TREATMENT BURDEN IN ADULTS LIVING WITH MULTIPLE CHRONIC CONDITIONS TRANSITIONING FROM A SKILLED NURSING FACILITY TO HOME

by

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Treatment Burden in Adults Living with Multiple Chronic Conditions
Transitioning from a Skilled Nursing Facility to Home

Abstract

by

Nathanial James Schreiner

Due the increasing complexity of managing multiple chronic conditions (MCC), the adult population living with MCC is experiencing high levels of treatment burden (TB). The definition of TB is the self-management and coordination of health services patients undertake in order to manage MCC resulting from the prescribed plan of treatment and disease trajectory. TB is associated with poor treatment adherence, which contributes to poor health-related outcomes, higher health care resource usage, and higher associated health care costs.

The purpose of study was to describe three constructs of TB: (1) the level of subjective TB experienced by this population, (2) the association between TB and potential antecedent factors, and (3) an exploration of an improvement or decline in TB and its antecedent factors during a 30-day transition period from baseline. This study characterized and correlated antecedent factors of TB at three conceptual levels: interpersonal, intrapersonal and organizational.

Eighty-two adult participants diagnosed with MCC transitioning from SNF to home enrolled in this exploratory, descriptive study. This longitudinally designed study
collected data at two time points: baseline prior to SNF discharge and 30 days post-discharge.

The level of TB at baseline (M=39.06; SD=25.97) and 30-day post-discharge home (M=37.01; SD=24.45) did not significantly change. The antecedent factors of anxiety, depression, fatigue, pain interference, pain intensity, physical function, the number of MCC, the severity of MCC, and self-rated health, as well as the presence of a caregiver, the Provider Prescribed Treatment Index (an objective measure of potential burdensome tasks) and emergency department visits were significantly correlated with TB (p < .05). In a multivariate model, antecedent factors of TB had the following effects on TB: fatigue (β = .44; p < .01), number of MCC (β = .28, p < .05), pain interference (β = .33, p < .05) and presence of a caregiver (β = -.35, p < .05), explaining 51% of the variance. The following antecedent factors of TB statistically improved over 30 days: anxiety, depression (p = .01) fatigue, pain interference, pain intensity, and physical function (p < .001). Study results filled gaps in current TB literature and provided important direction for future studies.
CHAPTER I

Introduction

In 2010, one in four Americans were living with multiple chronic conditions [MCC]; (Anderson, 2010). A chronic condition is a condition that lasts a year or more and requires ongoing medical attention and/or limits activities of daily living (Hwang, Weller, Ireys, & Anderson, 2001). Evidence has shown that the prevalence of MCC increases with age and that the US population 65 years and older has the highest number of persons with MCC (United States Department of Health and Human Services [DHHS], 2010). In 2010, 21.4 million older adults were diagnosed with MCC, which represents two-thirds of all adults 65 years of age and older (Centers for Medicare and Medicaid Services [CMS], 2012).

The 2010 US Census statistics showed a shift towards an aging population. Individuals aged 45 to 64 years of age grew by 31.5% and individuals aged 65 years and older grew by 15.1% between 2000 to 2010 (CMS, 2012), representing the most significant growth in the population. The impact of MCC on health-related outcomes and health care services utilization in adults living with MCC is expected to increase, particularly with advancements in medicine designed to prolong life. As the number of multiple chronic conditions increases, so does the risk for associated poor health related outcomes and higher utilization and costs of services (United States Census Bureau, 2011).

Complex self-management regimens are often a required part of a person’s daily routine when managing MCC. Self-management strategies vary depending on the nature of MCC diagnoses, but often include multiple medications, diet restrictions, exercise,
multiple physician visits, and increased medical related testing. When self-management regimens become complex, people living with MCC may experience high treatment burden. Treatment burden is the impact of health care on patients’ functioning and well-being, apart from specific treatment side effects (Tran et al., 2012). Based on the existing literature (Tran et al. 2012, Sav et al. 2013), and for the purpose of this study, treatment burden is defined as the self-management and coordination of health services patient undertakes in order to manage MCC resulting from the prescribed plan of treatment and disease trajectory. Treatment burden is the culmination of taking prescribed medications, monitoring various aspects of one's health, scheduling and attending office visits and ordered medical tests, adhering to prescribed behavior modification (such as a restrictive diet and increased exercise) and the associated administrative/paper work of interacting with the health care system. Not only are patients faced with the inherent disease burden (e.g. physical symptoms and medication side-effects) that accompanies chronic illness, but also with challenging treatment burden associated with managing those illnesses. People with MCC face the challenge of needing multiple providers, coordinating care between those multiple providers, and polypharmacy, which all contribute to treatment burden (May, Montori, & Mair, 2009).

Despite the importance of treatment burden in self-management of MCC, little is known about this phenomenon. The concept of treatment burden grew from healthcare professionals recognizing the need for minimally invasive medicine and the need to deliver effective treatments to reduce treatment burden, particularly among those with MCC (May et al., 2009). May et al. (2009) based their argument for minimally invasive medicine on the idea that streamlined, effective care delivered to people living MCC
would reduce the treatment burden, leading to improved treatment adherence, better outcomes, and decrease the associated cost of care. In other words, if people had less treatment burden they would be more likely to adhere to the prescribed treatment plan, thus improving health related outcomes. Understanding treatment burden and its impact on health-related outcomes of people living with MCC is essential in delivering effective care to the US population living with MCC, thereby containing the associated costs of care by improving outcomes.

**Background**

The Department of Health and Human Services (DHHS) created a strategic framework to guide research and practice, to optimize health and quality of life for individuals with MCC, to improve health outcomes, and to contain costs associated with MCC. This framework identified four goals: (1) Foster health care and public health system changes to improve the health of individuals with multiple chronic conditions; (2) Maximize the use of proven self-care management and other services by individuals with multiple chronic conditions; (3) Provide better tools and information to health care, public health, and social services workers who deliver care to individuals with multiple chronic conditions; and (4) Facilitate research to fill knowledge gaps about, and interventions and systems to benefit individuals with multiple chronic conditions (DHHS, 2010). As the US population ages and the incidence of MCC in the adult population becomes more prevalent, there is an urgent need to improve health related outcomes through optimizing health in this vulnerable population.

In the US, adults aged 65 years and older have the highest incidence of MCC, resulting in high rates of health care services utilization (e.g. hospitalizations, 30 day
readmissions, use of post-acute care and home care services) and associated costs (DHHS, 2010). Adults living with MCC experience a high level of treatment burden, which potentially increases as the number of chronic conditions increases. High levels of treatment burden decreases adherence to necessary therapeutic management of MCC, which may subsequently lead to poor health outcomes increasing hospitalization and decreasing survival rates in this population (Tran et al., 2012).

As previously stated, little is known about treatment burden in people living with MCC, which is a relatively new concept, first described, as defined in this study, in May et al. (2009). May et al. (2009) noted that people living with MCC encountered voluminous health related tasks in order to self-manage multiple diagnoses and conditions, leading to increased treatment burden that adversely impacts functioning and well-being. This increased treatment burden leads to poor treatment adherence, which negatively affected the health related outcomes of these individuals (May et al., 2009). May et al. (2009) asserted that minimally invasive healthcare, or healthcare that decreases the workload on people living with MCC, is needed to reduce treatment burden and increase the likelihood of treatment adherence.

Recent research efforts on treatment burden have been aimed at gaining a greater understanding of the phenomenon, establishing a conceptual model of treatment burden, and exploring ways to measure treatment burden. As in developing any new phenomenon, the conceptual definition of treatment burden in the literature has varied. For example, Sav et al. (2013) conducted a concept analysis and review of literature on treatment burden, employing a definition that encompassed medication side effects, while Tran et al. (2012) did not include medication side effects. Even though the definition of
treatment burden differed between research studies, both contributed to formulating a knowledge base about treatment burden in people living with MCC.

Multiple systematic reviews have been conducted to gain a better understanding of treatment burden. Qualitative systematic reviews were conducted by Gallacher, Bhautesh, et al. (2013) and Eton et al. (2013) that examined treatment burden in single comorbid conditions (stroke, heart failure, diabetes, and chronic kidney disease). Demain et al. (2015) conducted a systematic review of qualitative research examining treatment burden-related disruption in people living with MCC and how such disruptions can be reduced in this population.

Tran et al. (2012) developed the Treatment Burden Questionnaire-13 (TBQ-13), a rigorously tested, psychometrically strong instrument designed to assess treatment burden. The TBQ-13 was later adapted for use in English and added two new questions becoming the TBQ-15 (Tran et al, 2014). Eton et al. (2013) conducted a qualitative study finalizing the measurement framework for treatment burden based on the initial work conducted by Tran et al. (2012), furthering the qualitative understanding of treatment burden in the MCC population. Sav et al. (2016) measured treatment burden in Australian adults living with MCC while identifying associated risk factors leading to high treatment burden in these individuals.

Despite these initial studies on the impact and measurement of treatment burden, there is no study examining treatment burden in adults living with MCC transitioning from SNF to home, warranting further research in this area. Living with MCC is a multifaceted challenge for adults, particularly in the self-management of these conditions. Living with MCC has been associated with certain patient health characteristics, such as
lower levels of physical function (Gijsen et al., 2001; Kadam & Croft, 2007; Wensing, Vingerhoets, & Grol, 2001), higher levels of depression (Findley, Shen, & Sambamoorthi, 2011; Hitchcock-Noël et al., 2004; Lim, Jin, & Ng, 2012; Ozminkowski et al., 2012; Smith et al., 2014) and increased fatigue (Heckman, Mathew, & Carpenter, 2015; Wright, Hammer, & Melkus, 2014) in adults and older adults. These patient health characteristics may be associated with treatment burden in adults living with MCC, compounding the complexity of self-management of MCC in adults. Sav et al., (2014) described how patient health characteristics are antecedents of treatment burden, which could potentially increase or decrease the level of treatment burden in a person living with MCC. For example, a person with a higher level of fatigue may have a higher level of treatment burden as he/she is unable to make required follow-up appointments with health care providers due to the effects of high fatigue.

The population of interest in this study is adults living with MCC who are transitioning from a skilled nursing facility (SNF) to home. This population is important in the research on treatment burden due to it is the prevalence of MCC and high cost of care (National Institute on Aging, 2013). Additionally, individuals with a greater number of MCC have a greater risk of high treatment burden (Save et al., 2016). Literature also suggests that this transition period may leave individuals at higher risk of poor health outcomes, especially those who have MCC, medical complexity, and a lack of caregiver support (Reidt et al., 2016; Coleman et al., 2004; Naylor, 2000). Research in treatment burden has not focused on this population, which makes this medically complex population a priority in the measurement treatment burden and understanding its impact on health related outcomes.
Purpose

The purpose of this study is to: (1) Describe treatment burden in a population of adults with MCC who are transitioning from a SNF to home; (2) Examine the association between treatment burden and its potential, theoretically defined antecedent factors; and (3) Compare the mean differences of treatment burden and antecedent factors of treatment burden to explore the potential improvement or decline in the factors from baseline to 30 days after discharge home.

Research Questions

The research questions are:

1. What is the level of treatment burden experienced by the adult population living with MCC (at baseline and a 30-day time point post-discharge home) that transitioned from a skilled nursing facility to home?

2. Are intrapersonal (number of MCC, severity of MCC, depression, fatigue, anxiety, pain, physical function, and self-rated health), interpersonal (caregiver) and organizational (provider prescribed treatment index, transitional care, home care, outpatient therapy, hospital admissions, and emergency department visits) antecedent factors (measured at baseline and 30-day time points) correlated and predictive of treatment burden in adults with MCC that transitioned from a skilled nursing facility to home?

3. Is there a change in treatment burden and treatment burden’s antecedent factors from baseline in a skilled nursing facility to 30-days after discharge home in the adult population living with MCC?
**Conceptual Framework**

Sav et al., (2013) began constructing the conceptual framework for treatment burden. This framework consisted of three parts: antecedents of treatment burden, attributes of treatment burden, and consequences of treatment burden. This study focuses on the antecedents and measurement of treatment burden.

Finding a suitable conceptual framework to guide this study was a challenging task, as this theory had to meet four major criteria. The theory needed to be broad enough to encompass the many different conceptual levels of the antecedents of treatment burden. The theory needed soundly defined concepts. The theory’s concepts must mirror the operational concepts of Sav et al., (2013) conceptual model. In addition, this theory needed to be heavily researched and previously implemented in the area of self-management. The multi-leveled, Socio-Ecological Model strongly matched the criteria for the study design and an adapted version was used as the conceptual framework for this study.

The conceptual framework for this study is an adapted version of the Socio-ecological Model (McLeroy, Bibeau, Steckler, & Glanz, 1988). Social ecology studies the effect of social interrelationships, behaviors, and health (Simon-Morton, 2012). This framework has its origins in English and American studies conducted in the 1950s (Morris & Crawford, 1958; Simon-Morton, 2012) on the relationship between behaviors and health, and included investigations of the effects of tobacco use on cancer rates among physicians (Doll & Hill, 1954; Simon-Morton, 2012) and the effects of sedentary occupations on physical activity and its association with cardiovascular disease. This early research focused the connection between chronic disease, personal choice and
lifestyle behaviors, which were believed to be solely under the control of the individual. Contrary to this belief, Bronfenbrenner (Bronfenbrenner, 1979) published *The Ecology of Human Development*, and stated that human behavior occurs in multiple systems, not just on an individual level. Bronfenbrenner (1979) saw human behavior occurring on a micro (psychological and interpersonal influences), meso (organizational), exo (community) and macro (broader social and cultural influences) levels. The model and the application of the model in practice is referred to as Social Ecology, or the ecological framework of role of behavior in health (Simon-Morton, 2012). The Socio-Ecological Model is widely used and applied in public health research.

Modern versions of Bronfenbrenner’s (1979) Socio-Ecological Model were renamed and the levels of analysis were reorganized to better suit public health research. McLeroy et al. (1988) employ five levels of the Socio-Ecological Model (1) individual, (2) interpersonal, (3) organizational, (4) community, and (5) public policy. The concentric circles contain each level of health behavior analysis with the individual at the closest level extending outward to public policy. Each level is comprised of multiple factors that affect health behavior. Understanding these factors on each level is essential in the analysis of the individual’s health behavior and the interactions between levels of the model.

**Intrapersonal Factors.**

McLeroy et al. (1988) defines *intrapersonal factors* as “characteristics of the individual such as knowledge, attitudes, behavior, self-concept, skills, etc. This includes the developmental history of the individual,” (p. 355).
Interpersonal Factors.

McLeroy et al. (1988) defines *interpersonal factors* as “interpersonal processes and primary groups—formal and informal social network and social support systems, including the family, work group, and friendship networks,” (p. 355).

Organizational Factors.

McLeroy et al. (1988) defines *organizational factors* as “social institutions with organizational characteristics, and formal (and informal) rules and regulations for operation,” (p. 355).

Community Factors.

McLeroy et al. (1988) defines *community factors* as “relationships among organizations, institutions, and informal networks within defined boundaries,” (p. 355).

Public Policy.

McLeroy et al. (1988) defines *public policy* as “local, state, and national laws and policies,” (p. 355).

Derivation of the Socio-Ecological Model

The McLeroy et al. (1988) Socio-Ecological Model is a health behavior based model. The present study proposes to describe treatment burden longitudinally in the adult population living with MCC who are transitioning from a SNF to home. Thus, a portion of this study intends to examine how patient health characteristics, disease characteristics, family support and engagement, and healthcare systems associated with the management of MCC may also be associated with the concept of treatment burden; Sav et al., (2013) defines these concepts as antecedents of treatment burden. In order to use the Socio-Ecological Model as the conceptual framework for this study and to
achieve this study’s purpose, the conceptual definitions at each level of the Socio-Ecological Model were redefined. The number of concepts in the model reduced from five to three, focusing on the intrapersonal, the interpersonal, and the organizational factors that are potentially associated with treatment burden. This was accomplished through theoretical derivation, which allows scientists to transpose and redefine a concept, statement, or theory from one context or field to another, providing a means of theory building through shifting the terminology or the structure from one field or context to another (Walker & Avant, 2011).

An Explanation of the Adapted Conceptual Framework Guiding this Study

For the purpose of this study, the concepts of treatment adherence (proximal), health outcomes and health resource utilization (distal) replaced the pattern outcome of behavior found in the Socio-Ecological Model. Additionally, McLeroy’s et al. (1988) factor level definitions were expanded to included characteristics of health associated and management of MCC in adults living with MCC. The proposed study described treatment burden and the association to its theorized antecedent factors in adults living with MCC transitioning from a SNF to home over a period of 30 days. (Figure 1). The dotted line in Figure 1 divided the model into concepts that are measured in the model (concepts to the left of the line) and concepts that are measured in this study (concepts to the right of the line). Additionally, the conceptual model is visually cumbersome, thus the use of substruction provides (Figure 2) further conceptual clarity through an additional visual aid.
Figure 1

Adapted Socio-Ecological Model

Figure 2

Substruction on the adapted Socio-Ecological Model
Analysis and Evaluation of the Socio-Ecological Model

An analysis of the conceptual model is necessary to identify its strengths and weakness in describing the phenomenon of treatment burden in adults living with MCC. Silva and Sorrell (1992) state that this process: “highlights strengths and exposes problems inherent in a line of reasoning.” (p.17). The framework for analysis and evaluation of nursing models was first published by Fawcett (1980) and has undergone many revisions.

