ability in six domains: 1) self-management of symptoms; 2) engagement in activities to prevent health declines/maintain function; 3) involvement in treatment decisions; 4) collaboration with providers; 5) selection of providers based on quality; and 6) navigation of the health system (Hibbard et al., 2004), although the Patient Activation Measure is heavily focused on perceived ability or self-efficacy.
Cognitive, psychosocial, physical, demographic and sociocultural factors also have been identified as factors influencing self-care (Sidani, 2011). Experience with a health care condition can influence self-care actions for patients with heart failure (Carlson, Riegle, & Moser, 2001). Physical limitations, depression, weight problems, fatigue, lack of awareness, lack of knowledge, poor physician communication, financial constraints, logistics of obtaining care, lack of family and social/emotional support, combined effect of symptoms of multiple conditions, multiple problems with medications, and overwhelming effects of dominant conditions can negatively affect self-care ability (Bayliss, Steiner, Bernald, Crane, & Main, 2003; Jerant, von Friederichs-Fitzwater, & Moore, 2005; Jerant, Kravitz, Moore-Hill, & Franks, 2008).

Improvements in self-care and self-management can lead to other outcomes including better symptom control and lower risk of complications; lower mortality and disability, decreased health system costs and utilization (including hospital re-admissions); improvements in coping ability, a sense of control and meaning, well-being and quality of life, general recovery, and satisfaction (Jerant et al, 2005; Leenerts, Teel, & Pendleton, 2002; Schnell-Hoehn, Naimark, & Tate, 2008; Sidani, 2011; Song, 2010). Programs designed to improve self-management of targeted health conditions evaluate generic outcomes along with those specific to the diagnosis of interest. For example, one such program, the Chronic Disease Self-Management Program (CDSMP) has been effective in improving health behaviors and health status (i.e., reduced pain for patients with arthritis or back pain) and lower utilization of health care services (Bodenheimer et al., 2000; Lorig & Holman, 2003; Lorig, Ritter, & Plant, 2005).
Outcomes measured for self-management programs include relevant physical, psychological, and social health status outcomes; knowledge; use of medications; self-efficacy; self-management behaviors; use of health care resources; and quality of life. For disease-specific programs, outcomes are those associated with the disease, such as measurement of peak flow for asthma self-management programs (Barlow et al., 2002; Chodosh et al., 2005). The CDSMP scale for self-management behaviors for chronic conditions measures exercise, cognitive symptom management, mental stress management/relaxation, use of community services, communication with physician, and advance directives (Lorig et al., 1996; Lorig & Laurent, 2007). As discussed previously, a measure of self-management is currently being used across care settings as part of the Health Outcomes for Better Information and Care (HOBIC) project in Ontario, Canada.

**Summary**

Over the past several decades, research to identify and measure health care outcomes has assumed an central role in evaluation of U.S. healthcare services. Since the 1980s, nursing leaders and researchers have identified outcomes theoretically sensitive to nursing care. In HHC, the Centers for Medicare & Medicaid Services (CMS) sponsored the development of a national system of outcome measures for Medicare and Medicaid adult patients, resulting in the OASIS data set. Various other outcomes have been used in HHC research. One of the primary goals of HHC services is to promote and facilitate self-management. Self-management involves management of health symptoms, treatments, and psychosocial and lifestyle consequences of chronic health conditions. The currently-available outcomes for U.S. HHC include change in functional ability and ability to manage oral medications, but not other relevant self-management activities.
With ongoing emphasis in the health care community on the concept of self-care generally and self-management of chronic health conditions, it is important to identify a way to measure changes in self-management as an outcome of HHC. Thus, the purpose of this study was to evaluate the psychometric properties of a broad measure of self-management, the TSCS, for a U.S. adult HHC population and its potential utility for outcome measurement.
CHAPTER III

METHODS

A multi-site, descriptive design was used to assess psychometric properties of the Therapeutic Self-care Scale (TSCS) in adult home health care (HHC) patients. This study addressed reliability, validity and responsiveness of the instrument. The study was reviewed and approved by the Colorado Multiple Institutional Review Board (COMIRB).

**Home Health Agency (HHA) Recruitment**

Medicare-certified HHAs in the Denver, Colorado, metro area were identified through known contacts and from the Home Health Compare web site. An email was sent to six HHAs with a brief introduction to the project, requesting a response to indicate interest in participating. In addition, the Home Care Association of Colorado (HCAC) sent all participating agencies information on the project and encouragement to participate. Three HHAs responded to initial recruiting efforts. The investigator then contacted HHA administrators, providing a brief explanation of the study and data collection instruments, specific responsibilities for both the agency and the study team, and the need for study personnel to obtain clinical record (Outcome and Assessment Information Set [OASIS]) data with patient permission. Administrators were asked to participate in the project if they believe that they could identify at least 80 potential study patients over a four month period. Two HHAs agreed to participate in the study. One agency (Agency 1) served approximately 800 patients annually patients in a small town and surrounding areas northwest of the north Denver metropolitan area. The second agency (Agency 2) was a very large proprietary agency, serving approximately 20,000 patients annually across the Denver metro area. The HHA administrators signed letters of
agreement signifying both their understanding of the project and agreeing to continuing participation until the sample was filled.

**Training**

The investigator visited each site prior to the initiation of the data collection activities to discuss the study in detail with staff during a staff meeting. Staff were asked to inform newly-admitted patients about the study. For patients agreeing to participate, staff would notify the investigator and provide contact information. For a subsample of patients (identified by the investigator), staff would alert the investigator prior to HHC discharge. Staff were provided with study flyers and HIPAA-A forms to distribute to newly admitted patients meeting the following criteria: a) eligible to receive HHC services, b) without cognitive impairment, as assessed by the nurse during the admission visit using the OASIS scales for cognitive impairment and (negative) demonstrated behaviors, and other routine agency screening tools; and c) English-speaking. Although a substantial number of cognitively impaired patients receive HHC services, feedback from acute care nurses indicate that they may have difficulty understanding and responding to TSCS items (Sidani, Doran, Tracey, & Persaud, n.d.). While these patients were excluded from the current study, future studies should address these issues, perhaps by assessing psychometric performance of the TSCS when responses are provided by family or informal caregivers.

**Data Collection Procedures**

Registered nurses and physical therapists from participating HHAs identified potential study subjects during their regular admission visits. They provided study flyers to subjects, obtained signatures on the HIPAA-A form and requested permission to
provide their contact information to the investigator. Once the patient provided written consent to be contacted, the nurse or therapist provided the patient name, address and phone number to the investigator via phone or voicemail. The investigator subsequently contacted the patient and scheduled a visit to the patient home within five days of HHA admission.

The investigator visited the patient to obtain informed consent for study participation and to collect data. Informed consent included patient permission for the investigator to access selected data items from the HHC clinical record. During the approximately 20-30 minute home visit, the Mini-Mental Status Exam (MMSE) was conducted to verify that the patient was cognitively able to participate in testing. No patients scored lower than a 20 on the MMSE, higher than the minimum score of 19 needed to participate in the project. Following the MMSE administration, a brief interview was administered to obtain TSCS and General Symptom Distress Scale (GSDS) responses.

In addition to the full sample, additional data were required for two smaller subsamples of subjects. The investigator requested permission to conduct a follow-up telephone interview within three days to collect the TSCS data for test-retest reliability (until 30 patients were recruited for Subsample A). If the patient was admitted to the HHA for care related to an orthopedic surgical procedure (i.e., total or partial hip replacement, knee replacement, etc.) or for treatment of an open wound or lesion, the investigator requested permission to conduct a follow-up telephone interview within five days of HHA discharge (if discharged to the community) for the purpose of collecting data for the responsiveness analyses (Subsample B). In some cases, subsamples A and B overlapped (i.e., patients were eligible for both). Table 4 provides additional information
on the full sample and subsamples A and B. The investigator contacted patients agreeing to participate in the test-retest data collection (Subsample A) by telephone to collect the TSCS data within three days of the home visit. In addition, patients agreeing to participate in the responsiveness data collection (Subsample B) were contacted by telephone with five days of HHA discharge to administer the TSCS. In addition to the scale responses, the patient was asked two additional questions: a) “Did your ability to manage your health condition improve since home health care began?” and b) “If so, please rate how much you improved from 1 to 7, using the following scale: 1 - Not at all improved, 2 - A little improved, 3 - Somewhat improved, 4 - Moderately improved, 5 - A good deal improved, 6 - A great deal improved, or 7 - A very great deal improved.”

Table 4: Study Sample

<table>
<thead>
<tr>
<th>Sample</th>
<th>Analyses</th>
<th>Data</th>
<th>Time points</th>
</tr>
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<tbody>
<tr>
<td>Full sample</td>
<td><em>Internal</em></td>
<td>TSCS</td>
<td>Within 5 days of admission</td>
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<tr>
<td></td>
<td><em>Consistency</em></td>
<td>GSDS</td>
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<td></td>
<td><em>Reliability;</em></td>
<td>OASIS data (from chart)</td>
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<tr>
<td></td>
<td><em>Construct</em></td>
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<td></td>
<td><em>Validity</em></td>
<td></td>
<td></td>
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<tr>
<td>Subsample A</td>
<td><em>Test-retest</em></td>
<td>Time 1: same as full sample</td>
<td>Time 1: as above as part of full</td>
</tr>
<tr>
<td></td>
<td><em>reliability</em></td>
<td>Time 2: TSCS</td>
<td>sample</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time 2: within 3 days of Time 1</td>
<td>Time 2: within 3 days of Time 1</td>
</tr>
<tr>
<td>Subsample B</td>
<td><em>Responsiveness</em></td>
<td>Time 1: same as full sample</td>
<td>Time 1: as above as part of full</td>
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<td></td>
<td></td>
<td>Time 2: TSCS</td>
<td>sample</td>
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<tr>
<td></td>
<td></td>
<td>GSDS</td>
<td>Time 2: within 5 days of discharge</td>
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<td></td>
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<td>OASIS discharge</td>
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<td></td>
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<td>ADL data</td>
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<td>Global rating of self-mgt. changes</td>
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</table>
The investigator visited the HHA offices to obtain selected OASIS data from the patient clinical record. Data collected on HHA admission include age, gender, race, primary diagnosis, comorbidities, availability and involvement of informal caregivers, and baseline Activities of Daily Living and Instrumental Activities of Daily Living (ADL/IADL) functional status (see Appendix A). These variables have been identified as influencing outcomes and were used to describe the study population. For Subsample B only, discharge ADL/IADL functional status data were collected along with information on the number of visits by discipline.