As stated in the background on of the Socio-Ecological Model, the origins of the model stemmed from the field of sociology and the development of the framework was motivated by interest in behavior and its relationship to health with a focus on the effect of behaviors on chronic disease (Simon-Morton, 2012). A possible critique of this model is that it is not a nursing model. Northrup et al. (2004) state that a growing number of nursing scholars (Fawcett, 1992; Johnson, 1991; Parse, 2001) believe that research that borrows or uses theory from other disciplines or sciences advances that theory or discipline, and not nursing. This standpoint of only using a nursing model is counterproductive to the discipline of nursing, as the goal of all nursing knowledge development and practice ultimately aims to support service to clients and the health of society (Donaldson, 1995), thus regardless of the origin of the model, if the research meets Donaldson’s (1995) tenets, it advances nursing science.

Additionally, any theory that encompasses the three tenets of the nursing meta-paradigm: person, environment and health, becomes applicable to nursing when a nurse uses that theory to explain a phenomenon of interest. This argument is supported by two
major axioms. First, knowledge is not owned by any discipline (Barrett, 2002); all knowledge should be logically and empirically used to answer the research questions of the scientist. Secondly, when a nurse uses a model as the theoretical framework to explain a phenomenon observed in a nursing context, that researcher applies a nursing lens, which is defined as: “a viewpoint from which someone sees things holistically, considering the person, population, or community in a larger context,” (Disch, 2012, p. 170). By applying this “nursing lens” to the model, the use, knowledge, and insight gained from the research is unique to the discipline of nursing.

**Significance to Nursing Science**

Donaldson (1995) states that the purpose for the development of nursing as a discipline through scientific and non-scientific knowledge attained from scholarly inquiry is to provide knowledge for the professional practice of nursing. Donaldson (1995) further states that ultimately the knowledge of the nursing discipline must support service to clients and the health of society. The purpose of this study meets both defined criteria: treatment burden not only affects the health and health outcomes of adults living with MCC, but the concept of treatment burden is applicable to the health of all populations living with MCC.

Donaldson and Crowley (1978) remarked in their seminal article “The Discipline of Nursing,” that three general themes emerge in the scientific advancement of nursing: (1) Concern with principles and laws that govern life processes, well-being, and optimum function of human beings, both sick and well; (2) Concern with the patterning of human behavior in interaction with the environment in critical life situations; and (3) Concern with the processes in which positive health changes are affected. Donaldson and Crowley
(1978) state that these three common themes created a boundary for scientific inquiry in nursing. Thus, theory development and scientific research should stem from at least one of these common themes. The exploration of treatment burden in adults living with MCC touches on all three of these nursing themes. First, as stated in the definition of treatment burden, treatment burden is a phenomenon that affects the life process, well-being, and the optimization in health in adults living with MCC. Secondly, in the context of the Socio-Ecological Model, treatment burden, a human behavior related concept, is affected by many factors, including the individual and that individual’s environment. Lastly, a direct relationship exists between treatment burden and the concept of treatment adherence, a process that effects positive health change.

Hinshaw (1987) defines nursing research as a “systematic process of inquiry which utilizes a variety of methodological approaches to investigate the questions and concepts of interest in nursing.” (p.5). This systematic approach to the development of knowledge in nursing science is guided by three assumptions outlined by Meleis and May (1981; p. 32-33) : “(1) Nursing science is in an evolving, developing stage; (2) Nursing science incorporates the four constructs which the profession’s theorists agree form the boundaries of the profession’s mission: clients, nurses and environments within a health/illness context; and (3) There is a pluralistic ethic or tradition in nursing which underlies scientific work and the selection of methodological approaches.”

The exploration of treatment burden and its relationship to factors associated with MCC in adults living with MCC meet these three criteria. First, the aim of this study is to advance the discipline of nursing through scientific rigor, adding to the development of nursing science, building upon the work of prior investigators. Second, the conceptual
framework work is an adapted sociology model that encompasses the aforementioned meta-paradigm of nursing: the individual, or client, and the environment. These elements of the meta-paradigm, at an interpersonal and community level, are independent variables of interest while treatment burden, or a measure of health, is the dependent outcome variable. The construct of nursing is embedded in this research study; it is through the unique nursing lens that treatment burdened in adults living with MCC is conceptualized and explored through empirical rigor. Disch (2012) defines the nursing lens as “a viewpoint from which someone sees things holistically, considering the person, population, or community in a larger context.” (p. 170). Third, the development of nursing science is an ethical endeavor. Reed (1989) states that theorizing in nursing is an ethical endeavor and is linked to the theorist’s value choices and beliefs about human beings, the environment, and health. Yeo (1989) stressed that nursing ethics should drive nursing theory, and that the act of theory development is ethical in nature. The focus of this study is to explore treatment burden in a population with a high prevalence of MCC: the nursing adaptation of the Socio-Ecological Model as the conceptual framework of this study has ethical implications tied to how the researcher sees the phenomenon. The ethical impetus of this study is derived from Donaldson’s (1995) aforementioned statement that knowledge of the discipline must support service to clients and the health of society, and thus acknowledges the ethical impact of the adapted theory. Thus, the purpose of this study is not only to advance the discipline of nursing through research, but also advances nursing through the study’s ethical considerations.

With the theoretical underpinnings to the significance to nursing established, the study intends to have a significant impact on the state of the science for many reasons.
First, this study is the first study measuring treatment burden in an all US population.
Second, this is the first study to measure treatment burden and treatment burden’s antecedents in adults living with MCC transitioning to SNF to home, a population with a high incidence of MCC, poor health outcomes, and high resources usage and cost of care. Third, this study informed the US health care community about treatment burden from a conceptual perspective as well as describing the level of treatment burden in this specific population. Fourth, this descriptive study is the first step in understanding how treatment burden affects poor health outcomes, high resource use and cost of care in the adult population living with MCC transitioning from SNF to home. Greater understanding of treatment burden may lead to future interventions that could decrease treatment burden in this population, thus improving outcomes and decreasing the use of health resources and cost of care. Lastly, informing health care providers, especially those involved with care and discharge planning of patients transitioning from SNF to home (physicians, nurses, social workers, physical/occupational therapists), on the level of treatment burden or certain aspects of treatment burden a patient is experiencing, may improve the transition process of these patients by taking into account areas of need, such as medication issues, transportation deficiencies, or financial issues.
CHAPTER II

Review of Literature

This chapter is an overview of the literature associated with treatment burden in adults living with MCC. This chapter consists of three areas of review: (1) treatment burden, (2) the epidemiology of MCC in adults living in the US, a population with high incidence of MCC and usage of PAC, and (3) the factors associated with chronic conditions that may be antecedents of treatment burden in the adult population living with MCC.

Treatment Burden

The origins of treatment burden are found in the seminal article by Corbin and Strauss (1985): Managing Chronic Illness at Home: Three Lines of Work. Corbin and Strauss examined the illness trajectory (Corbin & Strauss, 1985; Glaser & Strauss, 1968), which is defined as: (1) the course of an illness, (2) all the illness related work, (3) the impact of the illness related work on both the ill individual and his/her caregiver, as well as their relationships, and (4) the effect the management of the illness and the subsequent outcome of the illness has on the ill individual (Schneider & Conrad, 2009). Corbin and Strauss’s (1985) qualitative work outlined the three types of work an individual undertook to manage chronic illness at home: (1) illness work, or work that consists of therapeutic regimen adherence, illness related crisis prevention and management, symptom management, and diagnostic-related work, (2) everyday life work, or work that encompasses daily living, and (3) biographical work, or the need for the individual to cope and reconstruct his/her life in the face of the changing illness trajectory, such as his/her family relationships and dynamics. Corbin and Strauss (1985) point out that care
is no longer acutely focused and treated in the hospital setting and the work that must be
done to manage chronic conditions is a dynamic, cost-intensive process, in which the
work needed to manage chronic illness adds treatment burden to the individual’s life.

Research into treatment burden in the population of adults living with MCC is
very limited. Early literature pertaining to treatment burden has been limited to disease
specific burden measured as a sub-set of the larger studies in various populations: adults
diagnosed with diabetes (R. Anderson et al., 2004; Brod, Hammer, Kragh, Lessard, &
Bushnell, 2010), adults diagnosed with asthma (Campbell, Kiebert, & Partridge, 2003),
adults diagnosed with cancer or women with cancer (Yoon et al., 2008). There has been
additional work examining treatment burden in the child/adolescent and people living
with mental illness, but these we not included in the review of literature as study
populations are not pertinent to adults living with MCC. Additionally, the definition of
treatment burden in the MCC has not been concretely defined (Demain et al., 2015; Sav
et al., 2013).

Treatment burden is different from the burden of illness (e.g. disease burden). The
burden of illness “represents the impact of chronic illness on a person, their family, and
health care system,” (Sav et al., 2013, pg. 666), whereas treatment burden is defined as
the impact of engaging in therapeutic treatment regimens in order to self-manage chronic
disease (May et al., 2009; Sav et al., 2013; Tran et al., 2012). The current literature on
global treatment burden in people with MCC is primarily qualitative as researchers begin
to formulate the conceptual framework of treatment burden in people living in MCC.
Recently, treatment burden (May et al., 2009; Sav et al., 2013; Tran et al., 2012) has been
identified a potential limiting variable in treatment adherence in people living with MCC.
and is the focus of current studies (Eton et al., 2013; Gallacher, Morrison, et al., 2013; May et al., 2009; Sav et al., 2013; Tran et al., 2012). No study has solely focused on global treatment burden in the US adult population living with MCC.

**Treatment Burden Literature in Single Chronic Conditions.**

Treatment burden is not a new phenomenon, but understanding treatment burden in populations living with MCC is a new dynamic that has not been investigated in depth. Health care providers are aware of the increased burden placed on the individual as he/she manages one or more chronic conditions. Tasks such as taking an increasing number of medications, monitoring symptoms, changing diet and exercise habits, and coordinating care and provider visits all add to treatment burden. As previously stated, measurement of treatment burden in current literature consists of single item questions or as a sub-set of single chronic conditions. A single chronic condition is rare, as most people who are diagnosed with a chronic condition usually report having two or more MCC (Caughey, Vitry, Gilbert, & Roughead, 2008). Table 1 is a reference list of quantitative studies that examined some form of treatment burden in a single chronic condition.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Population</th>
<th>Sample Size</th>
<th>Purpose of the study as related to Treatment Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R. Anderson et al. (2004)</strong></td>
<td>People living with diabetes</td>
<td>n= 170 and n= 402</td>
<td>Two stage confirmatory factor analysis that developed a 5-factor, 22-item instrument assessing regimen inconvenience, lifestyle flexibility, glycemic control, hypoglycemic control, and satisfaction with the insulin delivery device.</td>
</tr>
<tr>
<td><strong>Fried, Bradley, and Towle (2002)</strong></td>
<td>People aged 60 or older with a limited life expectancy secondary to congestive heart failure, chronic obstructive pulmonary disease, or cancer</td>
<td>n= 125</td>
<td>The development of the Willingness to Accept Life-Sustaining Treatment instrument (WALT) consisting of 6 scenarios in which respondents weigh treatment burden against treatment outcomes expressed in terms of the likelihood of different health states and length of life following treatment.</td>
</tr>
<tr>
<td><strong>Brod, Cobden, Lammert, Bushnell, &amp; Raskin (2007)</strong></td>
<td>Type 2 Diabetics</td>
<td>n= 17,488</td>
<td>Assessed the DiabMedSat as a measurement tool of overall Treatment Burden, and Symptom/Efficacy Treatment Satisfaction in diabetic patients who switch to NovoMixReg 30 insulin regimen.</td>
</tr>
<tr>
<td>Authors</td>
<td>Population</td>
<td>N</td>
<td>Study Description</td>
</tr>
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<tr>
<td>Campbell et al.</td>
<td>Adults with asthma n=131</td>
<td></td>
<td>Development of the Satisfaction with Asthma Treatment Questionnaire, a comprehensive instrument to measure patient satisfaction with inhaled asthma medication existed. The ASQ is a 26-item questionnaire that identified four domains reflecting four aspects of satisfaction: effectiveness of treatment, ease of use, medication burden, and side effects and worries.</td>
</tr>
<tr>
<td>Henry et al.</td>
<td>Adults with cancer n=1,569</td>
<td></td>
<td>The study examined the prevalence of chemotherapy or radiotherapy associated side effects and related treatment burden, and correlates of fatigue and missed workdays among cancer patients.</td>
</tr>
<tr>
<td>Vijan, Hayward, Ronis, &amp; Hofer</td>
<td>US Veterans with diabetes type 2 n=1,653</td>
<td></td>
<td>The evaluation of veterans’ views of the burdens of diabetic therapy and its impact on self-management.</td>
</tr>
<tr>
<td>Ribi et al.</td>
<td>Women with early or advanced stage breast cancer n=373</td>
<td></td>
<td>Use of the Checklist for Patients with Endocrine Therapy questionnaire measure the treatment burden of endocrine therapies in order to improve communication between patients and care providers.</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Sample Size</td>
<td>Findings</td>
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<td>------------------------------</td>
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<tr>
<td>Zucca, Boyes, Newling, Hall, &amp; Girgis (2011)</td>
<td>Adults with cancer</td>
<td>n= 1410</td>
<td>Assessed travel burden and travel-related financial burden experienced by cancer patients during the first year post-diagnosis.</td>
</tr>
<tr>
<td>Rodbard, Green, Fox, Grandy, &amp; Group (2010)</td>
<td>Adults diagnosed with Diabetes Type 2</td>
<td>n= 3551</td>
<td>The number of prescription medications and out-of-pocket expenses of individuals with diabetes type 2 were evaluated to assess the economic burden of their disease.</td>
</tr>
<tr>
<td>Brod et al. (2007)</td>
<td>Adults diagnosed with Diabetes Type 1</td>
<td>n= 299</td>
<td>Examined the association between treatment symptoms and treatment burden in adults diagnosed with diabetes type 1.</td>
</tr>
<tr>
<td>Tija, Micco, &amp; Armstrong (2008)</td>
<td>Women receiving chemotherapy for breast cancer</td>
<td>n= 457</td>
<td>Examined how aging-related factors such as diminished life expectancy, increasing comorbidity and medication burden influence chemoprevention interest.</td>
</tr>
<tr>
<td><strong>Moss &amp; Crane (2010)</strong></td>
<td>Older adult females, n= 86</td>
<td>Examined how post-myocardial related polypharmacy contributed to financial burden</td>
<td></td>
</tr>
</tbody>
</table>
Summary of single condition, treatment burden literature.

It is difficult to draw conclusions about the overall findings related to treatment burden in single conditions as the measures of and variables affecting treatment burden have not been consistent across the studies. There is evidence that treatment burden increases with the incidence of different types of cancer, diabetes (Type I & II), asthma, heart failure, chronic pulmonary obstructive disease, and in women post-myocardial infarction, but there is a need for further testing of this finding in the MCC population.

MCC Treatment Burden Literature.

Due to the recognition treatment burden as more than just a single chronic disease phenomenon, the current treatment burden literature has been primarily qualitative in nature as researchers try to understand how treatment burden is conceptualized and manifested in the MCC population. Qualitative research and systematic reviews dominate the current treatment burden literature. Systematic reviews (Gallacher, Bhautesh, et al., 2013; Gallacher, Morrison, et al., 2013) focus on treatment burden literature in single chronic conditions, such as heart failure, diabetes, and stroke. Eton et al. (2013) provided a systematic review of patient reported measures of treatment burden in heart failure, diabetes, and chronic kidney failure. Sav et al. (2013) used a mixed methods systematic review of literature and related concept analysis. Demain et al. (2015) used a qualitative systematic review focused on the treatment generated disruptions of treatment burden across all chronic conditions and how these treatment disruptions are minimized by the individual. Sav et al. (2013) reports on a qualitative study exploring treatment burden in people living with MCC and their unpaid caretakers. May et al. (2014) outlines the Burden of Treatment Theory, which explains the relationship between sick individuals,
social networks, and health care services, in the context of the changing dynamics of chronic illness. Eton et al. (2015) provides a qualitative study focused on finalizing a measurement framework for treatment burden in people living with MCC. Though the methods of these systematic reviews, qualitative studies, and conceptual/theory driven papers differed, the theories, concepts, and results are related and support the cohesive development and understanding of treatment burden. These studies are significant, as they have provided an important review of literature and qualitative information that describes treatment burden in specific populations, including people living with MCC.

The systematic review by Gallacher, Morrison, et al. (2013) used a framework synthesis based on the Normalization Process Theory (May & Finch, 2009), a theory which outlines the process of how work becomes embedded in an individual’s everyday routine., while analyzing 51 total papers, in an attempt to understand what treatment burden is to stroke patients. Gallacher, Morrison, et al. (2013) identified the 8 areas of treatment burden from the literature: “making sense of treatments e.g. gaining information from health professionals; planning recovery and care e.g. setting goals; interacting with others e.g. coping with multiple caregivers; institutional admissions e.g. admission to hospital; managing stroke in the community e.g. risk factor management at home; reintegration into society e.g. addressing financial difficulties; adjusting to life after stroke e.g. planning a new daily structure to accommodate treatments; and reflecting on management e.g. making decisions about adherence,” (p. 3). Through the results of their systematic review, Gallacher, Morrison, et al. (2013) articulated specific issues and barriers to treatment adherence and potential factors that increase treatment burden.
Gallacher, Bhautesh, et al. (2013) also conducted a systematic review on treatment burden in stroke patients. Gallacher, Bhautesh, et al. (2013) review included 69 papers, and concluded treatment burden in stroke patients was comprised of: (1) making sense of stroke management and planning care, (2) interacting with others, (3) enacting management strategies, and (4) reflecting on management. Gallacher, Bhautesh, et al. (2013) found that the delivery of care is fragmented, with poor communication between the patient/ patient’s family and health care providers. Patients reported the inadequate provision of information throughout the care process (Gallacher, Bhautesh, et al., 2013). Patients stated that inpatient care is unsatisfactory, indicating a perceived lack of empathy from health care professionals and a lack of stimulating and therapeutic activities on inpatient units (Gallacher, Bhautesh, et al., 2013). The discharge process, including home going education and transitions of care are poorly coordinated, and accessing post-discharge health and social care in the community is difficult for this population (Gallacher, Bhautesh, et al., 2013). Gallacher, Bhautesh, et al. (2013) concluded stroke management is highly burdensome for patients, and treatment burden is influenced on many different levels of the health care continuum, with both micro and macro causes affecting treatment burden. Gallacher, Bhautesh, et al. (2013) also noted that knowledge deficits led to poor organization of care and development of coping strategies, reducing the likelihood of treatment adherence. The weakness of Gallacher, Bhautesh, et al. (2013) is the focus on the treatment burden in stroke patients, a single chronic condition. The article did support other treatment burden study findings (Eton et al., 2013; Eton et al., 2015; Gallacher, Morrison, et al., 2013; Tran et al., 2012), of how lack of care
coordination, access to care, and a lack of disease specific and self-care knowledge increase treatment burden and, consequently, reduces treatment adherence.

The systematic review by Eton et al. (2013) compiled and examined 98 studies of treatment burden measurement reported in three chronic disease literature (diabetes, heart failure, and chronic kidney disease). Eton et al. (2013) identified 57 patient-reported measures of treatment burden. The majority of measures consisted of multi-item scales (89%) and assessed treatment burden in people diagnosed with diabetes (82%). Of the 57 treatment burden measures, only 15 measures were developed using direct patient input and demonstrated evidence of reliability, scale structure, and multiple forms of validity, while 6 measures demonstrated evidence of sensitivity to change (Eton et al., 2013). This review identified a lack of a psychometrically reliable, global treatment burden measure, especially for those people living with MCC.

Sav et al. (2013) conducted a concept analysis and review of literature of treatment burden. Sav et al. (2013) review included 30 articles in the final analysis that conceptually viewed treatment burden as comprised of antecedents (patient characteristics, disease conditions, treatment regimen, family support and engagement, and health care systems), which are compounded by attributes of treatment burden which are seen as dynamic (changing over time), multi-dimensional (physical, financial, temporal, psychological) and objectively and subjectively measured, in which ends in the consequences (adherence, health and well-being, resource use, employment, family and caregivers) of treatment burden. Sav et al. (2013) noted that many of the consequences of treatment burden could become antecedents, thus alluding to the cyclical nature of treatment burden. Sav et al. (2013) definition of treatment burden differed from the
dissertation definition, as defined by Tran et al. (2012), by including medication side effects as a result of treatment adherence.

The concepts in Gallacher, Morrison, et al. (2013) correspond with the consequence concepts described in the Sav et al. (2013) systematic review. Both Gallacher, Morrison, et al. (2013) and Sav et al. (2013) found that self-management tasks were identified as high contributors to treatment burden. This finding is important, yet troubling, as chronic disease self-management has focused on best practices to improve health related outcomes through treatment adherence, yet, the culmination of these self-management processes and goals may be counter-productive, increasing burden, thus decreasing treatment adherence. Furthermore, Gallacher, Morrison, et al. (2013) and Sav et al. (2013) demonstrate consensus in the literature in what treatment burden is to the population living with MCC. The Sav et al. (2013) conceptual model included antecedents to treatment burden, which is a strength of the model that incorporates potential variables of the individual living with MCC and his/her environment that the individual interacts with that potentially effects treatment burden. This is an important dynamic for the conceptual model of this proposed study. Understanding the association of factors on an intrapersonal, interpersonal, and community level is supported by Sav et al. (2013) in their conceptualization of treatment burden.

Demain et al. (2015) conducted a qualitative systematic review of treatment burden literature in order to identify treatment generated disruptions across all chronic conditions and how individuals minimize these disruptions. Eleven papers were included in the final analysis and treatment burden resulted in a wide variety of disruptions: “biographical disruptions involved in loss of freedom and independence, restriction of
meaningful activities, negative emotions and stigma; relational disruptions included strained family and social relationships and feeling isolated; and, biological disruptions involved physical side effects,” (Demain et al., 2015, p. 1). Individuals coped with these disruptions via two avenues: adaptive treatment work and rationalized non-adherence.

Adaptive treatment work includes three components. The first component is sentimental work, or work involved in self-soothing behaviors, using interaction with family and friends, and developing other strategies to reduce stress caused by treatment generated disruptions (Demain et al., 2015). Second, biographical work is work employed as a way to adapted to changes in one’s personal identity due to chronic disease and treatment burden (Demain et al., 2015). Third, relational work is the work that the individual uses to maintain relationships, either personal, professional, or healthcare related (Demain et al., 2015). The concept of adaptive treatment work is directly tied to Corbin and Strauss’s (1985) management of chronic illness.

Rationalized non-adherence is the second way to minimize the impact of treatment disruptions. Demain et al. (2015) found that non-adherence to a prescribed treatment regimen was not an arbitrary decision or a personal failing, but a rationalized process used to decrease treatment burden. Rationalized non-adherence is when an individual evaluates the impact, or cost-benefit of treatment adherence versus non-adherence, and decides to reduce, alter, or stop their prescribed treatment regimen. Demain et al. (2015) also found that health care providers in end-of-life situations support this decision of rationalized non-adherence, but, in less critical situations, rationalized non-adherence happened without the knowledge of the provider. This “secret” rationalized non-adherence causes coordination issues between patient and provider;
there is a disconnect between what the provider prescribes and thinks is being followed versus what the patient is actually accomplishing, which has potential clinical decision making implications (Demain et al., 2015). Demain et al. (2015) gives further support to the idea that treatment burden is dynamic, multi-dimensional, influencing the trajectory of chronic illness, and not fully understood.

May et al. (2014) outlines the Burden of Treatment Theory, which explains the relationship between sick people, their social networks, and healthcare services. The Burden of Treatment Theory explains the interaction between a sick individuals’ capacity for action and the work needed to self-manage chronic disease, as prescribed by the healthcare system. The model focuses on the work the sick individual and their social network must do to manage their chronic condition(s). The underpinnings of the Burden of Treatment Theory is a synthesis of the Normalization Process Theory (May & Finch, 2009), May et al. (2009) concept of Minimally Disruptive Medicine, and Shippe et al.’s (2012) Cumulative Complexity Model, which examines the relationship between the healthcare system and the sick individual and how work is delegated to the sick individual and how that sick individual meets those self-management demands, and Rogers et al. (2012) work on healthcare demand, self-care processes, and social networks. May et al. (2014) theorizes that capacity and work interact on societal, system, and granular levels; the definitions of these three levels are similar to the social ecological model levels. May et al. (2014) also note that instability in sick individuals with chronic conditions is normal, thus supporting the work by Sav et al. (2013) that treatment burden is dynamic, multi-faceted, and subjective leading to different illness trajectories. May et al. (2014) also supports the idea that the dysfunctional delivery of healthcare is a major
contributor to treatment burden, and streamlining this process could help sick individuals better utilize healthcare services, thus decreasing treatment burden and improving outcomes. Interventions that improve the patient experience, decrease the work that must be done to self-manage chronic disease, and increase the individual’s potential capacity to do the delegated work of self-management, is key to reducing treatment burden (May et al., 2014).

Sav et al. (2013) is a qualitative study examining treatment burden in Australians living with chronic conditions and their unpaid caregivers. The study (n = 97) collected data from participants either face to face or via telephone interviews. The findings of the study revealed that there exist four interrelated components: financial burden, time and travel burden, medication burden, and healthcare access burden. The most influential variable was financial burden, which subsequently affected the other three variables. Additionally, Sav et al. (2013) discussed the need for individualized treatment in people living with chronic conditions to reduce burden. A limitation of this study was that it was conducted in Australia, and thus the population interviewed, as well as the healthcare system they interact with and receive care from, cannot generalized to the US population. Additionally, 28 of these participants were caregivers, thus, treatment burden for caregivers is different than individual with chronic conditions, as burden is subjective and individualized, which comes from the separately published Sav et al. (2013) concept analysis of treatment burden. Despite the limitations, it provided further understanding of treatment burden in people living with MCC.

Eton et al. (2015) is a qualitative study finalizing a framework for treatment burden in patients with chronic conditions further supported the previous systematic
reviews of treatment burden (Gallacher, Bhautesh, et al., 2013; Gallacher, Morrison, et al., 2013; Sav et al., 2013). Eton et al. (2015) interviewed 50 participants (98% coping with MCC) and identified 3 overarching themes: 1) work patients must do to care for their health (e.g., taking medications, keeping medical appointments, monitoring health); 2) challenges/ stressors that exacerbate perceived burden (e.g., financial, interpersonal, provider obstacles); and 3) impacts of burden (e.g., role limitations, mental exhaustion). Eton et al. (2015) further demonstrated that treatment burden is dynamic, time and resource intensive, individualized, and has a significant impact on the health related outcome of the person living with MCC.

Tran et al. (2012) conducted the first major study examining treatment burden in people living with MCC. Establishing a weight of burden was the first major step in understanding treatment burden in individuals living with MCC. Tran et al. (2012) identified this need for a scale to measure treatment burden, as there was no scale to measure global treatment burden. In this study, Tran et al. (2012) defined treatment burden, conducted qualitative interviews to establish what treatment burden meant to people living with MCC, and conducted validity and reliability testing on the newly created measure. After rigorous statistical analysis, which included four steps: (1) reduction of the number of items, (2) assessment of factorial validity, (3) assessment of construct validity, and (4) assessment of reliability, a measure of global treatment burden for individuals with MCC was developed (Tran et al., 2012). The outcome of Tran’s et al. (2012) study was the development of the Treatment Burden Questionnaire 13 (TBQ-13), a measurement of treatment burden in people living with MCC that displayed strong psychometric properties (Cronbach’s alpha= .89, and Test-retest correlation= .76).
Tran’s et al. (2012) study is not without notable weaknesses. Tran et al. (2012) conducted the study in the France, which has a socialized health care system and the results of the study may not be applicable to the US health care system. In addition, Tran et al. (2012) conducted qualitative interviews on 22 persons who had a least one chronic condition. A person with only one chronic condition may have a different understanding of treatment burden than someone with MCC. Despite these limitations, Tran et al.’s (2012) study was the major step in measuring treatment burden in all populations living with MCC.

Tran et al. (2014) adapted the TBQ-13 for use in English speaking population, as the initial measure was initially created for use in French speaking populations. The study was conducted on a sample of 610 adults with chronic conditions from the US, the United Kingdom, New Zealand, Canada, and Australia. The English adapted TBQ-13 added two questions, one referencing treatment burden related to relationships with health care providers and the other referencing treatment burden related to the financial aspects of the participant’s healthcare (Tran et al., 2014). The new measure, the TBQ-15, showed high internal reliability: Cronbach’s alpha of 0.9 and a test-retest (n=282) correlation of 0.77 (Tran et al., 2014). Construct validity was tested by hypothesizing that the TBQ-15 would be negatively correlated with the Patients Like Me Quality of Life Survey (Tran et al., 2014). The results demonstrated a large, negative correlation (r = -0.50, p < 0.0001) between the two measures, confirming the hypothesis (Tran et al., 2014). Tran et al.’s (2014) adaptation provided a measure of treatment burden established for English speaking populations and further solidified the measure validity and reliability.
Sav et al. (2016) conducted a study on characteristics predisposing adults living with MCC to high levels of treatment burden. This study \((n = 581)\) used the adapted TBQ-15 to measure treatment burden in Australian adults living with MCC (Sav et al., 2016). The sample reported a mean treatment burden score of 56.5 out of 150, with a standard deviation of 34.5 (Sav et al., 2016). The statistical analysis of the data using multiple linear regression found that the number of MCC \((β = .34, p < 0.01)\), age, \((β = −.27, p < 0.01)\), the presence of an unpaid caregiver \((β = .22, p < 0.001)\) and the presence of diabetes mellitus/endocrine conditions \((β = .13, p < 0.01)\) were significant predictors of treatment burden (Sav et al., 2016). Sav et al.’s (2016) study provided results of statistically significant predictors of treatment burden in an English speaking, Australian population living with MCC, as well as further exploring and measuring treatment burden in the adult population living with MCC.

**State of Treatment Burden Science.**

The science of treatment burden has progressed from exploring burden a minor subset of the self-management process in single chronic conditions to complex phenomenon involving multiple chronic conditions that has major implications to the multifaceted self-management process of MCC. Developed by two non-US research teams, one from England, the other from Australia, treatment burden is a dynamic, subjectively/objectively measured phenomenon that heavily influences health related outcomes and the associated cost of care in people living with MCC. Qualitative studies focusing on treatment burden in the MCC population has produced a wealth of conceptual findings. These studies focused on the conceptual framework of treatment burden, what treatment burden is to the MCC population, how it affects self-
management, and has uncovered barriers/facilitators to exacerbate or decrease treatment burden as related to self-management. The research has demonstrated that low levels of treatment adherence is a significant outcome of high treatment burden. Additionally, the research has created strong psychometric tools, the TBQ-13 and TBQ-15, to measure treatment burden in people living with MCC. Research has progressed to measuring treatment burden in various populations and understanding health characteristics that predict high level of burden.

**Summary of Treatment Burden Literature.**

Currently, the state of the science is ready to progress from qualitative to quantitative research in order to advance by measuring treatment burden in the population most affected by the phenomenon, adults with MCC. The proposed study provides an understanding of the conceptual soundness of the current qualitative literature, further test the external reliability of the TBQ-15, measure treatment burden in a previously unstudied, high-risk population, and explore antecedent factors of treatment burden in the proposed population.