**Data Management**

All patients were assigned study ID numbers. A master list of names was kept under lock and key by the investigator and destroyed after all data were collected. Data were collected on paper and entered into a password-protected Statistical Package for the Social Sciences (SPSS, version 21) database at the University of Colorado College of Nursing Center for Nursing Research. Paper versions were stored in a locked file cabinet.

**Sample**

There were considerable challenges with subject recruitment. A sample size of 200 was proposed for the study, with the goal of performing a confirmatory factor analysis. Given the number of patients visited by the HHAs, it was anticipated that the sample could be achieved within a few months. However, six months following COMIRB approval and HHA training, less than 30 patients had been recruited. The investigator contacted HHA coordinators every two to three weeks and attended multiple staff meetings at both sites to remind and encourage nurses and therapists to continue attempts
to recruit subjects. Following the staff meeting presentations in September 2012 and January 2013, a spike was seen in referrals (see Fig. 2).

Figure 2. Subject Enrollment

However, over the course of 12 months, only 70 subjects were referred for study participation (see Figure 3). Of those, three referrals were provided after the required five-day window following HHA admission and one patient did not meet study criteria for no cognitive impairment. Seven patients either refused study participation when contacted by the investigator or were not available for a visit within the five-day window. A total of 59 patients were recruited and completed all study requirements. Due to a miscommunication with one HHA, six of the admitted subjects did not also have OASIS data collected because of a new HHA policy that no longer required OASIS data to be collected for private-pay patients. COMIRB was notified of the unanticipated event and approved the inclusion of data from those subjects for data analyses.
For test-retest analyses, power analysis indicated a minimum sample of 18 was required to detect differences between Time 1 and Time 2, with \( \alpha \leq .01 \). Thirty-seven subjects were contacted for the test-retest data collection. The investigator was unable to establish contact with seven of them, but continued sampling until test-retest data were collected for 30 subjects (Subsample A).

Power calculations indicated that a sample size of at least 24 was necessary to conduct responsiveness analyses (i.e., for detection of moderate effect sizes using paired t-tests \( \alpha \leq .01; \beta >.80 \)). Thirty-seven subjects were identified as eligible for responsiveness analysis (Subsample B), because their conditions identified them as likely
to improve over the course of the HHC episode. Eligible subjects were those admitted to the HHA with an orthopedic diagnosis or following an orthopedic surgical procedure (i.e., total or partial hip replacement, knee replacement, etc); or for treatment of open wounds or lesions. Literature indicates that patients with these diagnoses are positively associated with improved functional outcomes, one component of self-management (Keepnews, Capitman, & Rosati, 2004). In addition, Doran et al. (2006a) found a positive relationship between patient functional ability and therapeutic self-care ability, as measured by the TSCS. Because of the likely trajectory of self-management in these patients and because self-management improvements are a primary goal of HHC nursing, it was anticipated that responsiveness analyses would find moderate effect sizes. Of the 37 subjects identified as eligible, the investigator was not able to establish contact to obtain follow up information within 5 days of discharge for 5 subjects. A total of 32 subjects completed all data collection and were included in Subsample B analyses. 

**Instruments**

**Therapeutic Self-care Scale**

The TSCS was developed based on literature review and has been tested in acute and postacute care settings (Doran et al., 2006a, 2006b; Doran et al., 2002; Ontario Ministry of Health and Long-term Care, 2010), although until recently, psychometrics had only been reported for acute care (Doran, D.I., personal communication, 1/26/2011). The scale consists of 12 questions on ability to take medications, recognize and manage symptoms, carry out prescribed treatments, conduct daily activities, and handle emergencies (see Appendix A). The scale is administered by a nurse to patients in interview format, with responses from 0 (not at all) to 5 (very much so). The TSCS is scored using the average
of all responses. This allows for simplified interpretation of the results as the scale range is maintained and addresses potential issues with missing data (Sidani, S. personal communication, 8/31/2011).

The TSCS reliability has been assessed in several studies, with Cronbach’s alpha for the full scale reported as .88 (Doran, et al., 2002), .93 (Doran et al., 2006b), and .97 (Hall, Wodchis, Ma, & Johnson, 2013). In a study of the effects of patient-centered care performed by advanced practice nurses in hospitals, Sidani (2008) found the TSCS to have four subscales with \( \alpha = .78 \) for taking medications, .89 for managing symptoms, .81 for performing regular activities, and .66 for managing changes in condition. Chaboyer et al., (2012) performed factor analysis on the TSCS for post-trauma patients at three months following hospital discharge. Two items were removed based on negative or low correlations with other items; Items 11 (Do you perform your regular activities such as bathing, shopping, preparing meals, visiting with friends?) and 8 (do you do things or activities to look after yourself and to maintain your health in general). The factor analysis on the remaining 10 items found three components with eigenvalues >1: a) Taking Medications; b) Recognizing and Managing Symptoms and c) Managing Changes in Health Conditions. The three factors explained 59.8% of the variance.

The TSCS has identified small effect sizes in studies in acute care settings. Doran et al. (2002) evaluated the effect of nursing perceptions on therapeutic self-care outcomes using structural equation modeling. They reported that nurse perception of effective communication had a direct effect of 0.20 and a total effect of 0.15; perceptions of overall quality had both a direct and total effect of 0.15. Hall et al. (2013) reported a small change between hospital admission and discharge (effect size = .12, \( p < .001 \)) for a
sample of 59,157 hospitalized patients at 44 hospitals in Ontario, Canada. In another study, nursing interventions were not found to have a direct effect on therapeutic self-care, however there was a positive relationship between patient functional ability and therapeutic self-care ability. (Doran et al., 2006a). While the effects are small, it is important to note that the goals of nursing care in inpatient settings are substantially different than in a HHC setting. In HHC, where improved patient self-management is a primary goal, it is reasonable to anticipate greater changes as a result of nursing interventions. Chaboyer et al. (2012) used the TSCS to evaluate the stability of self-care over time for a sample of 194 adult patients with traumatic injuries in two hospitals in Australia. TSCS scores were high at 3 months (n = 125) and remained so 6 months (n = 103). There was no indication that HHC was provided for these patients. The authors noted a possible ceiling effect of the tool for their population.

**General Symptom Distress Scale**

To assess construct validity, the GSDS was used as a criterion measure. The GSDS is a brief scale requesting that the patient identify specific symptoms and rank the symptoms based on the degree of distress. Two additional questions request that the patient evaluate a) the overall distress associated with all symptoms on a scale of 1-10 (not at all distressing to extremely distressing) and b) symptom management on a scale of 1-10 (cannot manage at all to can manage extremely well). Psychometrics were tested in a sample of patients with cancer (n = 190) and their partners (n = 94), using a repeated measures design. Internal consistency was reported to be high (α = .75) for patients and for partners of English-speaking prostate cancer patients and Spanish-speaking breast cancer patients (α = .79). Test-retest was reported for time one to time two (r = .72, p <
.001) and time two to time three (r = .67, p < .001). Construct validity was established with positive correlations with scales measuring depression, affect, and general health. The researchers found that the GSDS total sum predicted depression and affect. In the known-groups validity testing, the GSDS was associated in a linear fashion with disease stage (Badger, Segrin, & Meek, 2011).

**OASIS**

OASIS content validity was assessed during the original development and the recent revisions (Deitz et al., 2010). Multiple technical expert panels have reviewed the items for clinical validity and utility, importance to patient health, and anticipated measurement precision. While validity testing of the OASIS has been limited, Madigan and Fortinsky (2000) conducted an exploratory factor analysis for the selected functional domain items. Items loaded onto one factor with loadings ≥ .61 (56.3% of the variance explained) for the items collected at admission and ≥ .74 (68.9% of the variance explained) at discharge. Tullai-McGuiness, Madigan, and Fortinsky (2009) tested convergent validity of OASIS items with gold standard instruments. They found robust correlation between OASIS ADLs and Older Americans Resources and Services (OARS) ADL items (r = .71) but only moderate correlations (r = .49) between OASIS and OARS IADL measures; OASIS cognitive items and the Short Portable Mental Status Questionnaire (SPMSQ) showed high to moderate correlation (r = .62). OASIS depression items exhibited low to moderate correlations with two criterion instruments: the Center for Epidemiology Studies Depression Scale (CES-D; r=.36) and the Brief Symptom Inventory (BSI; r = .26). OASIS developers reported two independent tests of inter-rater reliability (Hittle et al., 2003; Shaughnessy et al., 2002). For the first, two RNs
completed the OASIS independently during a single home visit for 35 patients. Inter-rater reliability for OASIS items was interpreted based on Landis and Koch (1977) recommendations, where weighted kappa values of .41-.60 indicate moderate agreement, values of .61 to .80 indicate substantial agreement, and values ≥ .80 indicate almost perfect agreement. Reported kappas for all but four items were ≥ .41 (Shaughnessy et al., 2002). Findings from a later OASIS reliability test yielded kappa in the range of .41-.91 for most items; and .60 or higher for functional status items (Hittle et al., 2003). Madigan and Fortinsky (2004) reported on an inter-rater reliability test using a concurrent visit approach. They found that 23 of 25 OASIS items studied had weighted kappa values ≥ .60. Kinaturkara et al. (2005) found much lower weighted kappa values for OASIS items in their reliability tests, with 39 items demonstrating poor reliability (kappa ≤ .40).

**Analysis**

**Internal Consistency Reliability**

Internal consistency reliability was assessed using data from the full sample (n = 59) to determine inter-item correlation and Cronbach’s alpha. Cronbach’s alpha estimates the average of all the split-half correlations that could be generated for an instrument (Ferketich, 1990). According to Nunnally and Bernstein (1994), alphas of .70 are acceptable for instruments at the early stage of development and .80 for more developed instruments. Recommended sample sizes for determination of Cronbach’s alpha are 5-10 subjects per item (Ferketich, 1990).

**Test-retest Reliability**

Test-retest reliability was evaluated on Subsample A (n=30). Based on the Streiner and Norman (2008) recommendations, intraclass correlation (ICC) was analyzed to test
individual TSCS items and the overall score (scale mean). Three days was chosen as the time interval between responses. This time frame, within the recommended two to 14 days for test-retest data collection (Streiner & Norman, 2008), was selected because patients’ health status may change rapidly in the first few weeks following hospital discharge and subsequent HHC admission, and it was important to minimize the risk of the underlying process changing while balancing that with the risk of subjects remembering their initial responses.

**Convergent Validity**

To assess convergent validity using the GSDS, correlations were made between the TSCS overall mean and a) the number of symptoms the subject reported experiencing, b) GSDS overall symptom distress and c) the GSDS rating of ability to manage symptoms. Because three of the TSCS items (6, 7 and 12) are specifically worded to assess symptom management, the same correlations were run with those TSCS items individually and the mean of those three items. In addition, the TSCS overall mean was correlated with the OASIS ADL score. Additional correlations were with the OASIS ADL total and the TSCS items specifically related to ADLs (TSCS 8 and TSCS 9), both individually and combined.