**Epidemiology of MCC in Adults Living in the US**

More than in four adults in the US have MCC, and the prevalence of MCC increase with age (DHHS, 2010). Though the population of interest in this study is adults living with MCC, the older adult population living with MCC is susceptible to poor health related outcomes and high financial costs associated with care. The prevalence of health related outcomes and associated economic impact of MCC (CDC, 2012) is significant and is illustrated in Table 2.
### Table 2

Center for Disease Control Data for MCC in Adults Aged 65 and Older (CDC, 2012)

<table>
<thead>
<tr>
<th>MCC by Sex</th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>35%</td>
<td>30%</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>Female</td>
<td>29%</td>
<td>34%</td>
<td>23%</td>
<td>15%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MCC by Race</th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic White</td>
<td>31</td>
<td>33</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>31</td>
<td>30</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>Asian/PI</td>
<td>32</td>
<td>33</td>
<td>23</td>
<td>11</td>
</tr>
<tr>
<td>Hispanic</td>
<td>34</td>
<td>28</td>
<td>22</td>
<td>16</td>
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<table>
<thead>
<tr>
<th>Dual Eligibility</th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
</tr>
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Percentage of Medicare Population with MCC:

<table>
<thead>
<tr>
<th>Percentage of Medicare Population with MCC</th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
</tr>
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<tbody>
<tr>
<td>32%</td>
<td>32%</td>
<td>23%</td>
<td>14%</td>
<td></td>
</tr>
</tbody>
</table>

MCC by Sex:

- Male: 35% (0-1 MCC), 30% (2-3 MCC), 22% (4-5 MCC), 13% (6 or more MCC)
- Female: 29% (0-1 MCC), 34% (2-3 MCC), 23% (4-5 MCC), 15% (6 or more MCC)

MCC by Race:

- Non-Hispanic White: 31% (0-1 MCC), 33% (2-3 MCC), 23% (4-5 MCC), 14% (6 or more MCC)
- Non-Hispanic Black: 31% (0-1 MCC), 30% (2-3 MCC), 23% (4-5 MCC), 16% (6 or more MCC)
- Asian/PI: 32% (0-1 MCC), 33% (2-3 MCC), 23% (4-5 MCC), 11% (6 or more MCC)
- Hispanic: 34% (0-1 MCC), 28% (2-3 MCC), 22% (4-5 MCC), 16% (6 or more MCC)
- Dual Eligibility: 30% (0-1 MCC), 34% (2-3 MCC), 22% (4-5 MCC), 16% (6 or more MCC)
(Medicare and Medicaid)

<table>
<thead>
<tr>
<th></th>
<th>Dual Eligible</th>
<th>Non-Dual</th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Admissions</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>0 Admissions</td>
<td>28</td>
<td>33</td>
<td>27</td>
<td>33</td>
<td>24</td>
<td>21</td>
</tr>
<tr>
<td>3+ Admissions</td>
<td>24</td>
<td>22</td>
<td>3</td>
<td>16</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
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<tbody>
<tr>
<td>Post-Acute Visit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1%</td>
<td>7%</td>
<td>19%</td>
<td>49%</td>
<td></td>
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<thead>
<tr>
<th></th>
<th>0-1 MCC</th>
<th>2-3 MCC</th>
<th>4-5 MCC</th>
<th>6 or more MCC</th>
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<tbody>
<tr>
<td>Home Health Care Visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 visits</td>
<td>99%</td>
<td>95%</td>
<td>86%</td>
<td>64%</td>
</tr>
<tr>
<td>1-12 visits</td>
<td>1%</td>
<td>1%</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>13 + visits</td>
<td>0%</td>
<td>3%</td>
<td>9%</td>
<td>27%</td>
</tr>
<tr>
<td></td>
<td>0-1 MCC</td>
<td>2-3 MCC</td>
<td>4-5 MCC</td>
<td>6 or more MCC</td>
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</tr>
<tr>
<td><strong>Emergency</strong></td>
<td></td>
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</tr>
<tr>
<td>Department</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visits</td>
<td>86%</td>
<td>75%</td>
<td>59%</td>
<td>30%</td>
</tr>
<tr>
<td>0 visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3+ visits</td>
<td>2%</td>
<td>4%</td>
<td>8%</td>
<td>27%</td>
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<tr>
<td><strong>Hospital</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Readmissions</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>0-1 MCC</td>
<td>2%</td>
<td>8%</td>
<td>20%</td>
<td>70%</td>
</tr>
<tr>
<td>2-3 MCC</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4-5 MCC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 or more MCC</td>
<td></td>
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</tr>
<tr>
<td><strong>Average</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Yearly Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per Medicare</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recipient</td>
<td>$2,025</td>
<td>$5,698</td>
<td>$12,174</td>
<td>$32,658</td>
</tr>
</tbody>
</table>

To summarize the CDC (2012) published Medicare data, older adults with MCC are more likely to use more healthcare services and have higher associated costs of care. Women have a higher incidence of MCC. Black and Hispanic peoples have a higher incidence of six or more MCC than White does or Asian peoples do. Dual-eligible recipients have a higher incidence of six or more MCC as compared to Medicare eligible recipients, which may indicate an economic health disparity. In addition to the data in Table 2, treatment for Medicare recipients with six or more MCC accounted for $140
billion, which represented 40% of all Medicare dollars spent that year, and 93% of all Medicare dollars were spent on beneficiaries living with MCC (CMS 2012).

In addition to this Medicare data, Ward and Schiller (2010) examined MCC using the National Health Survey data. They found that there were differences in the prevalence of MCC between (1) sex and age, (2) sex, age, and race, (3), and sex, age, race, and insurance coverage.

When examining the differences in MCC prevalence between sex and age, the most striking statistic was that men ages 18-44 were less likely than women to have 2-3 MCC, and men ages 18-44 and 45-64 were less likely to have four or more MCC than women. Conversely, men aged 65 and older were more likely to have four or more MCC than women (Ward and Schiller, 2010). When examining the differences in MCC prevalence between sex, age, and race, an important finding was that black females had higher incidence of 2-3 MCC than white females and that Asian females had a lower incidence of 2-3 MCC as compared to all other races (Ward and Schiller, 2010). The differences in MCC prevalence between sex, age, race, and insurance demonstrated that those individuals with private insurance, on average, had fewer MCC than those who had a public or other option (Ward and Schiller, 2010).

**Summary of the Epidemiology of MCC in Adults Living in the US.**

As the population in the US continues to age, the impact of treatment burden associated with MCC becomes an even more important issue. Per the Centers for Disease Control and Prevention [CDC] (2013), by 2040, there will be about 89 million older adults, more than twice their number in 2010. Treatment adherence is essential in the self-management of MCC. Poor treatment adherence is associated with poor health
related outcomes, a high health care utilization rate, and a high associated cost of the complex medical care needed to care for adults and older adults living with MCC (Jansà et al., 2010; Wong et al., 2014). These statistics are indicate a pressing need to understand treatment burden in adults living with MCC. Understanding treatment burden in adults living with MCC is the first step in potentially improving health related outcomes by reducing the impact of treatment burden on treatment adherence, thus providing direction for future studies.

Factors Associated with Chronic Conditions

Even though there is very little literature describing treatment burden in adults living with MCC, there is robust literature concerning factors associated with chronic conditions in various populations. This study tested the possible association of chronic condition related factors (depression, fatigue, anxiety, pain, physical function, self-rated health, and the number of MCC) found in the current literature and treatment burden. These potentially associated factors are described by Sav et al. (2013) as antecedents of treatment burden, specifically patient characteristics, disease conditions, family support and engagement, and health systems are represented in this study by intrapersonal, interpersonal, and organizational factors of this study’s adapted Socio-ecologic model. Additionally, past studies found in the current literature predominately studied the antecedent factors of treatment burden in single chronic conditions, though some factors were studied in individuals living with MCC.

Intrapersonal Factors of MCC (see Table 3).

McLeroy et al. (1988) define *intrapersonal factors* as “characteristics of the individual such as knowledge, attitudes, behavior, self-concept, skills, etc. This includes
the developmental history of the individual.” (p.355). This study proposed that physical and mental characteristics of the adult living with MCC have an association with treatment burden.

Depression, anxiety, pain, and fatigue are intrapersonal factors that may be associated with treatment burden. For example, an adult with MCC diagnosed with depression exacerbated by anxiety over his or her condition may have a different level of treatment burden than an adult without these factors. Women with breast cancer have a clustering of anxiety, depression, fatigue and pain (So et al., 2009). Depression, fatigue, and pain are highly clustered states found in a comparison of community-dwelling older adults without cancer to community-dwelling older adults with cancer (Reyes-Gibby, Aday, Anderson, Mendoza, & Cleeland, 2006), adults with cancer (Fleishman, 2004), and individuals with multiple sclerosis (Motl, Suh, & Weikert, 2010). A systematic review (Liddy, Blazkho, & Mill, 2014), exploring the challenges of self-management in people living with MCC found that pain and depression are two factors limiting effective self-management. Since current literature has associated the clustering of anxiety, depression, fatigue, and pain in people living with chronic conditions, including the adult population living with MCC, thus, this proposed study posited that this symptom cluster (1) exists in adults living with MCC and (2) an association exists between this cluster and treatment burden in adults living with MCC.

Depression is more common in veterans with MCC (Findley et al., 2011) and older adults with MCC (Hitchcock-Noël et al., 2004; Ozminkowski et al., 2012). Additionally, the greater number of chronic conditions an individual is diagnosed with is associated with higher levels of depression (Smith et al., 2014). Depression and anxiety
have been shown to be correlated with poor chronic physical functioning and a lower quality of life in individuals living in an urban setting (Lim et al., 2012).

Patients experiencing heavy treatment burden have been found to have high levels of treatment-related fatigue (Heckman et al., 2015). Additionally, there is an association between MCC and cancer-related fatigue in adults diagnosed with solid tumors (Wright et al., 2014).

Physical function may also be associated with treatment burden. For example, an adult with MCC who has limited physical function may have greater difficulty performing self-management tasks such as opening pill bottles, exercise, or even basic activities of daily living (ADL). Studies have shown that limited or declining physical function is associated with MCC (Wensing et al., 2001, Kadam et al., 2007, and Gijsen et al., 2001), thus supporting testing the association between physical function and treatment burden.

Self-rated health (SRH) is another individual factor that may be associated with treatment burden. SRH is not only a predictor of morbidity and mortality of an individual; it is a global assessment of overall individual health. Jylhä (2009) as defines SRH: “the general perception of an individual’s health status and is one of the most commonly used indicators for health status.” Poor SRH has been associated in people living with MCC (Mavaddat, Valderas, van der Linde, Khaw, & Kinmonth, 2014; McDaid et al., 2013).
Table 3

Interpersonal Factors Associated with Chronic Conditions

<table>
<thead>
<tr>
<th>Author</th>
<th>Aim</th>
<th>Design</th>
<th>Sample/Method</th>
<th>Major Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reyes-Gibby et al. (2006)</td>
<td>Identification of pain, depression and fatigue in Community Dwelling Adults without cancer as compared to Community Dwelling Adults with cancer.</td>
<td>Cross Sectional, Secondary Analysis</td>
<td>n= 17,210</td>
<td>Patients with cancer had higher incidences of pain, fatigue, and depression as well as a higher incidence of the clustering of these symptom states.</td>
</tr>
<tr>
<td>Liddy et al. (2014)</td>
<td>Explore the perspectives of people living with MCC and the challenges of self-management.</td>
<td>Systematic Review</td>
<td>23 Qualitative articles included in the review</td>
<td>Themes identified by people living with MCC related to self-management included living with undesirable physical and emotional symptoms, with pain and depression as major symptoms.</td>
</tr>
</tbody>
</table>
## Depression and Chronic Conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Population</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Findley et al., (2011)</td>
<td>Retrospective, Cross Sectional Analysis</td>
<td></td>
<td>Analyzed national administrative data on approximately 1.38 million Veteran Health Administration clinic users merged with Medicare claims data. Of all veterans, 5.6 percent were diagnosed with persistent depression. Persistent depression was significantly more likely among veterans with multi-morbidity than among those with only hypertension.</td>
</tr>
<tr>
<td>Hitchcock et al., (2004)</td>
<td>Cross Sectional Design</td>
<td></td>
<td>Patients aged 60 years and older (N = 1,801) who met diagnostic criteria for major depression or dysthymia participated in a baseline survey. A survey instrument included questions on sociodemographic characteristics, depression severity and chronicity, neuroticism, and the presence of 11 common chronic medical illnesses, as well as questions screening for panic disorder and posttraumatic stress disorder. Measures of 4 general health indicators (physical and mental component scales of the SF-12, Sheehan Disability Index, and global quality of life) were included. Depression co-existed with chronic illness, yet when chronic comorbid conditions were controlled for, depression had an independent impact on the 4 general indicators of health.</td>
</tr>
<tr>
<td>Ozminski et al., (2012)</td>
<td>Cross Sectional Secondary Data Analysis</td>
<td></td>
<td>Data were obtained from the Health Update Survey (HUS). The survey was mailed to a random sample of 30,000. On the depressive symptoms were common, with an estimated prevalence of</td>
</tr>
</tbody>
</table>
with various chronic conditions/health concerns among adults with Medicare Supplement Insurance. 

basis of relevant questions from the survey, respondents were categorized into two groups: those currently suffering from current depressive symptoms (N=2283) and those who never had depressive symptoms (N=7058). 

24.4%. The greatest impact of depressive symptoms in combination with various chronic conditions/health concerns on quality of life was on the ability to handle emotional roles, bodily pain, social functioning, and ability to handle physical roles.

| Smith et al., (2014) | Examined the association of multiple physical health comorbidities in Scottish primary care patients with depression | Cross Sectional secondary data analysis | The study examined records of 143,943 people with depression and 1,280,435 without depressions. The outcomes assessed were 32 common chronic physical health conditions, adjusted for age, sex, and socioeconomic status. | Individuals in primary care with depression were more likely than individuals without depression to have every one of the 32 comorbid physical conditions we assessed, even after adjusting for age, sex, and socioeconomic status. |

**Depression and Anxiety in Chronic Conditions**

| Lim et al., (2012) | Examined the effect of anxiety disorders and/or depression and chronic medical conditions on quality of life | Cross Sectional Design | Complete data of 2,801 participants from the National Mental Health Survey of Adults in Singapore were analyzed, using SCAN diagnoses of anxiety disorders and depression, self-reports of chronic medical conditions, and SF-12 measures of QOL. | Subjects diagnosed with anxiety and/or depression had a greater number more medical co-morbidities (59 vs. 33%, p<0.001). Subjects with anxiety and/or depression had |
### Fatigue and Chronic Conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Title</th>
<th>Methodology</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heckman et al., (2015)</strong></td>
<td>Examination of the association of treatment fatigue and treatment burden in people living with MCC</td>
<td>Systematic Review</td>
<td>5 studies were included in the analysis.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Created a modified workload–capacity model that incorporates evidence that treatment fatigue may be caused by increased workload due to treatment burden and lead to low treatment adherence.</td>
</tr>
<tr>
<td><strong>Wright et al., (2014)</strong></td>
<td>Summarized the current state of nursing knowledge related to the association of MCC and cancer-related fatigue in patients with solid tumors during chemotherapy</td>
<td>Systematic Review</td>
<td>21 studies were included in the analysis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The presence of one or more other comorbidities was significantly associated with the prevalence and severity of cancer related fatigue.</td>
</tr>
</tbody>
</table>

### Physical Function and Chronic Conditions

<table>
<thead>
<tr>
<th>Study</th>
<th>Title</th>
<th>Methodology</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wensing et al., (2001)</strong></td>
<td>Examine the relationship between functional status, health problems, age, and co-morbidities in primary care patients</td>
<td>Cross-sectional design</td>
<td>n= 4112 primary care patients completed a list of 25 health problems and the SF-36 to measure functional status</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Poorer functional status was associated with age and increased co-morbid conditions</td>
</tr>
<tr>
<td><strong>Kadam et al., (2007)</strong></td>
<td>Examined whether routinely collected primary care data could be used to classify multi-morbidity and its effect</td>
<td>Cross-sectional design</td>
<td>Morbidity consultation data for 9439 English patients aged 50 years and over in an 18-month time period were linked to their self-reported physical health status measured by the SF-36.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>The authors estimated 24% of poor physical function in the study sample may be attributable to poorer physical and mental functioning scores as compared to control.</td>
</tr>
<tr>
<td>Study</td>
<td>Methodology</td>
<td>Sample</td>
<td>Findings</td>
</tr>
<tr>
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**Self-Rated Health and Chronic Conditions**

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Sample</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>McDaid et al., (2013)</td>
<td>Cross Sectional Design</td>
<td>n= 6159 participants aged 50 years and older were interviewed at home.</td>
<td>Participants with MCC reported lower SRH and QOL, though no combination was more statistically significant than another.</td>
</tr>
<tr>
<td>Mavaddat et al., (2014)</td>
<td>Cross Sectional Design</td>
<td>n= 268 individuals, aged 39 to 79 years, completed a survey including self-rated health, psychosocial function and presence of common physical chronic conditions.</td>
<td>Odds of “moderate/poor” self-rated health worsened with increasing number of conditions, and relationship of SRH to MCC was stronger in men than in women.</td>
</tr>
</tbody>
</table>
Summary of Intrapersonal Factors associated with MCC.

There is sufficient evidence in the literature that associates the aforementioned intrapersonal factors with chronic conditions, but there is no study examining this association to treatment burden in adults living with MCC. Sav et al. (2013) alludes to the potential impact that antecedent factors have on treatment burden, yet this has not been quantitatively measured using these variables. It is logical to posit that adults with higher level of depression, fatigue, pain, and anxiety coupled with low levels of physical functioning and self-rate health have higher levels of treatment burden, but until measured, this is a hypothesis at best. This study aims to fill this gap in the literature by examining these potential associations.

Interpersonal Factors.

McLeroy et al. (1988) define interpersonal factors as “interpersonal processes and primary groups—formal and informal social network and social support systems, including the family, work group, and friendship networks,” (p. 355). Sav et al., (2013) defines this study’s interpersonal factors as family support and engagement, which is an antecedent of treatment burden. This study posits that the support given through caregivers may have an association with treatment burden in adults living with MCC.

In the current literature, there is limited research focusing on the caregiver of an adult with MCC. The few research articles that did examine caregivers and adults living with MCC suggested that caregivers were beneficial to adults and older adults living with MCC (Corry, While, Neenan, & Smith, 2015; Kuluski et al., 2013; Williams et al., 2016). Contrary to this underlying assumption in these articles, Sav et al. (2013) states that support and assistance by a caregiver could result in treatment burden for both the
individual with MCC and the caregiver. In a recent study exploring characteristics predisposing adults living with MCC to treatment burden, Sav et al., (2016) found that adults living with MCC who had a caregiver had lower levels of treatment burden compared those adults living with MCC who did not have a caregiver.