**Factor Analysis**

Exploratory factor analysis was used to evaluate construct validity. The small sample size did not permit a confirmatory factor analysis (Munro, 2005). Factor analysis is used to identify the number of latent variables measured by a scale (DeVellis, 1991). Exploratory factor analysis (EFA) was performed using a principal components analysis (PC) which assumes that the amount of variance to be analyzed is equal to the number of
variables, and was selected because the evaluation of scale components for this population is truly exploratory (Mertler & Vannatta, 2005). The EFA was conducted using SPSS (v. 21) to evaluate communalities, component loadings, between-factor loadings and explained variance.

**Responsiveness**

Responsiveness refers to an instrument’s ability to detect small, medium or large changes (effects) when they exist (Kirschner & Guyatt, 1985). To assess the ability of the TSCS to detect changes in self-management that occur during a home health care episode of care, the minimally important clinical difference (MICD) was assessed. MICD is “the smallest difference in score in the domain of interest which patients perceive as beneficial...” (Jaeschke, Singer, & Guyatt, 1989, p. 498). The identification of a MICD is helpful to evaluating efficacy of clinical interventions. MICD was assessed using a method originally developed by Jaeschke, et al. and adapted by Schwartz et al. (2002). The method utilizes global ratings of change in self-management across the care episode that the subjects provided during the discharge data collection telephone call and compares them to TSCS change scores.

Subsample B subjects were placed in one of four groups corresponding to the magnitude of their global rating of change: no change (0), small change (ratings of 1 to 3), moderate change (ratings of 4 or 5) and large changes (ratings of 6 or 7). For the analysis, first raw scores from the discharge time point were compared to the overall rating to assess the strength of the relationship. Next, change scores (discharge minus admission) were calculated for each item and the overall scale mean. Change scores were stratified for each of the four groups. Nonparametric analysis of variance (ANOVA)
(Kruskal-Wallis) was used to determine the differences in the TSCS for subjects based on groupings. According to Revicki, et al. (2006), the MICD would be the observed change in the small improvement group.

**Summary**

The TSCS has potential utility in HHC outcomes measurement, as it addresses a key goal of HHC services delivery, which is to improve a patient’s ability to self-manage his or her health needs. This study evaluated psychometric properties of the TSCS with an adult home health care population (n = 59). Both internal consistency and test-retest reliability were examined. Construct validity was assessed through factor analysis and convergent validity with the General Symptom Distress Scale and OASIS activities of daily living. Responsiveness was tested in a subsample of patients who are expected to improve in self-management. To determine the MICD, scale responses were compared with a global patient rating of self-management improvement.
CHAPTER IV

RESULTS

The Therapeutic Self-care Scale (TSCS) addresses aspects of self-management not addressed by current outcome measures but that are highly relevant to the goals of home health care (HHC) educational and other interventions. This chapter will present the demographic characteristics of the sample and the analysis results associated with the research questions. Psychometric properties of the TSCS were evaluated in a population of adult HHC patients to determine the feasibility of using the tool to develop an outcome measure (e.g., change in self-management) for HHC services. All analyses were performed in SPSS (v. 21).

Descriptive Analysis of the Sample

Descriptive statistics were analyzed for the full sample of 59 subjects (see Table 5). While OASIS data were used for patients for whom the data were available, other chart data were used for the six patients for whom OASIS data were not collected. The average age was 71 (S.D. = 13.65). There were slightly more women participants (54%), however, this is not unexpected given the higher proportion of women receiving HHC services nationally (National Association for Home Care and Hospice, 2010). The sample consisted of primarily white subjects (n=52), although there was some representation of other race/ethnicities. Living situation was derived from OASIS item M1100, which has 15 possible variations (see Appendix A). Fifty-six percent of subjects lived with another person and assistance was available around the clock. Seventeen percent lived alone but with assistance available around the clock. The remaining subjects lived with others or alone with available assistance and 5% lived in congregate living (e.g., senior housing).
with assistance available around the clock. OASIS item M1010 limits the number of allowable diagnoses to six. Subjects had a mean of 4.8 diagnoses (SD 1.5), although 28 (47%) had the maximum number of allowable diagnoses. Thirty-six (61%) had an orthopedic diagnoses and were receiving HHC services for rehabilitative treatment. Eight (13.6%) were receiving HHC services for wound care and management. Baseline activities of daily living (ADLs) were calculated by summing scores on all included OASIS items (see Appendix A) for the 53 subjects for whom OASIS data were available. The possible range of impairment scores ranged from 0 (no impairment) to 51 (totally dependent on every ADL data item). The mean ADL score was 14.8, with the actual score range of 2-28.

**TSCS Data Patterns**

The TSCS data were analyzed for missing data and descriptive patterns. For the discharge time point, two subjects were not on any medications, thus were not able to respond to TSCS questions regarding medication knowledge and adherence. For the analysis, the responses for those two subjects were coded as “5 = very much so” although none of the TSCS responses were fully appropriate.

Only Item #11 (Do you perform your regular activities such as bathing, shopping, preparing meals, visiting with friends?) showed substantial variance across respondents on admission and on re-test 3 days after the admission TSCS. On admission, there was no variance across subjects on Item #10 (Do you know whom to contact in case of a medical emergency?). Item #1 (Do you know what medication you have to take?) demonstrated no variation at discharge. Additional discussion about the variability of items and responses can be found in this chapter in the section on sensitivity.
### Table 5: Demographics

<table>
<thead>
<tr>
<th>Participant Characteristics (n=59)</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distribution of subjects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency 1</td>
<td>9</td>
<td>15.25</td>
</tr>
<tr>
<td>Agency 2</td>
<td>50</td>
<td>84.75</td>
</tr>
<tr>
<td><strong>Mean Age (S.D.)</strong></td>
<td>71 (13.65)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>26</td>
<td>46</td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
<td>54</td>
</tr>
<tr>
<td><strong>Race/ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>3.4</td>
</tr>
<tr>
<td>Black/African American</td>
<td>1</td>
<td>1.6</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>4</td>
<td>6.8</td>
</tr>
<tr>
<td>White</td>
<td>52</td>
<td>88.1</td>
</tr>
<tr>
<td><strong>Living Situation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone w/around the clock assistance</td>
<td>10</td>
<td>16.9</td>
</tr>
<tr>
<td>Alone w/daytime assistance</td>
<td>1</td>
<td>1.6</td>
</tr>
<tr>
<td>Alone w/occasional short-term assistance</td>
<td>5</td>
<td>8.5</td>
</tr>
<tr>
<td>With another person; around the clock assistance</td>
<td>33</td>
<td>55.9</td>
</tr>
<tr>
<td>With another person: regular nighttime assistance</td>
<td>3</td>
<td>5.1</td>
</tr>
<tr>
<td>With another person; occasional short-term assistance</td>
<td>4</td>
<td>6.8</td>
</tr>
<tr>
<td>Congregate living situation; around the clock assistance</td>
<td>3</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Diagnoses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean number of diagnoses = 4.8 (range 0-6; SD = 1.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number with 6 diagnoses</td>
<td>28</td>
<td>47.5</td>
</tr>
<tr>
<td>Number with orthopedic diagnosis</td>
<td>36</td>
<td>61.0</td>
</tr>
<tr>
<td>Number receiving home care for wound management</td>
<td>8</td>
<td>13.6</td>
</tr>
<tr>
<td><strong>Baseline (Admission) Functional Impairments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADL impairments (Total of OASIS ADL scores) (n=53): Range: 0 - 51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean: 14.8 (S.D. 6.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Reliability

Internal Consistency

Cronbach’s alpha based on standardized items for the TSCS admission sample (n = 59) was .781. TSCS #10 was dropped from the scale during the analyses due to lack of variability. Item-total statistics indicated that the alpha would be increased with the elimination of an additional item (TSCS 11: Do you perform you regular activities such as bathing, shopping, preparing meals, visiting with friends?). The alpha for the revised scale, which eliminated Items #10 and #11 was .804, meeting recommendations by Nunnally and Bernstein (1994) of .80 for more developed instruments. Inter-item correlations ranged from .08 - .59, with a mean inter-item correlation of .29, indicating little to no redundancy of items. The item to total correlations ranged from .26 - .56. All remaining analyses were conducted exclusively on the revised scale, the TSCS-rev.

Test-retest

Intraclass correlation (ICC) using a two-way mixed consistency were conducted for each item and the overall item scale. A power analysis indicated that a minimum sample size of 18 required to detect differences between Time 1 and Time 2, with α ≤ .01. Thirty subjects were included in the ICC analyses (Table 6). Two items, TSCS 1 and TSCS 7, showed adequate test-retest stability (r ≥ .70). Moderate to weak values were found for remaining items (r = .35 - .64) and one item (#3) showed no correlation between Time 1 and Time 2. However, despite the moderate to low ICCs for many items, the overall TSCS-rev. mean score ICC was quite high (r = .94), demonstrating overall acceptable test-retest reliability for the revised scale.
Table 6: *Test-retest Reliability*

<table>
<thead>
<tr>
<th>TSCS-rev. item</th>
<th>ICC (n=30)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Do you know what medication you have to take?</td>
<td>0.87</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>#2 Do you understand the purpose of the medications prescribed to you (that is, do you know what the medications do for your health condition)?</td>
<td>0.64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>#3 Do you take the medications as prescribed?</td>
<td>0.00</td>
<td>0.500</td>
</tr>
<tr>
<td>#4 Can you recognize changes in your body (symptoms) that are related to your illness or health condition?</td>
<td>0.42</td>
<td>0.009</td>
</tr>
<tr>
<td>#5 Do you know and understand why you experience some changes in your body (symptoms) related to your illness or health condition?</td>
<td>0.44</td>
<td>0.007</td>
</tr>
<tr>
<td>#6 Do you know what to do (things or activities) to control these changes in your body (symptoms)?</td>
<td>0.49</td>
<td>0.002</td>
</tr>
<tr>
<td>#7 Do you carry out the treatments or activities that you have been taught to manage these changes in your body (symptoms)?</td>
<td>0.70</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>#8 Do you do things or activities to look after yourself and to maintain your health in general?</td>
<td>0.45</td>
<td>0.005</td>
</tr>
<tr>
<td>#9 Do you know whom to contact to get help in carrying out your daily activities?</td>
<td>0.35</td>
<td>0.029</td>
</tr>
<tr>
<td>#12 Do you adjust your regular activities when you experience body changes (symptoms) related to your illness or health condition?</td>
<td>0.60</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TSCS-rev. Scale Mean</td>
<td>0.94</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Validity**

**Convergent Validity**

To assess convergent validity of the TSCS-rev., two criterion scales were used: the General Symptom Distress Scale (GSDS) and OASIS ADL items. Findings are presented in Table 7. Pearson’s r is reported for correlations using GSCS symptom distress and symptom management ratings. Spearman’s rho is reported for the number of symptoms
and OASIS ADL item comparisons because of the ordinal nature of the OASIS data. The overall TSCS-rev. mean score correlated negatively with the GSDS variable number of symptoms \(r = .32, p = .01\).