**Summary of Interpersonal Factors of MCC.**

The association of the caregiver on treatment burden in adult living with MCC has been recently quantified in research, thus this study is proposing to further explore and validate the impact of the caregiver on the treatment burden of adults living with MCC.

**Organizational Factors.**

McLeroy et al. (1988) define *organizational* factors as: “social institutions with organizational characteristics, and formal (and informal) rules and regulations for operation,” (p. 355). Sav et al., (2013) defines organizational factors as healthcare systems, another antecedent factor of treatment burden. This study aims to explore the association between organizational factors associated with chronic conditions (transitional care, home health care, outpatient therapy, emergency department visits, and hospital admissions) and treatment burden.

The association of transitional care models and treatment burden in adults living with MCC has not been previously explored. Transitional care models (Coleman, Parry, Chalmers, & Min, 2006; Jack et al., 2009; Naylor et al., 1999) improve health related outcomes, reduce readmission rates, and decreases the cost associated with the care of individuals who receive transitional care. What is not known is the impact of these transitional care models on treatment burden. Logically, transitional care should decrease
treatment burden as the adult with MCC receives additional, diagnosis related care in home, but, conversely, transitional care involves a disruption in daily living and routines, as well as additional time and coordination. This study aims to explore this gap in literature.

The association of home health care and treatment burden in adults living with MCC has not been explored in the literature, though a few articles did explore the impact of home health care and adults living with chronic conditions or MCC. Older adults living with MCC receiving home health care (Vilà et al., 2015) had decreased hospital admissions and the associated cost of health care, as well as improving patient and caregiver satisfaction with care. Madigan et al. (2012) found that Medicare home health care recipients diagnosed with heart failure achieved improved functional status, a variable measured in this study, through home health care. As with transitional care, adults living with MCC who receive home health care have improved health related outcomes, yet, the association with treatment burden is not known and this study proposes to test this association.

The association of outpatient therapy and treatment burden has not been explored. Outpatient therapy is defined as: “physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient who is under the care of a physician and with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished has been established by a physician or by a qualified physical therapist and is periodically reviewed by a physician.” (Legal
Information Institute, 2016). Adults diagnosed with MCC may have conditions that require additional physical therapy services, such as heart failure, hip/pelvic fracture, or stroke. Outpatient therapy, though needed as part of the prescribed medical regimen, is a potential disruption (Brinkley et al., 2009; Gijsen et al., 2001; Wensing et al., 2001) that could increase treatment burden and potentially increases time and travel burden (Sav et al., 2013), another facet of treatment burden. This study aims to explore the association between outpatient therapy services and treatment burden.

Whereas transitional care, home health care, and outpatient therapy services are seen as beneficial aspects of care for adults living with MCC, emergency room visits and hospital admissions are seen as negative outcomes for an adult living with MCC’s condition. Sav et al. (2013) stated that healthcare resource usage was a consequence of treatment burden. The epidemiologic data (CMS, 2012) demonstrates that adults living with MCC have a higher incidence of emergency department usage and hospitalizations than adults without MCC. Additionally, Mudge et al. (2011) showed that MCC are associated with increased 30-day readmission rates. What is not understood is the association between emergency department visits and hospital admissions in adults living with MCC and treatment burden in these individuals. This study intends to explore this association.

**Summary of Organizational Factors of MCC.**

The current literature pertaining to the study’s proposed organizational factors of MCC is very limited, but the literature does provide evidence that these organizational factors of MCC may have an association with treatment burden. Despite the potential
association of organizational factors of MCC and treatment burden, these associations
have not been explored, and, thus, this study proposes to explore this gap in the literature.
CHAPTER III

The purpose of this study was to explore treatment burden in adults living with MCC transitioning from skilled nursing facility (SNF) to home over a 30-day period. In the previous chapter, treatment burden, the epidemiology of the adult population living with MCC, and variables associated with MCC in various populations were examined through a review of literature. This chapter describes the methodology of this proposed study, with results discussed in Chapter IV.

This study proposed to address these research questions:

1. What is the level of treatment burden experienced by the adult population living with MCC (at baseline and a 30-day time point post-discharge home) that transitioned from a skilled nursing facility to home?

2. Are intrapersonal (number of MCC, severity of MCC, depression, fatigue, anxiety, pain, physical function, and self-rated health), interpersonal (caregiver) and organizational (provider prescribed treatment index, transitional care, home care, outpatient therapy, hospital admissions, and emergency department visits) antecedent factors (measured at baseline and 30-day time points) correlated and predictive of treatment burden in adults with MCC that transitioned from a skilled nursing facility to home?

3. Is there a change in treatment burden and treatment burden’s antecedent factors from baseline in a skilled nursing facility to 30-days after discharge home in the adult population living with MCC?
Research Design

A longitudinal, descriptive, correlational design was chosen in order to explore the relationship between multiple, potential independent predictor variables and the dependent outcome variable (Polit & Beck, 2004). The current state of treatment burden science, as described in Chapter II, guided the development of this study’s design. The science of treatment burden is qualitatively rich, producing saturated themes through grounded theory interviews with people living with MCC. Thus, the next step in the scientific exploration of treatment burden is the measurement of treatment burden and the associated variables in a specific population to substantiate the previous qualitative work through quantitative methods. Despite the wealth of qualitative information, quantitative treatment burden research has been very limited in the adult population living with MCC. This proposed exploratory study aims to fill that quantitative gap in the literature concerning treatment burden in adults living with MCC. Additionally, this study may provide statistically significant correlational relationships between independent variables described in the theoretical model and treatment burden for future studies to understand the causal relationships between the variables. Causation cannot be determined through correlation and is a major weakness of the correlational design (Polit & Beck, 2004).

Sample

This study employed a convenience sampling technique in participant recruitment. A weakness of convenience sampling is that, in heterogeneous populations, the risk for sampling bias is high (Polit & Beck, 2004). This weakness was acceptable in the study design as this study was exploratory in nature and was the first to measure
treatment burden and potential antecedent factors associated with treatment burden in the selected population.

The study consisted of a convenience sample of 82 men and women with complete data transitioning from a SNF to home and diagnosed with multiple chronic conditions. The inclusion/exclusion criteria for this study were:

Inclusion Criteria: (a) diagnosis of 2 or more chronic medical conditions as defined by the Centers for Medicare and Medicaid (CMS) Chronic Condition Warehouse (Centers for Medicare and Medicaid, 2015); (b) the participant is to be discharged home; and (c) understands English, both written and spoken.

Exclusion Criteria: (a) a brief interview for mental status (BIMS) score of less than eight, indicating severe cognitive impairment (Chodosh et al., 2008). The rationale for using the BIM score as the exclusion criteria is an adult with severe cognitive impairment was not be able to accurately answer the study’s self-report surveys.

The selection of adults living with MCC transitioning from a SNF to home as the population of interest in this study was based on the review of literature presented in Chapter II. Adults living with MCC have a disproportionately high use of health care resources including post-acute care services and home care, coupled with high rates of hospital readmission (CMS, 2012). This study proposed that adults living with MCC transitioning from SNF to home best represented a population most at risk for treatment burden.

**Setting**

Participants were recruited from Pebble Creek, a 100-bed SNF with an average discharge rate of 12 patients per week. Pebble Creek is a for-profit SNF, owned by the
Communi-Care Corporation, a private, for-profit corporation. Pebble Creek has an affiliation with Summa Health Systems, a non-for profit health system located in Akron, Ohio.

**Determination of Sample Size/Power Analysis**

The determination of sample size requires the consideration of power, significance and effect size (Cohen, 1988). Power analysis was estimated a priori, using G*Power software, for a multiple regression analysis, which was the statistical test requiring the largest sample in this study. With regression parameters of an alpha of .05, an expected large effect size of 0.35, 22 predictor variables, and a power of .80, the required sample size is 81 participants. Since this study is the first measuring treatment burden in the adult population living with MCC transitioning from SNF to home and antecedent factors that may be associated with treatment burden, there was no study to estimate the potential effect size for power analysis. When there is lack of effect size reported in the literature, a researcher must use logic and infer a plausible effect size for use in power analysis (Cohen, 1988). The best inference of effect size was based on Tran's et al., (2012) findings that those with higher treatment burden had significantly higher daily symptoms, need for assistance, hospitalizations and medical appointments per month. Per CMS (CMS, 2012), adults living with higher incidence of MCC have a greater use of post-acute care facilities due to the severity of illness and multiple comorbid conditions, thus an assumption of high levels of treatment burden and its potential associated antecedent factors is plausible in this population, suggesting that a large effect size is appropriate. Additionally the independent variables measured in this study are highly correlated with individuals living with chronic conditions, and since
treatment burden, the dependent outcome, is an outcome of living with MCC, it is logical to posit that a large effect size exists between the independent and dependent variables.

**Sample size justification**

By running a query via the SNF’s electronic medical record over a span of two months (October through November 2015), an average of 12 adults transitioned from SNF to home whom met inclusion/exclusion criteria. A systematic review of attrition rates in adults participating in longitudinal studies revealed attrition rates between 2% to 50% (Chatfield, Brayne, & Matthews, 2005). Additionally, the length of these review studies lasted 0.5 to 9 years with an initial baseline response rate of 53% to 92% (Chatfield, Brayne, & Matthews, 2005). Based on this information and using the most conservative approach, estimating a 50% refusal rate and then a 50% attrition rate, a minimum of three patients per week was expected to be eligible for recruitment for the study.

**Variables and Measures**

**Intrapersonal Factor Variables**

McLeroy et al. (1988) define intrapersonal factors as “characteristics of the individual such as knowledge, attitudes, behavior, self-concept, skills, etc. This includes the developmental history of the individual,” (p. 355). This definition was adapted to include physical and psychological characteristics of an adults living with MCC. Based on the review of literature, the conceptual model includes seven factors that are potentially associated with treatment burden at the intrapersonal level: depression, fatigue, anxiety, pain, physical function, self-rated health, the number of MCC, and the severity of MCC.
**Interpersonal Factor Variables**

McLeroy et al. (1988) define *interpersonal factors* as “interpersonal processes and primary groups—formal and informal social network and social support systems, including the family, work group, and friendship networks,” (p. 355). The interpersonal factor of interest in this study was the caregiver of the participant and that caregiver’s association with MCC.

**Organizational Factor Variables**

McLeroy et al. (1988) define *organizational factors* as “social institutions with organizational characteristics, and formal (and informal) rules and regulations for operation,” (p. 355). The adapted definition of organizational factors for this study included organizational based interfaces with the adult during his/her transition from a SNF to home. These organizational variables included provider prescribed treatment, transitional care, home health care, and outpatient therapy, and unintended consequences of the adult’s health status: emergency department visits and hospital admissions.

**Instruments**

This section focuses on the instruments used to measure the variables included in the proposed study. The PROMIS short form data bank, the Treatment Burden Questionnaire-15, and the single item question for self-rated health are discussed in this section, including the validity and reliability of each instrument, if applicable. Additionally, instruments measuring the number of chronic conditions, severity of chronic conditions, provider prescribed treatments, transitional care, home care, hospital admissions, emergency department visits, and outpatient therapy for each participant are discussed. Table 6 is a list of all included measures.
Intrapersonal Instruments

Patient Reported Outcomes Measurement Information System.

The Patient Reported Outcomes Measurement Information System (PROMIS) is a National Institute of Health developed system: “of highly reliable, precise measures of patient–reported health status for physical, mental, and social well–being,” (PROMIS 2016). The PROMIS tools: “measure what patients are able to do and how they feel by asking questions,” (PROMIS 2016). PROMIS measures are have undergone thorough psychometric testing (Cella et al., 2010, Lanting et al., 2013). Additionally, PROMIS measures have been adapted to include short forms of the original item banks, reducing the number of questions a participant needs to answer to measure a state while maintaining a high level of validity and reliability in various populations (Chaplin, John, and Goldberg (1988).

Reliability of PROMIS. Reliability is defined by Polit and Beck (2004) as the consistency with which an instrument measures the target attribute. This is obtained through three factors: stability, consistency, and equivalence (Polit & Beck, 2004). Stability is measured via the test-retest technique, in which a researcher administers the measure to a participant on two different occasions and compares score using a reliability coefficient, which numerically measures the test’s reliability (Polit & Beck, 2004). Reliability coefficients typically range between zero and one, and a coefficient above .70 is considered stable (Polit & Beck, 2004). The PROMIS short form measure reliability was calculated using this test-retest technique (Cella et al., 2010; Lanting et al., 2013). T-scores and standard deviations were correlated between full bank measures and short form measures (Bartlett et al., 2015; Cessna et al., 2016). All measures included in this
study had test-retest correlations at a .90 level, except for the fatigue short item form, which was correlated at .78, which is still at an acceptable level (Cella et al., 2010).

Internal consistency is how well instrument items measure the same trait (Polit & Beck, 2004). Cronbach’s alpha, or the coefficient alpha, is the widely accepted technique to measure internal consistency. Cronbach’s alpha ranges between 0 to 1 and higher scores indicate that the items of the measure are more highly correlated (Polit & Beck, 2004). Field (2013) states that correlations above .80 are acceptable, though correlations at the .70 level are acceptable for cognitive tests, such as tests of intelligence. Lanting et al. (2013) used Cronbach’s alpha to measure the reliability of the short form PROMIS measures, with all correlations measuring above .90, except for physical functioning, which measured at .89. Cella tested the reliability of PROMIS measures in people living with rheumatoid arthritis: test-retest reliability ranged from .73–.88, and Cronbach’s alpha from .91–.99 (Cella et al., 2010). Cessna et al. (2016) measured reliability in the PROMIS cancer fatigue short form in individual diagnosed with cancer: Cronbach's alpha = 0.86.

**Validity of PROMIS.** Validity is defined as the degree in which an instrument is measuring what it is supposed to measure (Polit & Beck, 2004). This is accomplished through four approaches: face, content, criterion, and construct validity. No PROMIS studies reviewed mentioned the use of face validity for establishing measure validity.

Content validity is defined as “the degree to which an instrument has an appropriate sample of items for the construct being measured,” (Polit and Beck, 2004, p.423). This is developed using a panel of experts in a field and/or qualitative interviews to determine what items should be included in a scale (Polit & Beck, 2004). The
PROMIS studies reviewed were not recently developed, thus content validity was not used to establish validity.

Criterion validity is defined as the relationship between an instrument and external criteria (Polit & Beck, 2004). This type of validity was most widely used in the review PROMIS studies. Cella et al. compared the PROMIS short form scores to existing measures, such as the SF-36 and Health Assessment Questionnaire, which resulted in correlations greater than .80 in all instruments (Cella et al., 2010). Cessna et al. (2016) measured criterion validity of the PROMIS cancer fatigue scale to other established scales, which resulted in statistically significant correlations at <.0001. Bartlett et al. (2015) found PROMIS measures in patients with rheumatoid arthritis to be strongly correlated (> .68) to other established measures.

The final form of validity is construct validity. A form of construct validity is the use of confirmatory factor analysis to establish convergent validity, in which like items load on the same factor, each factor representing a construct in the theoretical framework (Polit & Beck, 2004). Cessna et al. (2016) used this form of convergent validity to determine if questions in the scale measured fatigue.

Depression, fatigue, anxiety, pain interference, and physical function are measured by a short form version of the full set of PROMIS questions. All questions in the PROMIS short form survey refer to how the participant has felt in the last 7 days.

*Depression.* The PROMIS Depression Scale assesses negative mood (e.g., sadness, guilt), negative views of the self (e.g., self-criticism, worthlessness), negative
social cognition (e.g., loneliness, interpersonal alienation), and decreased positive affect and engagement (e.g., loss of interest, loss of meaning and purpose). Depression is reflected in high levels of negative affect and low levels of positive affect. It is often characterized by the experience of loss and feelings of hopelessness, helplessness, and worthlessness,” (PROMIS Depression Scoring Manual, 2015, p 1). Each question is answered on a 5-point Likert scale ranging from 1-Never to 5- Always, with higher scores indicating a higher level of depression.

**Fatigue.** The Fatigue PROMIS scale assesses “fatigue from mild subjective feelings of tiredness to an over-whelming, debilitating, and sustained sense of exhaustion that is likely to decrease one’s ability to carry out daily activities, including the ability to work effectively and to function at one’s usual level in family or social roles. Fatigue is divided conceptually into the experience of fatigue (such as its frequency, duration, and intensity), and the impact of fatigue upon physical, mental and social activities,” (PROMIS Fatigue Scoring Manual, 2015, p.1). Each question is answered on a 5-point Likert scale ranging from 1-Never to 5- Always, with higher scores indicating a higher level of fatigue.

**Anxiety.** The Anxiety PROMIS scale assesses “fear (e.g., fearfulness, feelings of panic), anxious misery (e.g., worry, dread), hyper-arousal (e.g., tension, nervousness, restlessness), and somatic symptoms related to arousal (e.g., racing or pounding heart, dizziness). Symptoms that best differentiate anxiety are those that reflect autonomic arousal and the experience of threat,” (PROMIS Anxiety Scoring Manual, 2015, p. 1). Each question is answered on a 5-point Likert scale ranging from 1-Never to 5- Always, with higher scores representing higher levels of anxiety.
**Pain Interference.** The PROMIS adult Pain Interference item bank measures self-reported consequence of pain interfering with one's life including “social, cognitive, emotional, physical, and recreational activities” (PROMIS Pain Interference Scoring Manual, 2015, p. 1). The Pain Interference short form measures universal pain rather than disease-specific pain and assesses pain behavior over the past seven days. The measure uses a 5 point Likert scale ranging from 1- Had no Pain to 5- Always, with higher scores indicating a higher level of pain.

**Pain Intensity.** Pain Intensity was measured by the participant rating pain from 0 (no pain) to 10 (high pain) with higher numbers indicating greater pain intensity. Pain Intensity measured a participant's pain intensity over the past 7 days.

**Physical Function.** The Physical Function PROMIS Scale was used to measure functional dependence. The Physical Function Scale assessed “one's ability to carry out activities that require physical actions, ranging from self-care (activities of daily living) to more complex activities that require a combination of skills, often within a social context. Physical function is conceptually multidimensional, with four related subdomains: mobility (lower extremity function), dexterity (upper extremity function), axial (neck and back function), and ability to carry out instrumental activities of daily living,” (PROMIS Physical Function Scoring Manual, 2015, p. 1). The measure employs a 5 point Likert Scale ranging 1- Without any difficulty, 5- Unable to do to, with higher scores indicating a worse level of physical functioning.

**Self-Rated Health.**
The World Health Organization measure of self-rated health (Subramanian, Huijts, & Avendano, 2010), a single item measure, was used in this study. Self-rated health was measured by asking the participant: How would you rate your overall health? A 5-point Likert scale was used ranging from 1 (very poor) to 5 (very good). Higher scores represent higher (better) rating of participant self-rated health. Self-rated health demonstrated a moderately strong test-retest in which nearly 40 percent of participants had different scores 1 month following the initial test (Zajacova & Dowd, 2011).

**Number of Multiple Chronic Conditions.**

In many research studies, the impact of MCC was measured by obtaining a total count of co-morbid chronic conditions. The Centers for Medicare & Medicaid Chronic Conditions Warehouse (2016) defined 27 chronic conditions and this information was collected via SNF EMR review and recorded numerically with higher numbers representing a greater number of chronic conditions. Table 4 is a list of the Centers for Medicare and Medicaid Chronic Conditions Warehouse Chronic Conditions (2016).

Table 4

<table>
<thead>
<tr>
<th>Centers for Medicare and Medicaid Chronic Conditions Warehouse Chronic Conditions (2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired Hypothyroidism</td>
</tr>
<tr>
<td>Acute Myocardial Infarction</td>
</tr>
<tr>
<td>Alzheimer's Disease</td>
</tr>
<tr>
<td>Alzheimer's Disease, Related Disorders, or Senile Dementia</td>
</tr>
</tbody>
</table>
Anemia  Anemia
Glaucoma  Glaucoma
Asthma  Asthma
Heart Failure  Heart Failure
Atrial Fibrillation  Atrial Fibrillation
Hip / Pelvic Fracture  Hip / Pelvic Fracture
Benign Prostatic Hyperplasia  Benign Prostatic Hyperplasia
Hyperlipidemia  Hyperlipidemia
Cancer, Colorectal  Cancer, Colorectal
Hypertension  Hypertension
Cancer, Endometrial  Cancer, Endometrial
Ischemic Heart Disease  Ischemic Heart Disease
Cancer, Breast  Cancer, Breast
Osteoporosis  Osteoporosis
Cancer, Lung  Cancer, Lung
Rheumatoid Arthritis / Osteoarthritis  Rheumatoid Arthritis / Osteoarthritis
Cancer, Prostate  Cancer, Prostate
Stroke / Transient Ischemic Attack  Stroke / Transient Ischemic Attack
Cataract  Cataract

Additionally, CMS lists another set of chronic conditions (see Table 5) which totals 19 chronic conditions (CMS, 2017). For the purposes of this exploratory study, inclusion of chronic conditions from both lists was included in this study.

Table 5

Centers for Medicare and Medicaid Chronic Conditions (2017)

Alzheimer’s Disease and Related Dementia  Heart Failure
Arthritis (Osteoarthritis and Rheumatoid)  Hepatitis (Chronic Viral B & C)
Asthma  HIV/AIDS
Atrial Fibrillation  Hyperlipidemia (High cholesterol)
Autism Spectrum Disorders  Hypertension (High blood pressure)
Cancer (Breast, Colorectal, Lung, and Prostate)  
Ischemic Heart Disease

Chronic Kidney Disease  
Osteoporosis

Chronic Obstructive Pulmonary Disease  
Schizophrenia and Other Psychotic Disorders

Depression  
Stroke

Diabetes

**Severity of MCC.**

This study posited that the severity of each individual MCC on treatment burden is not equal. An adult with diagnosed with chronic, non-symptomatic anemia and osteoarthritis that does not interfere with daily activities of daily living (ADLs) has a potentially different severity of MCC on treatment burden than an adult diagnosed with chronic, symptomatic (orthostatic hypotension and fatigue) anemia that requires bi-weekly blood transfusions and severe osteoarthritis that limits ADLs. The severity of each MCC was measured using a 10-point Likert scale ranging from 0 (no severity of MCC) to 10 (high severity of MCC), with higher scores indicating a higher greater severity of each individual MCC as reported by the participants. This scoring mechanism gave the PI the opportunity to understand which chronic conditions had the greatest severity in this study sample.
Interpersonal Instruments

Caregiver.

The presence or absence of a caregiver for the participant was answered by a dichotomous question, with answers being 0 (No) or 1 (Yes). That question was: “Do you have a caregiver that assists you in your daily activities?” If the participant had a caregiver, a second question was asked: “Who is your caregiver?” was be asked, with answers being 0 (spouse), 1 (family member), 2 (friend), or 3 (employed professional). If a caregiver was present, the participant was asked to answer an adapted Outcome and ASsessment Information Set (OASIS) Care Management: Types and Sources of Assistance questionnaire (Centers for Medicare and Medicaid, nd.). The questionnaire was comprised of 7 questions and each question is scored using a 4 point Likert scale ranging from: 0 (no assistance), 1 (minimal assistance), 2 (moderate assistance), and 3 (maximum assistance). The seven questions that comprised the Caregiver Questionnaire were: (1) ADL assistance (transfer/ambulation, bathing, dressing, toileting, eating/feeding), (2) IADL assistance (meals, housekeeping, laundry, telephone, shopping, finances), (3) Medication Administration, (4) Medical procedures/treatments (changing wound dressing, ostomy care, home exercise program), (5) Management of Equipment (oxygen, IV/infusion equipment, enteral/parenteral nutrition, ventilation equipment or supplies), (6) Supervision and Safety (due to physical or cognitive impairment), and (7) Advocacy or facilitation of patient's participation in appropriate medical care (transportation to or from appointments) (OASIS 2014). Higher scores indicated a greater use of care giving services.
Additionally, though this proposed study is not qualitative in nature, if the participant answered yes to having a caregiver, one open ended question was asked: (1) “Do you think your caregiver has increased or decreased your level of treatment burden?” This information was recorded for future analysis.

**Organizational Instruments**

**Provider Prescribed Treatment (PPT).**

Sav et al., (2013) stated that treatment burden can be measured objectively. An objective measure of treatment burden does not exist, thus, this study proposed the use of an index based off certain questions in the TBQ-15. The Provider Prescribed Treatment (PPT) Index was not psychometrically tested, thus can not be considered a measure. The PPT Index was a rough estimate of the potential impact of the PPT on treatment burden, which was analyzed through percent agreement (Kappa statistic), correlation, and hierarchical multiple regression in the statistical analysis. This study was hypothesizing that the PPT Index would be positively correlated with treatment burden, thus as the individual’s amount of work increases to manage MCC, so does the level of treatment burden.

The index consisted of four questions with higher scores representing a more time consuming PPT with scores ranging from 0 to 4. Question 1: “How many times a day do you take your medication?” Medications taken two times a day or less received a score of 0, medications taken more than two times a day received a score of 1, indicating medications taken at times other than morning and evening disrupted daily activities. Questions 2: “How many lab test or radiology exams did you have in the last 30 days?” Participants who did not have any scheduled lab or radiology test scored a 0, participants
who do have a scheduled lab or radiology test scored a 1, indicating more time interacting with healthcare facilities and personnel. Question 3: “How many times do you perform self-monitoring activities (e.g., blood pressure, blood glucose, weight, etc.) a day?” Participants who did not have any self-monitoring activities scored a 0, and participants who have at least one self-monitoring activity scored a 1, indicating more time spent self-monitoring one’s health status. Question 4: “How many doctor or other health care professional visits have you had in the past 30 days?” Participants that had 1 or less visits scored a 0, participants that had 2 more visits scored a 1, indicating additional coordination of visits between multiple providers. The PI verified all participant answers with the SNF Discharge Summary and facility EMR.

**Transitional Care.**

The presence or absence of transitional care given to the participant was answered via self-report of two questions, with answers being 0 (No) or 1 (Yes). The questions were: (1) Have you received a home visit from a physician or nurse practitioner in the last 30 days? (2) Have you had a scheduled transitional care visit in your primary care physician’s office in the past 30 days? For each question answered yes, the participant was asked how many of each transitional encounter they received in the past 30 days. Higher scores indicated a higher number of transitional care encounters. The order for transitional care was verified via SNF electronic medical record (EMR) chart review. Additionally, though this proposed study is not qualitative in nature, if the participant answered yes to having transitional care, two open ended questions were asked: (1) “Do you think transitional care increased or decreased your level of treatment burden?”, (2) “Do you think that the timing of the first transitional care visit after your discharge to
home increased or decreased your level of treatment burden?” This information was recorded for future analysis.

**Home Care.**

The presence or absence of home care given to the participant was answered via self-report of two questions, with answers being 0 (No) or 1 (Yes). Those questions are: (1) Have you received any in-home care from a healthcare provider other than your physician or nurse practitioner in the last 30 days? (2) Have you been using any technology-related monitoring of your health status in the last 30 days? For each question answered yes, the participant was asked how many of each home care interactions they received in the past 30 days. Higher scores indicated a higher number home care encounters. The order for home care, frequency and involved services, and the name and number of the agency to verify the self-reported information was obtained from the SNF EMR. Additionally, though this proposed study is not qualitative in nature, if the participant answers yes to having home care, two open ended questions were asked: (1) “Do you think home care increased or decreased your level of treatment burden?” (2) “Do you think that the timing of the first home care visit after your discharge to home increased or decreased your level of treatment burden?” This information was for future analysis.

**Hospital Admissions.**

The participant was asked via a self-report question if he or she was admitted to the hospital for care, with answers being 0 (No) or 1 (Yes). The question was: “Were you admitted to the hospital in the past 30 days?” If the participant answered yes, the participant was asked how many hospital admissions occurred in the past 30 days. Higher
scores represented more hospital admissions over a 30-day period. Self-report data was by examining the participants’ EMR record, but may not be comprehensive if the patient was admitted to a hospital outside the participating facility’s EMR. Additionally, though this proposed study is not qualitative in nature, if the participant answered yes to having hospital admissions, an open ended question was asked: “Do you think hospital admissions increased or decreased your level of treatment burden?” This information was for future analysis.

**Emergency Department Visits.**

The participant was asked via self-report if they received care in the ED by answering one question, with answers being 0 (No) or 1 (Yes). The question was: “Have you received care in the ED in the past 30 days?” If the question is answered yes, the participant was asked how many emergency department visits occurred in the past 30 days. Self-report data was confirmed by examining the participant’s EMR, but may not be comprehensive if the patient was seen at an emergency department outside the participating facility’s EMR. Additionally, though this proposed study is not qualitative in nature, if the participant answered yes to having emergency department visits, an open ended question was asked: “Do you think visiting the emergency department increased or decreased your level of treatment burden?” This information was recorded for future analysis.

**Outpatient Therapy.**

The use of outpatient therapy was answered via self-report one question, with answers being 0 (No) or 1 (Yes). The question was: “Have you received outpatient therapy in the past 30 days?” If the question was answered yes, the participant was be
asked how many outpatient therapy interactions they received in the past 30 days. Higher scores represent a higher number of outpatient therapy visits. Additionally, though this proposed study is not qualitative in nature, if the participant answers yes to having outpatient therapy, an open ended question was asked: “Do you think having outpatient therapy increased or decreased your level of treatment burden?” This information was recorded for future analysis.

**Dependent Outcome Instrument- Treatment Burden**

**Treatment Burden Questionnaire 15 (TBQ-15).**

The TBQ-13 was developed specifically for individuals living with MCC. The TBQ-13 is a subjective global assessment of treatment burden with specific items that focus on management of chronic conditions such as medication regimen, physician visits, diet and exercise regimens, and how the impact of frequent healthcare-related activities reminds the patient of other health issues (Tran et al., 2012). The measure’s Cronbach’s alpha is 0.89 and demonstrates a retest reliability of 0.76. Validity was established using construct validity. Tran et al. (2012) found through factor analysis that the TBQ-13 loaded onto a single factor. Tran et al. (2012) continued the use of construct validity by hypothesizing a negative correlation between treatment burden and treatment satisfaction, comparing the correlation between the TBQ-13 and Treatment Satisfaction Questionnaire for Medication, and a positive correlation between treatment burden and workload variables.

When translated to English for use in the US population living with MCC, two questions were added, expanding the questionnaire to 15 items (TBQ-15): the first item focused on the financial impact of treatment burden and the second item reflected the
impact of the relationship between healthcare provider and the patient on treatment burden (Tran et al., 2014). The respondent was asked to rank the level of burden for each question from 0, no burden, to 10, very high burden, with scores totaling between 0-150.

**Demographics**

Demographic factors were collected during the initial interview with the subject and confirmed via review of medical record. The design of this study controlled for the potential effects demographic factors had on the statistical analysis. Demographic factors included age, race, sex, education, and income. This study recorded age in number of years, reflecting the age of the participant at the time of the consent, and the recorded age was verified via the SNF EMR. Race categories were: White American, African American, Native American and Alaska Native, Asian American, Native Hawaiian and Other Pacific Islander (United States Census Bureau, 2016). Sex categories were: male and female. Education categories were: What is the highest level of education completed: (0) No formal education, (1) Grades 1-11, (2) High School, (3) Some College, (4) College Graduate, (5) Post-College (+17 years) (HRS 2014). Income categories were: (1) $5,000 or less, (2) $10,000 or less, (3) $25,000 or less, (4) $50,000 or less, (5) $99,999 or less, (6) $100,000 or more (HRS 2014).

**Table 6**

Summary of Instruments

<table>
<thead>
<tr>
<th>Model</th>
<th>Variable</th>
<th>Measure</th>
<th>Number of Items</th>
<th>Reliability</th>
<th>Time point *1- Baseline, 2- 30 Days</th>
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<td>Age</td>
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<td>Number of MCC</td>
<td>Chart Review</td>
<td>As recorded in EMR</td>
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<td>Severity of MCC</td>
<td>Self-Report Survey</td>
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<td>Cronbach .96</td>
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<td>Cronbach .96</td>
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<td>Reliability</td>
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<td>Cronbach .95</td>
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<td>Physical Function</td>
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<td>Cronbach .89</td>
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<td>N/A</td>
<td>1,2*</td>
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<td>Interpersonal Factors</td>
<td>Caregiver Adapted OASIS Care Management Survey: Types and Sources of Assistance</td>
<td>7</td>
<td>N/A</td>
<td>2*</td>
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<td>Organizational Factors</td>
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<td>6</td>
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<td>Transitional Care</td>
<td>Self- Report Survey</td>
<td>3</td>
<td>N/A</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Home Care</td>
<td>Self- Report Survey</td>
<td>3</td>
<td>N/A</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>--------------------------</td>
<td>-------------------------</td>
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<tr>
<td>Outpatient Therapy</td>
<td>Self-Report Survey</td>
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<td>2*</td>
<td></td>
</tr>
<tr>
<td>Hospital Admissions</td>
<td>Self-Report Survey</td>
<td>3</td>
<td>N/A</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>Self-Report Survey</td>
<td>3</td>
<td>N/A</td>
<td>2*</td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td>Treatment Burden</td>
<td>15</td>
<td>Cronbach .89</td>
<td>1.2*</td>
<td></td>
</tr>
</tbody>
</table>

**Research Procedures**

**Recruitment**

Participants were recruited from Pebble Creek, a transitional care facility serving adults transitioning from hospitalization to home. The PI has obtained support from the administration within Pebble Creek to conduct this study. The PI partnered with an advanced practice nurse who identified potential participants for the study, thereby only exposing the research team to potentially interested participants and protecting all parties from interference with direct healthcare activities. The advanced practice nurse was trained about the inclusion/exclusion criteria for the study, and screened newly admitted patients to identify potential study candidates. The advanced practice nurse approached eligible participants at an appropriate time interval to determine whether they were interested in participating in the study. The PI, a doctoral student, was available on site, and only approached participants who expressed interest in participating in the study.
Consent

The PI obtained Institutional Review Board approval from Case Western Reserve University. The PI received a letter of support from the Communi-Care Corporation, the parent corporation of Pebble Creek, which allowed the PI to conduct the study at Pebble Creek. The PI approached potential candidates at the SNF after identification by the facility NP, thus ensuring the interested candidate met inclusion and exclusion criteria. The PI explained the study and, if the potential candidate was interested, the PI consented the participant into the study. The PI went through each portion of the consent ensuring understanding of study procedures were clear to the participant. The PI obtained the participant’s private health information via EMR review for study use, thus HIPAA language was a focal point of the consent process. There was no financial incentive for participating in the study.