Table 7: Criterion Validity Correlations

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scale mean</td>
<td>(r_s = -.32) ((p = .01))</td>
<td>(r = -.20) ((p = .12))</td>
<td>(r = .30) ((p = .82))</td>
<td>(r_s = .26) ((p = .06))</td>
</tr>
<tr>
<td>Item 6</td>
<td></td>
<td>(r = 10) ((p = .45))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 7 mean</td>
<td></td>
<td>(r = .01) ((p = .89))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 12 mean</td>
<td></td>
<td>(r = .08) ((p = .52))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined items #6,7,12</td>
<td>(r = .08) ((p = .53))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 8</td>
<td></td>
<td></td>
<td>(r_s = .14) ((p = .30))</td>
<td></td>
</tr>
<tr>
<td>Item 9</td>
<td></td>
<td></td>
<td>(r_s = .05) ((p = .70))</td>
<td></td>
</tr>
<tr>
<td>Combined Items 8 and 9</td>
<td></td>
<td></td>
<td>(r_s = .14) ((p = .32))</td>
<td></td>
</tr>
</tbody>
</table>

Neither the TSCS scale mean nor the TSCS items specific to symptom management (Items 6, 7 and 12) were correlated with the GSDS symptom management rating. Likewise, the correlation between the OASIS ADL item sum and the TSC-rev scale mean did not reach the .05 criteria for statistical significance \(p = .06\). Two TSCS items specific to activities that a patient may perform to maintain “look after yourself and maintain health in general” (TSCS 8) and “daily activities” (TSCS 9) were analyzed for correlation with the OASIS ADL item sum, both individually and in combination, but the correlations were non-significant.
Exploratory Factor Analysis

The ten items from the TSCS-rev. were subjected to an exploratory factor analysis to identify the underlying scale dimensions. A principal components extraction method (PC) was used, which assumes that the amount of variance to be analyzed is equal to the number of variables, and is the preferred method for factor extraction when the exploration of components is truly exploratory (Mertler & Vannatta, 2005). The extraction criteria was an Eigenvalue > 1. The default orthogonal varimax rotation was retained based on the assumption that the underlying dimensions were independent. Despite the low sample size (subject to item ratio was 5.9:1), all communalities were above .610 (range: 613 - .884) and six of the ten items had communalities above the recommended .70 (MacCallum, Widaman, Zhang, & Hong, 1999). The Kaiser-Meyer-Olkin measure of sampling adequacy (.745) suggested that the sample was adequate given the items to be analyzed. Bartlett’s Test of Sphericity was significant (chi-square = 186.23; p.<.001), thus the null hypothesis that the variables in the correlation matrix were uncorrelated was rejected.

Four components emerged from the initial EFA with eigenvalues of 3.80, 1.35, 1.14 and 1.06 respectively, explaining a total variance of 73.54%. Table 8 provides component loadings for the TSCS items. Tabachnick and Fidell (2007) recommended minimum component loadings of .32 or higher. TSCS 1 (medication knowledge) and TSCS 12 (adjusting activities for symptoms) loaded exclusively on the first component. TSCS 2 (medication adherence), TSCS 4 (symptom recognition), and TSCS 6 (knowledge of symptom control) loaded on the first component but also on another factor: TSCS 2 also loaded on Component 4, TSCS 4 and TSCS 6 also loaded on
Table 8: Principal Components Analysis Loadings

<table>
<thead>
<tr>
<th>TSCS Item</th>
<th>Component 1 Medications and Symptom Knowledge</th>
<th>Component 2 Symptom management</th>
<th>Component 3 Self-care activities</th>
<th>Component 4 Medication Adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCS 1</td>
<td>.810</td>
<td>.043</td>
<td>.297</td>
<td>.085</td>
</tr>
<tr>
<td>TSCS 2</td>
<td>.636</td>
<td>.122</td>
<td>.350</td>
<td>.520</td>
</tr>
<tr>
<td>TSCS 3</td>
<td>.057</td>
<td>.117</td>
<td>-.054</td>
<td>.930</td>
</tr>
<tr>
<td>TSCS 4</td>
<td>.474</td>
<td>.638</td>
<td>.059</td>
<td>-.083</td>
</tr>
<tr>
<td>TSCS 5</td>
<td>.022</td>
<td>.787</td>
<td>.233</td>
<td>.055</td>
</tr>
<tr>
<td>TSCS 6</td>
<td>.618</td>
<td>.433</td>
<td>.036</td>
<td>-.217</td>
</tr>
<tr>
<td>TSCS 7</td>
<td>.207</td>
<td>.788</td>
<td>.054</td>
<td>.312</td>
</tr>
<tr>
<td>TSCS 8</td>
<td>.291</td>
<td>.209</td>
<td>.768</td>
<td>.152</td>
</tr>
<tr>
<td>TSCS 9</td>
<td>-.036</td>
<td>.089</td>
<td>.882</td>
<td>-.122</td>
</tr>
<tr>
<td>TSCS 12</td>
<td>.767</td>
<td>.191</td>
<td>-.099</td>
<td>.164</td>
</tr>
</tbody>
</table>

% of variance explained: 38.03% 13.51% 11.43% 10.59%

Component 2. Along with TSCS 4 and TSCS 6, TSCS 5 (symptom understanding) and TSCS 7 (symptom management) loaded on Component 2. Two items loaded on Component 3: TSCS 8 and TSCS 9, which address activities patients do to maintain health and general daily activities. Two items, TSCS 2 and TSCS 3, related to medication knowledge and medication adherence loaded on the fourth component while several other items showed small negative loadings. The results from this analysis hold some similarities with underlying dimensions found in other populations, including Sidani
(2008): a) taking medications, b) recognizing and managing symptoms, c) managing changes in health condition, and d) ADLs and Chaboyer et al. (2012): a) taking medications, b) changes in body symptoms, and c) managing changes in health. However, TSCS 6 (symptom management knowledge) and TSCS 12 (adjusting activities for symptoms) loaded with medication items instead of symptom management items. In addition, this analysis found some overlap across factors with TSCS 2, TSCS 4 and TSCS 6 loading on two components; the between factor loadings TSCS 2 and TSCS 4 exceeded the recommended ≥ .20.

To refine the analysis due to the double loadings of some items, a second factor analysis was performed using a principal components extraction method with a two-component criteria for extraction and varimax rotation, producing cleaner loadings (Table 9). The two components explained 51.51% of the variance. TSCS items 1, 2, 3, 4, 5, 6, 7, 8 and 12 loaded on Component 1, meeting the recommended minimum loading of .32 (Tabachnick & Fidell, 2007). Inter-item correlations for these eight items primarily ranged from r = .27 to .60, although correlations were less than .20 for TSCS 3 and TSCS 1, TSCS 4, TSCS 5, TSCS 6 and TSCS 12; likewise the inter-item correlation between TSCS 1 and TSCS 5 was .18. TSCS 8 and TSCS 9 loaded on Component 2 and had an inter-item correlation of .49. While, components with fewer than three item loadings are generally considered unstable (Costello & Osborne, 2005), it is interesting to note that these two items focus on activities to maintain health in general and daily activities. This is consistent with a theoretical difference between general self-care activities, which encompass a broad perspective on health, and self-management activities, which are more narrowly focused on activities related to a health condition or
chronic disease. As reported above, Cronbach’s alpha for the two subscales was .800 for Self-management and .658 for Self-care.

Table 9: Principal Components Analysis Loadings with Two Components

<table>
<thead>
<tr>
<th>Item</th>
<th>Component 1: Self-management</th>
<th>Component 2: Self-care</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCS 1</td>
<td>.673</td>
<td>.245</td>
</tr>
<tr>
<td>TSCS 2</td>
<td>.770</td>
<td>.135</td>
</tr>
<tr>
<td>TSCS 3</td>
<td>.479</td>
<td>-.393</td>
</tr>
<tr>
<td>TSCS 4</td>
<td>.663</td>
<td>.187</td>
</tr>
<tr>
<td>TSCS 5</td>
<td>.484</td>
<td>.313</td>
</tr>
<tr>
<td>TSCS 6</td>
<td>.601</td>
<td>.187</td>
</tr>
<tr>
<td>TSCS 7</td>
<td>.710</td>
<td>.051</td>
</tr>
<tr>
<td>TSCS 8</td>
<td>.449</td>
<td>.671</td>
</tr>
<tr>
<td>TSCS 9</td>
<td>.042</td>
<td>.861</td>
</tr>
<tr>
<td>TSCS 12</td>
<td>.723</td>
<td>-.122</td>
</tr>
<tr>
<td>% of variance explained</td>
<td>38%</td>
<td>13.5%</td>
</tr>
</tbody>
</table>

Sensitivity

Ceiling Effect

Chaboyer et al. (2012) noted the presence of a possible ceiling effect of the TSCS. Similarly, these analyses found high scores on the TSCS at all time points and minimal variation for most items. Table 10 provides TSCS item means with standard deviations and variance for each data collection time point. As noted previously, only TSCS 11 (Do you perform your regular activities (such as bathing, shopping,
Table 10: \textit{TSCS Variability}

<table>
<thead>
<tr>
<th>TSCS Item</th>
<th>Time 1 (Admission) (n=59) Mean(SD)/Variance</th>
<th>Time 2 (3 days after adm.) (n= 30) Mean(SD)/Variance</th>
<th>Time 3 (Discharge) (n=32) Mean(SD)/Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCS 1</td>
<td>4.36 (1.13) /1.27</td>
<td>4.57 (1.25) / 1.60</td>
<td>5.00(.00) / .00</td>
</tr>
<tr>
<td>TSCS 3</td>
<td>4.71 (.67) / .45</td>
<td>4.73 (.52) / .27</td>
<td>4.97 (.18) / .03</td>
</tr>
<tr>
<td>TSCS 3</td>
<td>4.90 (.36) / .13</td>
<td>5.0 (.00) / .00</td>
<td>4.9 (.30) / .09</td>
</tr>
<tr>
<td>TSCS 4</td>
<td>4.66 (.61) / 37</td>
<td>4.57 (.57) / .32</td>
<td>4.78 (.61) / .37</td>
</tr>
<tr>
<td>TSCS 5</td>
<td>4.30 (1.23) / 1.5</td>
<td>4.37 (.81) / .65</td>
<td>4.41 (1.1) / 1.21</td>
</tr>
<tr>
<td>TSCS 6</td>
<td>4.48 (.73) / .53</td>
<td>4.30 (.88) / .77</td>
<td>4.63 (.55) / .31</td>
</tr>
<tr>
<td>TSCS 7</td>
<td>4.53 (.90) / .81</td>
<td>4.40 (.89) / .80</td>
<td>4.69 (.54) / .29</td>
</tr>
<tr>
<td>TSCS 8</td>
<td>4.41 (.87) / .76</td>
<td>4.43 (.86) / .74</td>
<td>4.81 (.40) / .16</td>
</tr>
<tr>
<td>TSCS 9</td>
<td>4.80 (.76) / .58</td>
<td>4.93 (.25) / .06</td>
<td>4.91 (.30) / .09</td>
</tr>
<tr>
<td>TSCS 10</td>
<td>5.0 (0) / 0.00</td>
<td>4.87 (.43) / .19</td>
<td>4.97 (.18) / .031</td>
</tr>
<tr>
<td>TSCS 11</td>
<td>3.14 (1.50) / 2.19</td>
<td>3.53 (1.57) / 2.46</td>
<td>4.06 (1.05) / 1.09</td>
</tr>
<tr>
<td>TSCS 12</td>
<td>4.56 (.68) / .46</td>
<td>4.60 (.62) / .39</td>
<td>4.81 (.40) / .16</td>
</tr>
<tr>
<td>TSCS Score</td>
<td>4.48 (.43) / .18</td>
<td>4.53 (.42) / .17</td>
<td>4.75 (.23) / .05</td>
</tr>
</tbody>
</table>

preparing meals, visiting with friends?) showed substantial variance across respondents on admission and on re-test 3 days after the admission TSCS. Other issues with variance of TSCS items included no variance across subjects on TSCS 10 at admission and TSCS 1 at discharge. Overall TSCS means trended toward the high end at all time points, but the high mean (4.48, SD .43) and low variance (.18) at admission suggests ceiling effects.


**Responsiveness**

The raw TSCS-rev. scores at the discharge time point were correlated with the global rating scale to determine the strength of the relationship. There was a moderate correlation of $r = .329$ that did not reach statistical significance ($p = .076$). The TSCS-rev. scale means at admission (mean = 4.80, S.D. = .23) and discharge (mean = 4.29, S.D. = .28) were moderately correlated ($r = .46$, $p = .007$). The overall TSCS-rev. change scores ranged from -.7 to .6 (mean = -.006, S.D. = .270). It is interesting to note that there were some negative changes between admission and discharge on the TSCS. However, none of the subjects reported a decrease in self-management on the global rating, thus the decline in self-management scores was likely not reflective of actual worsening in patient-self-management ability but instead due to measurement error.

T-tests for difference of means between time points found only two statistically significant differences at the item level and no significant differences in the overall scale means (Table 11). Effect sizes were calculated by dividing the mean change score by the standard deviation of the baseline (admission) score. The mean change score was 0 for two items (TSCS 2 and TSCS 6). TSCS 1 mean difference was significant but negative, indicating a decline in patient perception of knowing which medications to take, with a moderate effect size of .413. TSCS 7 mean differences suggested that the item measured a perception of improvement in ability to carry out symptom management activities, with a large effect size of .736. Moderate effect sizes were seen also for TSCS 3, TSCS 5 and TSCS 12. The overall scale means between the time points was not significant ($t = 131$, $p=.897$).
Table 11: *TSCS Time 1 to Time 2 Comparisons*

<table>
<thead>
<tr>
<th>Item</th>
<th>t-tests Time 1 – Time 3 (d/c); n=32</th>
<th>Effect size (mean change; T3-T1/T1 S.D.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCS 1</td>
<td>$t= -2.330^*$</td>
<td>0.413</td>
</tr>
<tr>
<td>TSCS 2</td>
<td>$t= -0.032$</td>
<td>0.000</td>
</tr>
<tr>
<td>TSCS 3</td>
<td>$t= 1.438$</td>
<td>-0.356</td>
</tr>
<tr>
<td>TSCS 4</td>
<td>$t=0.329$</td>
<td>-0.068</td>
</tr>
<tr>
<td>TSCS 5</td>
<td>$t=1.215$</td>
<td>-0.415</td>
</tr>
<tr>
<td>TSCS 6</td>
<td>$t=0.000$</td>
<td>0.000</td>
</tr>
<tr>
<td>TSCS 7</td>
<td>$t=2.521^*$</td>
<td>0.736</td>
</tr>
<tr>
<td>TSCS 8</td>
<td>$T=-0.941$</td>
<td>0.211</td>
</tr>
<tr>
<td>TSCS 9</td>
<td>$t=1.000$</td>
<td>-0.356</td>
</tr>
<tr>
<td>TSCS 12</td>
<td>$t=-0.571$</td>
<td>0.124</td>
</tr>
<tr>
<td>TSCS-rev. mean</td>
<td>$t=0.131$</td>
<td>-0.027</td>
</tr>
</tbody>
</table>

*Note.* $^*$p<0.05

The TSCS-rev. scale mean difference was correlated with the mean of the global rating. The two variables were not significantly correlated ($r=.192$, $p=.292$). Because the only significant difference found was for TSCS 7, the mean change in that item was correlated with the global rating mean. The mean change score for TSCS 7 was -.220 (S.D. = .491). The TSCS 7 change score and the global self-management change rating were not correlated ($r = -0.024; p = .895$).

Next, the global rating of change in self-management was recoded into the four groups: 0 = 0 (no change); 1-3 = 1 (small change); 4-5 = 2 (moderate change); 6-7 = 3 (large change), using the Schwartz et al. (2002) cut-points. For the 32 subjects in
Subsample B, two (6%) perceived that their self-management ability did not change between home care admission and discharge; the remaining subjects (94%) rated their changes as 5, 6 or 7. Thus, there were no subjects in the “small change” group. Because the definition of the MICD is the amount of changes as quantified by a scale for a “small change” group, this distribution of responses made determination of the MICD impossible. Fig. 4 provides a graphic illustration of the distribution of global self-management ratings (Therapeutic Self-care Overall Rating [TSCOvrt]).

![Histogram of TSCOvrt ratings](image)

**Figure 4. Distribution of Global Self-management Ratings**

A Kruskal–Wallis one-way analysis of variance by ranks (nonparametric ANOVA) analysis was performed, using the TSCS-rev. change scale means (T3 minus T1) as the dependent variable and change group as the independent variable. The TSCS scale mean did not demonstrate significant differences across the global rating of self-management change groups ($H = 0.253; p = 0.282$). Instead, variation in TSCS-rev. change scores
clustered in only one of the groups ("moderate change"). Because TSCS 7 demonstrated ability to measure change between admission and discharge, the Kruskal-Wallis analysis was performed using the mean change score for that item only, despite the lack of correlation between the TSCS 7 change score and the global rating of self-management change. TSCS 7 mean changes were distributed among both the "moderate change" and "large change" groups, but there were no statistically significant differences ($H=1.12; p=.571$) in the mean score by group.

The responsiveness analysis indicated that the TSCS overall was not able to detect statistically significant changes between admission and discharge in Subsample B ($n=32$). While one item, TSCS 7 did demonstrate a large effect size, the mean was not significantly different between the "moderate change" and "large change" groups. In addition, the lack of any global self-management change ratings in Group 1 ("small change") made it impossible to calculate a MICD.

**Summary**

The TSCS was subjected to several analyses to evaluate reliability, validity and responsiveness in an adult home health population. Statistics were presented on scale means and variability, which suggested that the scale may have a ceiling effect.

Reliability was assessed with Cronbach’s alpha, and the scale modified to eliminate TSCS10 and 11. All remaining analyses were conducted for the revised scale. Cronbach’s alpha for the revised scale was .80 and inter-item correlation indicated little redundancy. To evaluate test-retest reliability, TSCS responses from the admission visit to those from a telephone interview three days later were compared. The overall TSCS-
rev. mean score ICC was quite high ($r = .94$), demonstrating overall acceptable test-retest reliability for the revised scale.

Convergent validity was tested by correlating the TSCS-rev. scale mean with external criteria measures that were theoretically related. The TSCS-rev. scale mean was compared with three variables from the GSDS: a) number of reported symptoms, b) rating of overall symptom distress, and c) rating of ability to manage symptoms. While the overall direction of the TSCS scale mean correlation with the GSDS symptom management rating was in a positive direction, the correlation was not significant. In addition, the TSCS-rev. scale mean was correlated with an ADL score calculated from OASIS ADL items. The correlation between the OASIS ADL item sum and the TSC-rev scale mean was in a positive direction, although it was weak ($r_s = .26$) and did not reach the .05 criteria for statistical significance ($p = .06$). Three TSCS items specifically related to symptom management were correlated with the GSDS variables individual and in combination. Likewise, two TSCS items related to ADLs were correlated individually and in combination with the overall OASIS ADL score. None of the latter analyses found significant correlations.

Validity also was assessed using a principal components analysis. Four components were extracted, explaining 73.45% of the variance. Due to multiple double-loaded items, a second principal components analysis forced a two-component extraction. The two-component extraction produced cleaner loadings and explained 51.51% of the variance. While less variance was explained, the two components were consistent with a theoretical difference between general self-care activities which encompass a broad perspective on
health, and self-management activities which are more narrowly focused on activities related to a health condition or chronic disease.

To evaluate responsiveness, the TCS5-rev. change score (discharge score minus admission score) were calculated and correlated with a patient global rating of perception of change in self-management over the course of the home health care episode. The overall scale was not able to show change over time, however, one item (TCS 7) did demonstrate a large effect size. To determine a minimally important clinical difference, change scores were classified into four groups, based on global rating score. Kruskal-Wallis analysis was performed, using the TCS5-rev. scale mean change from admission to discharge as the dependent variable and group as the independent variable. The same analysis was conducted for just the Item 7 changes. However, because of the lack of any ratings in Group 1 “small change” and the lack of statistically significant changes across groups, it was not possible to identify a MICD for the scale overall or TCS 7.
CHAPTER V
DISCUSSION

Findings from the psychometric evaluation of the Therapeutic Self-care Scale (TSCS) in a U.S. adult home health care (HHC) population were mixed. A discussion of the results from each kind of psychometric test and an overall summary of findings are presented in this chapter. A summary with study limitations, implications for nursing and areas for future work conclude this section.