Data Collection and Follow-up Procedures

After consenting the participant into the study, the PI collected baseline data. Following administration of the baseline survey, the PI asked the participant for his or her home and/or cell number in order to call the participant approximately 30 days from discharge home in order to conduct the follow-up survey. The PI inquired as to when is the best time of the week, and when was the best time of day to contact the individual. The follow-up phone call lasted approximately 30 minutes, once again keeping survey fatigue down to a manageable level.

Data Management

Patient data was de-identified and each participant was assigned a study ID number. All data were initially stored in a locked cabinet. The PI entered all study data
into SPSS, where the data was cleaned for outliers before statistical analysis. The PI ensured all data were complete by checking the completed surveys and contacting the participants by phone if data was missing or the input was not clear to the PI. At the end of the study, the PI destroyed all personal health information as indicated in the IRB-approved study protocol.

**Human Subjects**

**Potential Risks**

The minimal risks associated with participating in this study included: loss of privacy and confidentiality due to collection of personal health information, survey fatigue, and the identification of depressive symptoms. The risks of this study are reasonable in relation to the added benefit of the information obtained.

There was a small risk of fatigue during data collection, but the PI attempted to keep survey related fatigue at a minimum. No participant demonstrated signs of survey fatigue during data collection.

According to Kroenke, Yu, Wu, Kean, and Monahan (2014), a participant who rates his/her depression score eight or higher, using the four item PROMIS Depression scale, is considered positive for depressive symptoms. Additionally, because the study measured depression longitudinally, increasing levels of depression were identified.

During this study, at baseline, 34 individuals had depression scores of eight or greater. The PI informed the nurse staff of these findings, who passed this information onto the participants' provider. At the 30-day data point, 24 participants scored eight or higher on the PROMIS Depression scale. The PI suggested these participants inform their
PCPs of this finding and the PI followed up with the participant approximately 48 hours later to confirm this was done.

**Protection against Risks**

**Loss of Privacy and Confidentiality.**

All rooms at Pebble Creek, thus ensuring privacy during data collection. The PI diligently worked to ensure accurate and safe collection of participant data to maintain subject confidentiality. The PI assigned a de-identified study IDs to all study participants, for example TB-001. The PI also complied a master list of participants and their associated names and kept this master list on an encrypted computer that was password protected. Only the PI and dissertation chair had access to this master list. The PI kept all consents in a locked drawer separate from any other study data, and only the PI and dissertation chair had access to the consent binder. The PI entered all study data into SPSS, which was secure and password protected.

**Fatigue.**

Participation in the proposed study involved minimal risk to patients. The instruments employed in the study are widely used in psychometric testing, with many of the instruments coming from the PROMIS data bank. There are no invasive procedures involved in this study. The PI reduced the risk of fatigue by allowing the participant to take breaks between questionnaires. The PI monitored for signs of participant fatigue that necessitated stopping data collection and, once the participant was rested, returned to finish data collection. The PI also instructed the participant to stop data collection at any time for any reason.
**Depression.**

If at any time point during the study a participant had a depression score of 8 or greater, the PI recommended the participant follow-up with his/her primary care physician (PCP) if at home, and if the participant was still receiving care in the SNF, the nursing staff was notified by the PI. Additionally, the PI followed-up with the participant within 48 hours to see if the participant made an appointment with his/her PCP.

**Potential Benefits to the Subjects and Others.**

There were no guaranteed benefits to patients for participating in the study. The results obtained from this study provided contributions to the science of treatment burden by exploring treatment burden in adults living with MCC transitioning from SNF to home.
CHAPTER IV

Results

This chapter reports the findings of the statistical analysis of the study’s research questions as stated in Chapter III. This study conducted data analysis using SPSS software. This chapter is comprised of three sections: a description of the sample, examination of the study variables in regards to the normality of data and assumptions for linear regression that may affect results, and the analysis of the 3 research questions.

Description of the Sample

The sample collected for this study included 82 adults transitioning from SNF to home. This study collected data at baseline and 30 days after from SNF to home. During data collection 97 potential participants were approached, 15 potential participants refused, and 17 screened SNF patients were excluded due to BIMS scores of less than 8. Additionally at the 30-day time point, eight participants were lost to follow-up: three participants were lost due to death unrelated to the study and five participants were lost due to either having non-working phones numbers or not responding to multiple contact attempts. The eight participants lost to follow-up yielded a 9.75% attrition rate for this study.

A demographic description of the sample is provided in Table 7. The demographic variables for this study sample included: age, sex, race, education, and income. The mean age of the participants was 75.4 with a mean of 74.5, thus indicating a sampling of an older adult population. Seventy-two percent of the sample was females, which is representative of Pebble Creek’s SNF population. Most (92.7%) of the sample was white, which is also representative of Pebble Creek’s SNF population. Education
provided some interesting detail with the nearly 20% of the sample having less than a high school education. The majority, 78% of the sample, was on a fixed, Social Security based income.

Table 7
Demographics (n=82)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Range</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age:</td>
<td>48-96</td>
<td>75.4</td>
<td>10.26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of Responses</th>
<th>Percent of Total Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>23</td>
<td>28</td>
</tr>
<tr>
<td>Female</td>
<td>59</td>
<td>72</td>
</tr>
<tr>
<td>Race:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>75</td>
<td>92.7</td>
</tr>
<tr>
<td>Black</td>
<td>7</td>
<td>7.3</td>
</tr>
<tr>
<td>Education:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Formal Education</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Grades 1-11</td>
<td>16</td>
<td>19.5</td>
</tr>
<tr>
<td>High School</td>
<td>31</td>
<td>37.8</td>
</tr>
<tr>
<td>Some College</td>
<td>22</td>
<td>26.8</td>
</tr>
<tr>
<td>College Graduate</td>
<td>12</td>
<td>14.6</td>
</tr>
<tr>
<td>Post-College (+17 years)</td>
<td>1</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Income:  

Examination of the Study Variables

Descriptive Statistics and Normality of Sample Variables.

An examination of the study variables was performed as the next part of the statistical analysis. Descriptive statistics and measures of dispersion with a focus on normality of the sample variables was done. All variables were normally distributed (skewness range= 3 to -3; kurtosis 8 to -8), except for the demographic variable of race, which was skewed at 3.34, and was kurtotic at 9.38, due to the sample being primarily white. Table 8 provides detail on baseline variables and Table 9 provides detail on 30-day variables.

Intrapersonal Factors: All variables of interest improved over the 30-day transition period from SNF to home for the study participants except self-rated health (M= 3.11 at baseline compared to M= 3.01 at 30-days).

Interpersonal Factors: At the 30-day time point (n = 74), 70.3% (n= 52) of study participants had some sort of caregiver assisting them with their medical needs, resulting
in a mean score of 4.99 for the Caregiver Assistance Index, higher score indicating more assistance received by the participant.

Organization Factors: At the 30-day time point (n = 74), 81% (n = 60) of participants received transitional care, 81% (n = 60) of participants received home care, and only 22% (n =16) of participants received some sort of outpatient therapy. Additionally, 8.1% (n = 6) of the 30-day participants had a hospital admission during the 30-day transition period and 27% (n = 20) had a visit to the emergency department. The Provider Prescribed Treatment Index showed participants having approximately two (mean = 1.74) objective indices of treatment burden, with having to take medications three or more times a day the most occurring index (mean = 0.5854).

Table 8
Baseline Variables (n = 82)

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Range</th>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>82</td>
<td>4-20</td>
<td>8.27</td>
<td>8</td>
<td>4.09</td>
</tr>
<tr>
<td>Depression</td>
<td>82</td>
<td>4-20</td>
<td>7.39</td>
<td>6</td>
<td>3.78</td>
</tr>
<tr>
<td>Fatigue</td>
<td>82</td>
<td>4-20</td>
<td>12.41</td>
<td>13</td>
<td>4.97</td>
</tr>
<tr>
<td>Number MCC</td>
<td>82</td>
<td>4-20</td>
<td>4.73</td>
<td>4</td>
<td>1.52</td>
</tr>
<tr>
<td>Variable</td>
<td>n</td>
<td>Range</td>
<td>Mean</td>
<td>Median</td>
<td>SD</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----</td>
<td>-------</td>
<td>-------</td>
<td>--------</td>
<td>------</td>
</tr>
<tr>
<td>Pain Intensity</td>
<td>82</td>
<td>4-20</td>
<td>5.50</td>
<td>6</td>
<td>3.21</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>82</td>
<td>0-10</td>
<td>11.68</td>
<td>12.5</td>
<td>5.55</td>
</tr>
<tr>
<td>Physical Function</td>
<td>82</td>
<td>1-5</td>
<td>15.24</td>
<td>17</td>
<td>4.98</td>
</tr>
<tr>
<td>Self-Rated Health</td>
<td>82</td>
<td>2-9</td>
<td>3.11</td>
<td>3</td>
<td>0.97</td>
</tr>
<tr>
<td>Severity MCC</td>
<td>82</td>
<td>0-60</td>
<td>19.17</td>
<td>18.5</td>
<td>13.34</td>
</tr>
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<td>Treatment Burden</td>
<td>82</td>
<td>0-125</td>
<td>39.06</td>
<td>35.5</td>
<td>25.97</td>
</tr>
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</table>

Table 9
30-Day Variables (n = 74)
<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Range</th>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number MCC</td>
<td>74</td>
<td>2 - 9</td>
<td>4.76</td>
<td>4</td>
<td>1.55</td>
</tr>
<tr>
<td>Pain Intensity</td>
<td>74</td>
<td>0 - 10</td>
<td>3.89</td>
<td>4</td>
<td>2.63</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>74</td>
<td>4 - 20</td>
<td>9.11</td>
<td>8</td>
<td>4.65</td>
</tr>
<tr>
<td>Physical Function</td>
<td>74</td>
<td>4 - 20</td>
<td>11.19</td>
<td>11</td>
<td>4.53</td>
</tr>
<tr>
<td>Self-Rated Health</td>
<td>74</td>
<td>1 - 5</td>
<td>3.01</td>
<td>3</td>
<td>1.04</td>
</tr>
<tr>
<td>Severity MCC Index</td>
<td>74</td>
<td>0 - 50</td>
<td>18.26</td>
<td>17.5</td>
<td>13.19</td>
</tr>
<tr>
<td>Treatment Burden</td>
<td>74</td>
<td>0 - 100</td>
<td>37.01</td>
<td>37</td>
<td>24.45</td>
</tr>
<tr>
<td>Caregiver</td>
<td>74</td>
<td>0 - 1</td>
<td>0.70</td>
<td>1</td>
<td>0.46</td>
</tr>
<tr>
<td>Caregiver Assistance Index</td>
<td>74</td>
<td>0 - 16</td>
<td>5.20</td>
<td>4</td>
<td>4.99</td>
</tr>
<tr>
<td>Emergency Department Visits</td>
<td>74</td>
<td>0 - 3</td>
<td>0.37</td>
<td>0</td>
<td>0.63</td>
</tr>
<tr>
<td>Homecare Visits</td>
<td>74</td>
<td>0 - 30</td>
<td>7.62</td>
<td>6</td>
<td>8.48</td>
</tr>
<tr>
<td>Hospital Admits</td>
<td>74</td>
<td>0 - 1</td>
<td>0.08</td>
<td>0</td>
<td>0.28</td>
</tr>
</tbody>
</table>
Outpatient Therapy Visits
74  0 - 12  2  0  3.99

Transitional Care Home Visits
74  0 - 2  0.41  0  0.59

Transitional Care Office Visits
74  0 - 1  0.57  1  0.50

Provider Prescribed Treatment Index.

Provider Prescribed Treatment (PPT) Index is conceptualized as an Organizational variable collected at the 30-day time point, but is presented separately in Table 10 (overall index descriptive statistics) and Table 11 (individual PPT question descriptive statistics).

Table 10

<table>
<thead>
<tr>
<th>Variable Provider Prescribed Treatment Index</th>
<th>n</th>
<th>Range</th>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Prescribed Treatment Index</td>
<td>74</td>
<td>0 – 4</td>
<td>1.74</td>
<td>2</td>
<td>1.22</td>
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</table>
Table 11
Provider Prescribed Treatment Individual Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>n</th>
<th>Range</th>
<th>Mean</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider Follow-up</td>
<td>82</td>
<td>0 - 1</td>
<td>0.45</td>
<td>0</td>
<td>0.50</td>
</tr>
<tr>
<td>Medication Taken 3 or More Times</td>
<td>82</td>
<td>0 - 1</td>
<td>0.59</td>
<td>1</td>
<td>0.50</td>
</tr>
<tr>
<td>Daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed Self-Management</td>
<td>82</td>
<td>0 - 1</td>
<td>0.44</td>
<td>0</td>
<td>0.45</td>
</tr>
<tr>
<td>Procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed Tests</td>
<td>82</td>
<td>0 - 1</td>
<td>0.27</td>
<td>0</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Table 12 presents the percent agreement between PPT questions and the corresponding TBQ-15 questions. For statistical analysis purposes, the corresponding TBQ-15 question results were dichotomized (0 for no burden and 1 for burden) during the calculation of the Kappa statistic. There was no statistical significance in percent agreement between the PPT questions and their corresponding TBQ-15 questions.
Table 12
Percent Agreement (Cohen’s Kappa) between PPT Questions and Corresponding TBQ-15 Questions

<table>
<thead>
<tr>
<th>PPT Question</th>
<th>Participant Scoring 0 on</th>
<th>Participant Scoring 1 on</th>
<th>Corresponding TBQ Question with # Participants Rating 0 (no burden)</th>
<th>Corresponding TBQ Question with # Participants Rating 1-10 (burden)</th>
<th>Kappa Statistic</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>29</td>
<td>45</td>
<td>58</td>
<td>16</td>
<td>.14</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Taken 3 or More Times Daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed</td>
<td>54</td>
<td>20</td>
<td>42</td>
<td>32</td>
<td>.06</td>
<td>&gt;.05</td>
</tr>
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<td>Tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed</td>
<td>41</td>
<td>33</td>
<td>57</td>
<td>17</td>
<td>.12</td>
<td>&gt;.05</td>
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<td>Self-Management Procedures</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Assumptions of Regression

In this section, I address the four major assumptions of multiple regression: additivity and linearity, multivariate normality, auto-correlation, and homoscedasticity (Field, 2013). Violations of any of these four assumptions may lead to false test statistics and p-values, causing the study to draw wrong conclusions from the statistical analysis (Field, 2013).

The first assumption of multiple regression is additivity and linearity, which is defined as the independent variables (IPVs) having a linear relationship to the dependent variable (DV), thus the combined (additive) effects of the IPVs explain a certain amount of variance of the DV. The testing of the linearity of all IPV’s and the DV’s is conducted through examining partial regression plots and adding lines of fit to the scatterplots looking for a change between the 3 lines of fit (linear, quadratic, and cubic) of greater than .02. This study tested for linearity and found no violations of linearity in any variables. An additional part of this assumption is the testing for outliers, or extreme cases, which may affect linearity. Outliers are tests using Cook’s D to identify potential outliers, or a case having a Cook’s D greater than 1. The maximum statistic for Cook’s D for the baseline regression analysis was .13 and 30-day regression analysis was .14, thus variables in this study did not violate this assumption.
The second assumption of multiple regression is multivariate normality, or the normality of residuals, is the error between observed and predicted values (i.e., the residuals of the regression) being normally distributed (Field, 2013). This study assessed for the normality of residuals by plotting residuals on a histogram with a normal curve, running and examining Q-Q plots, and by running descriptive statistics on the residuals looking for skewness and kurtosis in the distribution. The analysis resulted in a normal distribution of the variable’s residuals, thus not violating the assumption.

The third assumption of multiple regression is autocorrelation, which is defined as the non-independence of variables’ residuals (Field, 2013), or dependencies in the data. The use of Durbin-Watson statistic tested for autocorrelation. The Durbin-Watson tests the null hypothesis that the residuals are not linearly auto-correlated. The test results values between 0 and 4, with values around 2 indicating no autocorrelation. Values between 1.5 and 2.5 signify the absence of auto-correlation between the data. In this study, the Durbin-Watson statistic showed no auto-correlation: Baseline: 2.39 and 30-Day: 2.46.