Exploratory Factor Analysis

A striking finding from this study was made from the exploratory factor analysis (EFA). The first EFA using a principal components analysis found four primary subscales that explained nearly 80% of the variance, although several factors double-loaded on components. One component incorporated items that theoretically should have loaded more strongly on a different component (e.g., TSCS 6 and TSCS 12 were related to symptoms but loaded with medication knowledge). However, a second EFA with extraction forced on two components resulted in particularly interesting loadings. While this analysis explained less variance, item loadings for the two components could be interpreted in light of the theoretical difference between self-management activities related to an illness or health condition vs. self-care activities that are concerned more broadly with activities to maintain general health.

Reliability and Convergent Validity

In general, the analyses found fairly strong evidence for reliability of the TSCS, particularly with the scale revisions dropping Items 10 and 11 (Do you perform your regular activities such as bathing, shopping, preparing meals, visiting with friends?). The
investigator found that during the data collection visit, several of the subjects had difficulty responding to Item 11 because of the multiple examples in the item wording. With the elimination of these items, Cronbach’s alpha for the revised scale was .80 and the inter-item correlations for the revised scale indicated little to no redundancy of items. The principal components analysis conducted as part of the validity analysis found two subscales, Self-management and Self-care. Cronbach’s alpha was acceptable at .800 for Self-management, but lower (\( \alpha = .66 \)) for Self-care.

The test-retest reliability findings suggested that while only two TSCS items (1 and 7) showed strong correlations, there was evidence of moderate test-retest reliability (\( r \geq .35 \)) for most of the other items with the exception of TSCS #3. Overall intraclass correlation (ICC) for the TSCS-rev. was quite high (\( r = 0.94, p = .000 \)), demonstrating overall excellent test-retest reliability for the revised scale. Thus, this study supports the reliability of the TSCS in its revised form in a U.S. adult home health population. However, issues with the sample prevented a thorough analysis of convergent validity. While the TSCS correlated in the expected negative direction with one of the criterion measures, number of symptoms (from the GSDS), none of the other findings were statistically significant.

**Sensitivity**

**Item and Overall Scale Variability**

In general, the overall means and standard deviations for scale items and the overall scale trended high for all data collection time points, but the high mean (4.4; S.D. 0.43) and low variance (0.19) at admission suggests ceiling effects. There was no variability in one item TCS 10 (Do you know whom to contact in case of a medical emergency?) on
admission. In the U.S., the 911 emergency system is well-known to the general population, and this information is typically reinforced with newly admitted patients and families during a HHC admission visit. This question was excluded from further analyses. Overall, the lack of item variance across the sample negatively influenced the analyses.

**Responsiveness**

The final aim of this study was to evaluate the ability of the TSCS to measure change between HHC admission and discharge. The analyses conducted for this study did not demonstrate that the TSCS-rev. was sensitive to changes between HHC admission and discharge. Only one item (TSCS 7) showed a statistically significant difference in means between the two time points and a large effect size. However, there were no demonstrated differences in mean change score by global change in self-management ratings, thus it was not possible to identify a MICD. This inability of the TSCS-rev. to discriminate across groups of global self-management ratings may have been affected by social desirability response bias, or an overestimation of self-management ability in the patient global rating, resulting in a skewed pattern of responses. This is may be particularly important to consider with an elderly home health care population, for whom self-management deficits potentially could impact their ability to remain in the home. In addition, the time window for the admission data collection visit (within 5 days of home health agency [HHA] admission) may have affected the admissions ratings. Specifically, patients seen at or near the end of the window may have rated their self-management higher on admission than if the TSCS had been administered on the same day as HHA admission, resulting in a response bias. Nonetheless, in this sample the
TSCS-rev. was unable to measure changes in self-management that may have resulted across the HHC episode.

**Conclusions**

While the TSCS demonstrated adequate reliability, it was not possible to fully assess validity with the study sample. In addition, it was not able to effectively measure change in self-management over the episode of HHC. It may not be surprising that the instrument performed well on reliability tests but was not able to detect changes over time. There are several factors that determine an instrument’s ability to be responsive that are different from the instruments internal consistency or stability. The very high test-retest ICC may indicate that the tool is measuring a more static “trait” of self-management vs. a “state” which is conceptualized as dynamic (Waltz, Strickland, & Lenz, 2005). In addition, the observed ceiling effect may indicate that patients are near the limits of their potential as measured by the TSCS, thus restricting the tool’s ability to show change (Steiner & Norman, 2008). While lack of responsiveness does not support the instrument’s use in longitudinal or interventional studies, it may be useful at a single time point for cross-sectional investigations. The exploratory factor analysis findings suggest that the scale measures some aspects of self-management and more generally self-care. Thus, the TSCS-rev. may be particularly helpful for HHA nurses or therapists as part of an admission assessment that can guide the development of the plan of care. However, it would not useful to re-administer at discharge to measure the effectiveness of HHC in terms of improving (or failing to improve) perceived self-management abilities.

Despite demonstrating adequate reliability, there may be room for improvement in the wording of certain items and the 6-point scale. During data collection, several subjects
found some of the questions difficult to understand, particularly TSCS 11 that incorporated several variables related to daily activities. In addition, these results would support dropping TSCS 10 for application to a U.S. HHC population, or rewording to focus on a situation where the patient’s health condition changes did not rise to the level of an emergency that would require a call to emergency services (911).

Two subjects did not know how to respond to TSCS 3 (Do you take your medications as prescribed) because no prescription or over-the-counter medications were needed. A response option (n/a) would be useful for that item. Patients frequently found the rating scale to be difficult to use for some questions, preferring to respond simply “yes” or “no.” It may be desirable to simplify the scale to make response options more intuitive for patients, such as a four point scale: “no,” “yes; some of the time,” “yes; most of the time,” and “yes; all of the time.” In addition to improving the understandability of the scale, such changes could address the ceiling effect seen in this study.

Limitations

A primary limitation of this study is sample size. The original project design called for a sample size of 200 subjects. However, it was challenging to find and recruit subjects and after a 12-month data collection period, only 59 subjects had enrolled. Several factors contributed to the low enrollment. Key among them was the need for a “gatekeeper” HHA nurse or therapist to obtain a signed HIPAA-A form and forward information to the researcher. Also, there were no incentives for patient participation (i.e., gift cards, etc.) which could have improved the rate of participation.

It should be noted that subjects consenting to participate in the study may have been different from typical HHA patients in terms of overall health on admission, higher levels
of education and living in higher socioeconomic status areas. During the initial visit, several subjects noted that they were happy to participate because they encountered data collection challenges when conducting their graduate work. While data on overall health, education level and socioeconomic status were not collected as part of this study, the study setting was urban and suburban, located in or near cities with major universities. Thus, it is possible that study participants in this area were not a representative sample of HHA patients.

Another study limitation related to the initial time frame for data collection. A five-day window after the admission visit was selected to correspond to the requirements that HHAs complete the comprehensive initial assessment which includes OASIS data within five days of the first visit. This timeframe had the advantage of allowing sufficient time for the admitting nurse or therapist to obtain a signed HIPAA-A and contact the investigator, who then could schedule an appointment with the patient and travel to their home for the study visit. However, patient condition can change rapidly after discharged from the hospital to home. Thus, the admission responses to the TCSC may have been higher for subjects visited later in the 5-day window than if the visit were made immediately after the initial HHA visit. This limitation in particular may have contributed to the observed ceiling effect.

**Future Work**

Work remains to develop an instrument that can effectively measure the construct of self-management for a U.S. home health population. While the TSCS may serve as a starting point, it may not be sufficient to fully measure the construct. In addition, the TSCS cannot effectively assess the impact of HHA services on patient perceptions of
self-management. Research to refine the TSCS should consider wording changes, and testing of alternate scales should be undertaken. The scale could be further assessed across U.S. care settings, as it is used in Canada (e.g., at hospital discharge, HHC admission and HHC discharge). Once a revised instrument with acceptable psychometric properties is developed for use in the HHC setting, then additional research can be pursued to evaluate the Home Health Care Research Organizing Model domains of patient, contextual, and action focus strategies that influence self-management, and to address longer-range outcomes of improved self-management, such as those occurring after home health care discharge.

**Significance of the Research**

Current outcome measures for HHC services in the U.S. include several related to physiological changes, functional status changes and healthcare utilization outcomes, such as the use of emergency departments and hospitals. There are concerns shared anecdotally by HHC providers and documented in the literature that existing HHC outcome measures do not sufficiently reflect the goals and care provided by nurses, therapists and other HHC providers. The literature is clear in that the primary goal of HHC services in most cases is for patients (in conjunction with their caregivers) to be able to self-manage their health care condition. In addition to ADLs associated with self-care, this includes the ability to follow the treatment plan; recognize and manage symptoms; alter daily routines or take other actions in response to symptoms that are difficult to manage; and know when and how to seek additional healthcare services. While some condition-specific tools exist to assess change in self-management abilities, the goal of self-management applies to HHC patients regardless of diagnosis. Self-care,
and thus, self-management, are considered outcomes sensitive to nursing care, the discipline that provides the majority of HHC services. HHAs need a tool to evaluate the effect of their care on a generic outcome of self-management. In addition, the lack of an instrument that is sensitive to change hinders research to establish an evidence base for HHC nursing or therapy interventions designed to improve self-management outcomes.

Thus, this research was undertaken in response to the need for an instrument to measure self-management for U.S. adult HHC patients. While the TSCS was developed to measure the construct across acute and subacute healthcare settings in Canada, including HHC, there were no reports in the literature on its ability to measure self-management for HHC patients, nor any reports of testing in a U.S. patient population. This study adds to the state of the science in the area of HHC outcome measurement. It highlights the need for a tool that can measure change in self-management ability as an indicator of the effectiveness of HHC services, demonstrates that the TSCS cannot effectively serve that function in its current form, and provides rationale for future work in this area.

**Summary**

Results from psychometric testing of the TSCS in a U.S. adult HHC population were mixed. The scale demonstrated good internal consistency and test-retest reliability. An exploratory factor analysis forcing two components found that items loaded on two components that could be interpreted in light of the theoretical difference between activities and knowledge required for self-management vs. those required more broadly for self-care, although these two components only explained 51.51% of the variance. However, results from an analysis comparing the TSCS-rev. to the GSDS rating of
symptom management and OASIS ADL scores found only weak evidence for convergent validity. TSCS overall means and standard deviations for scale items and the overall scale skewed high for all data collection time points, with a lack of variance suggesting a ceiling effect. In addition, responsiveness testing found that the scale did not demonstrate sensitivity to change between HHC admission and discharge.

The TSCS-rev. may be helpful for HHA nurses or therapists as part of an admission assessment that can guide the development of the plan of care. Lack of responsiveness does not support the instrument’s use in longitudinal or interventional studies, thus it is not appropriate for outcomes measurement. However, because of the central importance of the construct of self-management to HHC providers, there remains a need to develop a tool that can measure change in self-management as an outcome of HHC services. This study indicates that while the TSCS in its current form cannot serve that purpose, it is possible the scale can be further refined with the goal of improving validity and responsiveness. Further work to develop an instrument with acceptable psychometric properties to measure self-management change over time in HHC settings is a prerequisite for future research to assess the effectiveness of interventions that providers can take to influence self-management during HHC episodes of care.
REFERENCES


Mitchell, P.H., & Lang, N.M. (2004). Framing the problem of measuring and improving healthcare quality: Has the quality health outcomes model been useful? Medical Care, 42(2), Supplement, II-4 – II-11.


APPENDIX A

INSTRUMENTS
THERAPEUTIC SELF-CARE TOOL (Home Care Settings)

Each of the following statements is about an aspect of your care related to your present health condition. Indicate how much you are able to do each care related activity, by choosing the number between “0” and “5” that is most appropriate.

<table>
<thead>
<tr>
<th>Care Activity</th>
<th>Not at all</th>
<th>Very much so</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you know what medication you have to take?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you understand the purpose of the medications prescribed to you (that is, do you know what the medications do for your health condition)?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you take the medications as prescribed?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Can you recognize changes in your body (symptoms) that are related to your illness or health condition?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you know and understand why you experience some changes in your body (symptoms) related to your illness or health condition?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you know what to do (things or activities) to control these changes in your body (symptoms)?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you carry out the treatments or activities that you have been taught to manage these changes in your body (symptoms)?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you do things or activities to look after yourself and to maintain your health in general?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you know whom to contact to get help in carrying out your daily activities?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you know whom to contact in case of a medical emergency?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you perform your regular activities (such as bathing, shopping, preparing meals, visiting with friends)?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Do you adjust your regular activities when you experience body changes (symptoms) related to your illness or health condition?</td>
<td>0 1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>
Overall Self-care Change Rating

a) “Did your ability to manage your health condition improve since home health care began?”

b) “If so, please rate how much you improved from 1 to 7, using the following scale:

1- Not at all improved
2- A little improved
3- Somewhat improved
4- Moderately improved
5- A good deal improved
6- A great deal improved
7- A very great deal improved
**General Symptom Distress Scale**

*Examiner: I am going to read a list of symptoms. I want you to tell me which ones you have at the present time.*

Put a check mark “√” in the box to the left of the symptom, for each one symptom the participant indicates as being present. Leave the check box blank if the symptom is not present.

<table>
<thead>
<tr>
<th>□ Depression ( )</th>
<th>□ Pain ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Anxiety ( )</td>
<td>□ Sleep Difficulties ( )</td>
</tr>
<tr>
<td>□ Fatigue ( )</td>
<td>□ Bowel Problems ( )</td>
</tr>
<tr>
<td>□ Shortness of Breath ( )</td>
<td>□ Difficulty Concentrating ( )</td>
</tr>
<tr>
<td>□ Nausea ( )</td>
<td>□ Loss of Appetite ( )</td>
</tr>
<tr>
<td>□ Vomiting ( )</td>
<td>□ Cough ( )</td>
</tr>
</tbody>
</table>

*Examiner: Now of those symptoms you told me you had, which is the most distressing? Score (1) which one is the most distressing? Score (2) which one is the next most distressing? Score (3) and so on until all the symptoms that were reported have been ranked in order (i.e., assigned a numerical score).*

For each symptom that has a check mark “√” in the box to the left, write the corresponding number (i.e., 1, 2, 3) related to which is the most distressing in the parentheses to the right of the symptom. Every symptom with a “√” to the left should have a number indicating its level of distress to the right.

*Examiner: Now on a scale of 1 to 10 with 1 being not at all distressing and 10 being extremely distressing:*

In general, how distressing are all of your symptoms to you?

Not at all distressing………………………………………Extremely distressing

1 2 3 4 5 6 7 8 9 10

*Examiner: Again on a 1 to 10 scale with 1 being cannot manage at all and 10 being manage extremely well:*

How well are you able to manage your symptoms?

Cannot manage at all………………………………………Can manage extremely well

1 2 3 4 5 6 7 8 9 10
Selected OASIS Data Items

(M0066) Birth Date: __ __ / __ __ / __ __ __ __
month / day / year

(M0069) Gender:

☐ 1 - Male
☐ 2 - Female

(M0140) Race/Ethnicity: (Mark all that apply.)

☐ 1 - American Indian or Alaska Native
☐ 2 - Asian
☐ 3 - Black or African-American
☐ 4 - Hispanic or Latino
☐ 5 - Native Hawaiian or Pacific Islander
☐ 6 - White

(M1010) List each Inpatient Diagnosis and ICD-9-C M code at the level of highest specificity for only those conditions treated during an inpatient stay within the last 14 days (no E-codes, or V-codes): Inpatient Facility Diagnosis

<table>
<thead>
<tr>
<th>Inpatient Facility Diagnosis</th>
<th>ICD-9-C M Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>__ __ __ - __ __</td>
</tr>
<tr>
<td>b.</td>
<td>__ __ __ - __ __</td>
</tr>
<tr>
<td>c.</td>
<td>__ __ __ - __ __</td>
</tr>
<tr>
<td>d.</td>
<td>__ __ __ - __ __</td>
</tr>
<tr>
<td>e.</td>
<td>__ __ __ - __ __</td>
</tr>
<tr>
<td>f.</td>
<td>__ __ __ - __ __</td>
</tr>
</tbody>
</table>
### (M1020) Primary Diagnosis & (M1022) Other Diagnoses

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnoses (Sequencing of diagnoses should reflect the seriousness of each condition and support the disciplines and services provided.)</td>
<td>ICD-9-CM and symptom control rating for each condition. Note that the sequencing of these ratings may not match the sequencing of the diagnoses</td>
<td>Complete if a V-code is assigned under certain circumstances to Column 2 in place of a case mix diagnosis.</td>
<td>Complete only if the V-code in Column 2 is reported in place of a case mix diagnosis that is a multiple coding situation (e.g., a manifestation code).</td>
</tr>
<tr>
<td>Description</td>
<td>ICD-9-CM / Symptom Control Rating</td>
<td>Description/ICD-9-CM</td>
<td>Description/ICD-9-CM</td>
</tr>
</tbody>
</table>

#### (M1020) Primary Diagnosis

a. (V-codes are allowed)
   a. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4

#### (M1022) Other Diagnoses

b. (V-or E-codes are allowed)
   b. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4
c. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4
d. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4
e. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4
f. \(_\_\_\_\_\_\cdot\_\_\_\_\_\_\)  
   □ 0 □ 1 □ 2 □ 3 □ 4

### (M1100) Patient Living Situation: Which of the following best describes the patient's residential circumstance and availability of assistance? (Check one box only.)

<table>
<thead>
<tr>
<th>Living Arrangement</th>
<th>Availability of Assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Around the clock</td>
</tr>
<tr>
<td>a. Patient lives alone</td>
<td>□ 01</td>
</tr>
<tr>
<td>b. Patient lives with other person(s) in the home</td>
<td>□ 06</td>
</tr>
<tr>
<td>c. Patient lives in congregate situation (e.g., assisted living)</td>
<td>□ 11</td>
</tr>
</tbody>
</table>
**ADL/IADLS**

**(M1800) Grooming:** Current ability to tend safely to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).
- 0 - Able to groom self unaided, with or without the use of assistive devices or adapted methods.
- 1 - Grooming utensils must be placed within reach before able to complete grooming activities.
- 2 - Someone must assist the patient to groom self.
- 3 - Patient depends entirely upon someone else for grooming needs.

**(M1810) Current Ability to Dress Upper Body** safely (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:
- 0 - Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
- 1 - Able to dress upper body without assistance if clothing is laid out or handed to the patient.
- 2 - Someone must help the patient put on upper body clothing.
- 3 - Patient depends entirely upon another person to dress the upper body.

**(M1820) Current Ability to Dress Lower Body** safely (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:
- 0 - Able to obtain, put on, and remove clothing and shoes without assistance.
- 1 - Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.
- 2 - Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.
- 3 - Patient depends entirely upon another person to dress lower body.

**(M1830) Bathing:** Current ability to wash entire body safely. **Excludes grooming (washing face, washing hands, and shampooing hair).**
- 0 - Able to bathe self in shower or tub independently, including getting in and out of tub/shower.
- 1 - With the use of devices, is able to bathe self in shower or tub independently, including getting in and out of the tub/shower.
- 2 - Able to bathe in shower or tub with the intermittent assistance of another person:
  - (a) for intermittent supervision or encouragement or reminders, **OR**
  - (b) to get in and out of the shower or tub, **OR**
  - (c) for washing difficult to reach areas.
- 3 - Able to participate in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision.
- 4 - Unable to use the shower or tub, but able to bathe self independently with or without the use of devices at the sink, in chair, or on commode.
- 5 - Unable to use the shower or tub, but able to participate in bathing self in bed, at the sink, in bedside chair, or on commode, with the assistance or supervision of another person throughout the bath.
- 6 - Unable to participate effectively in bathing and is bathed totally by another person.

**(M1840) Toilet Transferring:** Current ability to get to and from the toilet or bedside commode safely and transfer on and off toilet/commode.
- 0 - Able to get to and from the toilet and transfer independently with or without a device.
- 1 - When reminded, assisted, or supervised by another person, able to get to and from the toilet and transfer.
- 2 - **Unable** to get to and from the toilet but is able to use a bedside commode (with or without assistance).
- 3 - **Unable** to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.
- 4 - Is totally dependent in toileting.
(M1845) **Toileting Hygiene:** Current ability to maintain perineal hygiene safely, adjust clothes and/or incontinence pads before and after using toilet, commode, bedpan, urinal. If managing ostomy, includes cleaning area around stoma, but not managing equipment.

- 0 - Able to manage toileting hygiene and clothing management without assistance.
- 1 - Able to manage toileting hygiene and clothing management without assistance if supplies/implements are laid out for the patient.
- 2 - Someone must help the patient to maintain toileting hygiene and/or adjust clothing.
- 3 - Patient depends entirely upon another person to maintain toileting hygiene.

(M1850) **Transferring:** Current ability to move safely from bed to chair, or ability to turn and position self in bed if patient is bedfast.

- 0 - Able to independently transfer.
- 1 - Able to transfer with minimal human assistance or with use of an assistive device.
- 2 - Able to bear weight and pivot during the transfer process but unable to transfer self.
- 3 - Unable to transfer self and is unable to bear weight or pivot when transferred by another person.
- 4 - Bedfast, unable to transfer but is able to turn and position self in bed.
- 5 - Bedfast, unable to transfer and is unable to turn and position self.

(M1860) **Ambulation/Locomotion:** Current ability to walk safely, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.

- 0 - Able to independently walk on even and uneven surfaces and negotiate stairs with or without railings (i.e., needs no human assistance or assistive device).
- 1 - With the use of a one-handed device (e.g., cane, single crutch, hemi-walker), able to independently walk on even and uneven surfaces and negotiate stairs with or without railings.
- 2 - Requires use of a two-handed device (e.g., walker or crutches) to walk alone on a level surface and/or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.
- 3 - Able to walk only with the supervision or assistance of another person at all times.
- 4 - Chairfast, unable to ambulate but is able to wheel self independently.
- 5 - Chairfast, unable to ambulate and is unable to wheel self.
- 6 - Bedfast, unable to ambulate or be up in a chair.

(M1870) **Feeding or Eating:** Current ability to feed self meals and snacks safely. Note: This refers only to the process of eating, chewing, and swallowing, not preparing the food to be eaten.

- 0 - Able to independently feed self.
- 1 - Able to feed self independently but requires:
  - (a) meal set-up; OR
  - (b) intermittent assistance or supervision from another person; OR
  - (c) a liquid, pureed or ground meat diet.
- 2 - Unable to feed self and must be assisted or supervised throughout the meal/snack.
- 3 - Able to take in nutrients orally and receives supplemental nutrients through a nasogastric tube or gastrostomy.
- 4 - Unable to take in nutrients orally and is fed nutrients through a nasogastric tube or gastrostomy.
- 5 - Unable to take in nutrients orally or by tube feeding.

(M1880) Current **Ability to Plan and Prepare Light Meals** (e.g., cereal, sandwich) or reheat delivered meals safely:

- 0 - (a) Able to independently plan and prepare all light meals for self or reheat delivered meals; OR
  - (b) Is physically, cognitively, and mentally able to prepare light meals on a regular basis but has not routinely performed light meal preparation in the past (i.e., prior to this home care admission).
- 1 - Unable to prepare light meals on a regular basis due to physical, cognitive, or mental limitations.
- 2 - Unable to prepare any light meals or reheat any delivered meals.
(M1890) Ability to Use Telephone: Current ability to answer the phone safely, including dialing numbers, and effectively using the telephone to communicate.

☐ 0 - Able to dial numbers and answer calls appropriately and as desired.
☐ 1 - Able to use a specially adapted telephone (i.e., large numbers on the dial, teletype phone for the deaf) and call essential numbers.
☐ 2 - Able to answer the telephone and carry on a normal conversation but has difficulty with placing calls.
☐ 3 - Able to answer the telephone only some of the time or is able to carry on only a limited conversation.
☐ 4 - Unable to answer the telephone at all but can listen if assisted with equipment.
☐ 5 - Totally unable to use the telephone.
☐ NA - Patient does not have a telephone.

(M2020) Management of Oral Medications: Patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes injectable and IV medications. (NOTE: This refers to ability, not compliance or willingness.)

☐ 0 - Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times.
☐ 1 - Able to take medication(s) at the correct times if:
(a) individual dosages are prepared in advance by another person; OR
(b) another person develops a drug diary or chart.
☐ 2 - Able to take medication(s) at the correct times if given reminders by another person at the appropriate times.
☐ 3 - Unable to take medication unless administered by another person.

(M2030) Management of Injectable Medications: Patient's current ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate times/intervals. Excludes IV medications.

☐ 0 - Able to independently take the correct medication(s) and proper dosage(s) at the correct times.
☐ 1 - Able to take injectable medication(s) at the correct times if:
(a) individual syringes are prepared in advance by another person; OR
(b) another person develops a drug diary or chart.
☐ 2 - Able to take medication(s) at the correct times if given reminders by another person based on the frequency of the injection.
☐ 3 - Unable to take injectable medication unless administered by another person.
☐ NA - No injectable medications prescribed.
APPENDIX B

COMIRB FORMS
Certificate of Approval

26-Feb-2013

Investigator: Angela Richard
Sponsor(s): COMIRB Protocol 12-0190 Continuing Review
Subject: COMIRB Protocol 12-0190 Continuing Review
Effective Date: 22-Feb-2013
Expiration Date: 21-Feb-2014
Expedited Category: 5,7
Title: Psychometric Testing Of A Self-Management Tool In Home Health Care

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- Use only a copy of the COMIRB signed and dated Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form. Consent and/or assent forms must include the name and telephone number of the investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

Review Comments:

This approval includes:
Continuing Review, CRV001
Application and Attachments A, F, I, 3/22/12
Consent and Authorization, 03/22/12
Protocol, 03/06/12
HIPAA-A, noted

Note to PI: Unless the Study Instruments and Flyer change, they do not need to be re-submitted.
Authorization To Release
Health Information About Me
For Research Purposes
Authority: Research Recruitment

Research Area: Self-management in Home Health Care

Study Title (if known): Psychometric Testing of a Self-management Tool for Home Health Care

COMIRB number (if known): 12-C 01-90

[Signature]
(Patient’s Full Name) authorize

[Signature]
(Referring Physician Name)

and staff members of ___________________________ (Facility Name) working for him/her to use or give the following health information about me for the purpose of research recruitment:

☐ Name, Address and/or phone number
☐ Other (Specify)__________________________

This information will be given to: Angela Richard, the study Principal Investigator

I give my authorization knowing that:

• I do not have to sign this authorization. If I do not sign it, my information will not be released for research recruitment.
• I can cancel this authorization any time.
  ▪ I have to cancel it in writing.
  ▪ If I cancel it, the researchers and the people my information was given to may have already used the information, but they will not use it in the future.
  ▪ I can read the Notice of Privacy Practices at the facility where the research is being conducted to find out how to cancel my authorization.
• The records given out to other people may be given out by them and might no longer be protected.
• I will be given a copy of this form after I have signed it.

This authorization will expire on: __________________________ OR ☐ Will not expire

ADDITIONAL INFORMATION:

________________________
Patient’s Signature Date

________________________
Signature of Legal Representative (If applicable) Date

Name of Legal Representative (please print)

Description of Legal Authority to Act on Behalf of Patient

RECEIVED
JAN 18 2013
COMIRB

HIPAA A Form: Research Recruitment
CF-005, Effective 4-25-2010
Consent and Authorization Form Approval

FEB 2 2 2013

Date: Valid for Use Through: 2-21-14

Study Title: Psychometric testing of a Self-management Tool in Home Health Care

Principal Investigator: Angela Richard
COMIRB No: 12-0190
Version Date: 3/22/2012
Version #: 3/22/2012

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about an interview tool that assesses patient abilities to self-manage their health conditions. We are testing whether the interview tool is a valid tool to use in home health care and whether it can measure changes that occur during the time you are receiving home care. You are being asked to be in this research study because you are receiving home health care.

Other people in this study

Up to 200 people from the Denver area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to answer 11 questions that test memory and 12 questions about your ability to manage your medications, symptoms, activities and emergencies. You will also be asked another 4 questions about your symptoms. We will need to obtain a few pieces of information from your clinical record, including some demographic information and information about your ability to conduct regular activities in your home, and the number of visits that you receive from the home health agency staff. For 30 patients, we will request to call again three days after the visit and ask the 12 questions about ability to manage your medications, symptoms, activities and emergencies. For another group of 30 patients, we will request to call again around the time of home health care discharge or 60 days (whichever is first), to ask the 12 questions about ability to manage your medications, symptoms, activities and emergencies and the 4 additional questions about symptoms. The first 30 individuals agreeing to participate in the additional data collection groups will be selected, then remaining patients will only be in the large (one-time) data collection group. All the information collected for this study is

Combined Biomedical Consent and HIPAA authorization
CF-151, Effective 8-31-11

Page 1 of 6

Initials____
Consent and Authorization Form Approval

for research purposes only. The researcher cannot provide any health care assessments or treatments.

For most patients, study participation will only last the length of the visit, approximately 30 minutes. If you are in the group who will receive the phone call three days after the visit, your participation will end after that phone call. If you are in the group who will receive the phone call at discharge, then your participation will end after that phone call.

What are the possible discomforts or risks?

We do not anticipate that you will experience any discomfort during your experience while in this study as a result of participation in the study.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

If you become concerned about any of your responses to the questions about your ability to manage your health care and symptoms, you will be reminded to share those concerns with the home health agency staff.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about an interview tool to measure your ability to manage your health condition.

This study is not designed to treat any illness or to improve your health. Also, there may be a small risk of people outside the research team seeing your research information, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This study is being conducted as part of the researcher's graduate studies. It is not funded by any organization.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.
Consent and Authorization Form Approval

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?
The researcher may decide to stop your participation without your permission if the she thinks that being in the study may cause you harm, or for any other reason. If you are taken out of this study, you will not lose any of the benefits that you would normally get outside of the study. Being taken out of the study will not affect your employment status or your reputation. Being taken out of the study will not change your ability to get government assistance.

What happens if I am injured or hurt during the study?
Participation in the study presents no risk of being injured or hurt, as it only involves answering a few questions.

Things That Must be Reported to The Authorities

We respect your right to privacy. But there are some things we cannot keep private. If you give us information about child neglect or child abuse, we have to report that to Social Services. If you give us information about someone hurting someone else, we have to report that to the police. If a court orders us to hand over your study records, we have to hand them over to the court.

Who do I call if I have questions?
The researcher carrying out this study is Angela Richard. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Angela Richard at (303) 724-2442. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Angela Richard with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?
The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Combined Biomedical Consent and HIPAA authorization

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Initials______
Consent and Authorization Form Approval

Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include the University of Colorado College of Nursing.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study’s Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Angela A. Richard, MS, RN  
Doctoral Student  
University of Colorado Anschutz Medical Campus  
College of Nursing  
13120 East 19th Avenue  
Campus Box 288-8  
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The researcher and the rest of the study team.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

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Initials
Consent and Authorization Form Approval

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, functional abilities

What happens to data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- The investigators may study your data.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study. I will get a signed and dated copy of this consent form.

Signature: ___________________________ Date: ______

Print Name: __________________________

Consent form explained by: __________________________ Date: ______

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Initials: ______
Consent and Authorization Form Approval

Print Name: _______________________________

Investigator: ______________________________ Date: ______

Investigator must sign within 5 days

Witness of Signature  □  Date: ______

Witness of consent process  □