The final assumption of multiple regression is homoscedasticity, or the homogeneity of variance between the error terms of the variables. This is tested by placing the error terms of the variables in a scatterplot and examining for the scatter/fanning effect greater than 3:1. Testing for homoscedasticity of error terms occurs through examining the normal distribution of error along a regression line in the presence of a fanning effect of the error terms greater than 3:1, which indicates violation of the assumption. This study tested for homoscedasticity and demonstrated constant error
variance or homogeneity of variance between the error terms of the variables, thus not violating the assumption.

Even though mutlicolinearity is not an assumption of regression, having multicolinearity, or high correlated IPVs, can result in biased coefficients, limit the size of R, and limits the ability to assess the importance of predictors (Field, 2013). This study tested for multicolinearity in each regression and no multicolinearity was found amongst IPVs.

**Measures of Internal Reliability**

Cronbach’s alpha, a measure of internal reliability, was determined for all PROMIS measures and treatment burden. Test-retest was determined for self-rated health and the severity of MCC index. The results are presented in the Table 13 below:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Cronbach’s Alpha</th>
<th>30-Day Cronbach’s Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>.73</td>
<td>.77</td>
</tr>
<tr>
<td>Depression</td>
<td>.76</td>
<td>.72</td>
</tr>
<tr>
<td>Fatigue</td>
<td>.87</td>
<td>.84</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>.89</td>
<td>.84</td>
</tr>
<tr>
<td>Physical Function</td>
<td>.84</td>
<td>.79</td>
</tr>
<tr>
<td>Treatment Burden</td>
<td>.77</td>
<td>.80</td>
</tr>
<tr>
<td>Self-Rated Health</td>
<td>Test-Rest</td>
<td>.80</td>
</tr>
</tbody>
</table>
Severity of MCC Index .77

Analysis of Research Questions

Research Question 1

The first research question analyzed in this section: What is the level of treatment burden experienced by the adult population living with MCC (at baseline and a 30-day time point post-discharge home) that transitioned from a skilled nursing facility to home? Basic descriptive statistics were run to establish a baseline (M= 39.06; SD= 25.97) and 30-day (M= 37.01; SD= 24.45) level of subjective treatment burden. Histograms of baseline (Figure 3) and 30-day (Figure 4) levels of treatment burden are displayed for additional analysis using graphical representations of the data. Distribution curves are very similar for each time point: Baseline (range: 0-125; skewness: 0.53; kurtosis: 0.28) and 30-Day (range: 0-100; skewness: 0.29; kurtosis: -0.80), with treatment burden at both time points being relatively normally distributed.
Figure 3
Baseline Subjective Treatment Burden Histogram

Figure 4
30-Day Subjective Treatment Burden Histogram
Research Question 2

The second research question analyzed in this section: Are intrapersonal (number of MCC, severity of MCC, depression, fatigue, anxiety, pain, physical function, and self-rated health), interpersonal (caregiver) and organizational (provider prescribed treatment index, transitional care, home care, outpatient therapy, hospital admissions, and emergency department visits) antecedent factors (measured at baseline and 30-day time points) correlated and predictive of treatment burden in adults with MCC that transitioned from a skilled nursing facility to home? Correlational and hierarchical multiple regression analysis were used to answer this research question. Correlation analyses were run first to test the relationships between treatment burden and antecedent factors of treatment burden contained in each conceptual level at baseline and 30-day time points.

The results of correlations between demographics and baseline, subjective treatment burden are presented in Table 14. A small negative correlation (r = -.20; p < .05) was found between age and baseline treatment burden indicating that as the age of the participant decreased the treatment burden score increased. No other correlations were significant.
Table 14

Correlations between Demographics and Baseline Treatment Burden

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<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Burden</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>2 Age</td>
<td>-0.20 *</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Education</td>
<td>0.13</td>
<td>-0.09</td>
<td>-</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4 Income</td>
<td>-0.14</td>
<td>0.07</td>
<td>0.21</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Race</td>
<td>-0.15</td>
<td>-0.12</td>
<td>0.07</td>
<td>-0.02</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>6 Sex</td>
<td>-0.10</td>
<td>0.17</td>
<td>-0.02</td>
<td>0.03</td>
<td>0.18</td>
<td>-</td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed)

The results of correlations between baseline antecedent factors and treatment burden are represented in Table 15. Small, positive correlations were found between the number of MCC (r = .28; p < .01), pain intensity (r = .28; p < .01), physical function (r = .29; p < .01) and baseline, subjective treatment burden. This indicates as the number of MCC,
the severity of pain, or the worse physical function of the participant increased, so did the treatment burden score. Moderate, positive correlations were found between anxiety ($r = .38; p < .001$), depression ($r = .32; p < .01$), pain interference ($r = .40; p < .001$), severity of MCC ($r = .39; p < .001$) and baseline, subjective treatment burden. These correlations indicate that as the level of anxiety, depression, pain interference, or the severity of MCC increased in the participant, so did the treatment burden score.

Additionally, a moderate, negative correlation was found between self-rated health ($r = -.43; p < .001$) and baseline, subjective treatment burden. This correlation indicates that having lower self-rated health scores resulted in higher treatment burden scores. A large, positive correlation was found between fatigue ($r = .60; p < .001$) and baseline, subjective treatment burden indicating that as fatigue increased, so did treatment burden.

Table 15

Correlations between Baseline Antecedent Factors and Treatment Burden

<table>
<thead>
<tr>
<th></th>
<th>1</th>
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<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Treatment Burden</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Anxiety</td>
<td>0.38</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
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<td>***</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Depression</td>
<td>0.32</td>
<td>0.50</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
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<td>**</td>
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<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>
4 Fatigue 0.64 0.37 0.24 - *** *** *

5 Number 0.28 -0.03 0.09 0.25 -
MCC ** *

6 Pain 0.28 0.10 0.13 0.36 0.12 -
Intensity ** ***

7 Pain 0.40 0.26 0.23 0.46 -0.01 0.66 -
Interference *** ** * *** ***

8 Physical 0.29 0.07 0.14 0.47 0.18 0.25 0.38 -
Function ** *** * ***

9 Self-Rated -0.43 -0.11 0.05 -0.46 -0.43 -0.26 -0.21 -0.39 -
Health *** *** *** * * ***

10 Severity 0.39 0.23 0.24 0.49 0.48 0.18 0.33 0.30 -0.36 -
MCC *** * * *** *** *** ** ***

* Correlation is significant at the 0.05 level (2-tailed)
** Correlation is significant at the 0.01 level (2-tailed)
*** Correlation is significant at the 0.001 level (2-tailed)

The results of correlations between demographics and 30-day, treatment burden are presented in Table 16. A small, positive correlation was found between education ($r = .22; p < .05$) and 30-day, subjective treatment burden indicating those participants that completed high school or a higher level of education also had a higher level of treatment burden. None of the other correlations were significant.
### Table 16

Correlations between Demographics and 30-Day Treatment Burden

<table>
<thead>
<tr>
<th></th>
<th>1</th>
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<th>6</th>
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<tbody>
<tr>
<td>1 Treatment Burden</td>
<td>-</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2 Age</td>
<td>-0.18</td>
<td>-</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3 Education</td>
<td>0.22*</td>
<td>-0.01</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Income</td>
<td>-0.03</td>
<td>0.23</td>
<td>-0.17</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Race</td>
<td>-0.14</td>
<td>-0.08</td>
<td>0.01</td>
<td>0.09</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>6 Sex</td>
<td>-0.07</td>
<td>0.11</td>
<td>0.12</td>
<td>0.12</td>
<td>0.16</td>
<td>-</td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed)

The results of correlations between antecedent, intrapersonal factors and 30-day, treatment burden are presented in Table 17. At the 30-day time point, all correlations between the antecedent, intrapersonal factors and treatment burden were significant at a .05 level or lower. At the 30-day time point, there is a small, positive correlation (r = .22, p < .05) between number of MCC and treatment burden. At the 30-day time point, there is a medium, positive correlation between anxiety (r = .31, p > .01), depression (r
= .31, p < .01), and treatment burden. At the 30-day time point, there are large, positive correlations between fatigue (r = .60, p < .001), pain intensity (r = .42, p < .001), pain interference (r = .54, p < .001), physical function (r = .52, p < .001), severity of MCC (r = .40, p < .001) and treatment burden. Additionally, at the 30-day time point, there is a large, negative correlation between self-rated health (r = -.53, p < .001) and treatment burden.

Table 17

Correlations between Antecedent, Interpersonal Factors and 30-Day Treatment Burden

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Treatment Burden</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2 Anxiety</td>
<td>0.31***</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3 Depression</td>
<td>0.31**</td>
<td>0.60***</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>**</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Fatigue</td>
<td>0.60***</td>
<td>0.35**</td>
<td>0.30**</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5 Number MCC</td>
<td>0.21*</td>
<td>0.00</td>
<td>0.07</td>
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<tr>
<td>6 Pain Intensity</td>
<td>0.42***</td>
<td>0.18***</td>
<td>0.15**</td>
<td>0.44***</td>
<td></td>
<td></td>
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<tr>
<td>7 Pain Interference</td>
<td>0.54***</td>
<td>0.17***</td>
<td>0.19***</td>
<td>0.48***</td>
<td>0.61***</td>
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</tr>
<tr>
<td>8 Physical Function</td>
<td>0.52***</td>
<td>0.09***</td>
<td>0.11***</td>
<td>0.45***</td>
<td>0.33***</td>
<td>0.51***</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>9 Self-Rated Health</td>
<td>-0.53***</td>
<td>-0.57***</td>
<td>-0.30***</td>
<td>-0.52***</td>
<td>-0.55***</td>
<td>-0.49***</td>
<td>-0.22***</td>
<td>-0.14***</td>
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<td></td>
</tr>
</tbody>
</table>
The results of correlations between antecedent, interpersonal factors and 30-day, subjective treatment burden are presented in Table 18. At the 30-day time point, there was a moderate, negative correlation between the caregiver variable \( (r = -0.27, p < .01) \) and treatment burden indicating that not having a caregiver increases the level of treatment burden.

Table 18
Correlations Between Antecedent, Interpersonal Factors and 30-Day Treatment Burden

<table>
<thead>
<tr>
<th>Variable</th>
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</tr>
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<tbody>
<tr>
<td>Treatment Burden</td>
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<td>0.27</td>
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<tr>
<td>Caregiver</td>
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</tr>
<tr>
<td>Assistance Index</td>
<td>-0.12</td>
<td>0.68</td>
<td>-</td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed)
*** Correlation is significant at the 0.001 level (2-tailed)

The results of correlations between antecedent, organizational factors and 30-day, subjective treatment burden are presented in Table 19. At the 30-day time point, there is a small, positive correlation between emergency department visits \( (r = 0.24, p < .05) \), provider prescribed treatment index \( (r = 0.24, p < .05) \) and treatment burden indicating that
visiting the emergency department or having a higher provider prescribed treatment index increases the level of treatment burden.

Table 19

Correlations between Antecedent, Organizational Factors and 30-Day Treatment Burden

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<td>1 Treatment Burden</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Department Visits</td>
<td>0.24 *</td>
<td>-</td>
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</tr>
<tr>
<td>3 Homecare</td>
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<td>0.22 *</td>
<td>-</td>
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</tr>
<tr>
<td>4 Hospital</td>
<td>0.15</td>
<td>0.27 *</td>
<td>0.14</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admissions</td>
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<td>-0.25 *</td>
<td>-0.04</td>
<td>-</td>
<td></td>
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<tr>
<td>5 Outpatient</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Therapy</td>
<td>0.24 *</td>
<td>-0.01</td>
<td>0.21 *</td>
<td>0.09</td>
<td>-0.11</td>
<td>-</td>
<td></td>
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<tr>
<td>6 Provider</td>
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<tr>
<td>Treatment</td>
<td>0.05</td>
<td>-0.02</td>
<td>0.21 *</td>
<td>0.14</td>
<td>0.17</td>
<td>0.07</td>
<td>-</td>
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<tr>
<td>7 Transitional</td>
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<td></td>
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</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed)
Following the correlation analysis of the data, the relationship between treatment burden and the antecedent factors of treatment burden is further explored through hierarchical multiple regression. Hierarchical multiple regression allows for the antecedent factors of treatment burden at each level of the conceptual model (intrapersonal, interpersonal, and community) to be entered in blocks, or separate regression analyses. This method allows the researcher to determine if the addition of the antecedent factors at the different conceptual level improves the prediction of treatment burden over the previous model. Results of the baseline regression model are presented in Table 20.

At the baseline time point, this study used a standard multiple linear regression to analyze the baseline data. The overall model explained 41% of treatment burden variance with only one significant predictor: fatigue ($\beta=.43$, $p < .001$), while controlling for demographics (age, education, income, race, and sex).

The dichotomizing of demographic variables of education, income, and race allowed for inclusion of these variables in the regression analysis. Education was coded as 0 for individuals completing grades 1-11, and 1 for high school education and higher. Income was coded as 0 for categories of participants with incomes $\leq$ $10,000 or less a year, and 1 for individuals with incomes greater than $10,000 a year. Race was dichotomized with white participants coded as 0, and non-white participants coded as 1.
Table 20

Baseline Treatment Burden Regression Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardized coefficient</th>
<th>Standardized coefficient (β)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.22</td>
<td>-0.09</td>
<td>0.34</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.38</td>
<td>0.06</td>
<td>0.57</td>
</tr>
<tr>
<td>Depression</td>
<td>0.91</td>
<td>0.13</td>
<td>0.19</td>
</tr>
<tr>
<td>Education</td>
<td>10.6</td>
<td>0.16</td>
<td>0.06</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2.26</td>
<td>0.43</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Income</td>
<td>8.89</td>
<td>0.1</td>
<td>0.25</td>
</tr>
<tr>
<td>Number MCC</td>
<td>3.04</td>
<td>0.18</td>
<td>0.12</td>
</tr>
<tr>
<td>Pain Intensity</td>
<td>-0.19</td>
<td>-0.02</td>
<td>0.84</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>0.84</td>
<td>0.18</td>
<td>0.17</td>
</tr>
<tr>
<td>Physical Function</td>
<td>-0.18</td>
<td>-0.03</td>
<td>0.74</td>
</tr>
<tr>
<td>Race</td>
<td>-15.23</td>
<td>-0.15</td>
<td>0.12</td>
</tr>
<tr>
<td>Self-Rated Health</td>
<td>-3.92</td>
<td>-0.15</td>
<td>0.19</td>
</tr>
<tr>
<td>Severity MCC</td>
<td>-0.15</td>
<td>-0.08</td>
<td>0.51</td>
</tr>
<tr>
<td>Sex</td>
<td>-4.92</td>
<td>-0.09</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Instead of a single linear regression, analysis of the 30-day time point required a hierarchical multiple regression. The use of hierarchical regression determined if subsequent predictive regression models improved variance explained over the initial model, which contained only the Intrapersonal antecedent factors of treatment burden and
demographic information, with the addition of the Interpersonal (step 2) and Organizational (step 3) antecedents of treatment burden. The hierarchical multiple regression was significant in all three steps (p < .001) with the final step explaining 51% of the variance with four significant IPVs: fatigue (β = .44; p < .01), number of MCC (β = .28, p < .05), pain interference (β = .33, p < .05) and caregiver (β = -.35, p < .05).

Fatigue was the best predictor of treatment burden in this sample as it had the largest standardized beta. Race (β = -.19, p > .05) was not considered a significant predictor of treatment burden in the regression model due to its statistical significance of .053. The second step in the hierarchical multiple regression yielded significant changes to the model, though the third did not (Step 2: Δ in r² = .06, p = .02; Step 3: Δ in r² = .05, p = .27). Results are presented below in Table 21.

Table 21
30-Day Hierarchical (3 Step) Regression Results

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Variable</th>
<th>Unstandardized coefficient</th>
<th>Standardized coefficient (β)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age</td>
<td>-0.17</td>
<td>-0.07</td>
<td>0.51</td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td>0.41</td>
<td>0.07</td>
<td>0.57</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>0.75</td>
<td>0.11</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>Education</td>
<td>4.85</td>
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<td>0.40</td>
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<tr>
<td>Variable</td>
<td>Unstandardized coefficient</td>
<td>Standardized coefficient (β)</td>
<td>P value</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------</td>
<td>------------------------------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Age</td>
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<td>0.06</td>
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<td>Anxiety</td>
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<tr>
<td>Depression</td>
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<td>Standardized coefficient (β)</td>
<td>P value</td>
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<tr>
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<tr>
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<td>Value 3</td>
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<td>--------------------------</td>
<td>---------</td>
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<tr>
<td>Pain Interference</td>
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<td>Physical Function</td>
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<tr>
<td>Severity MCC</td>
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<tr>
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<td>0.59</td>
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</tbody>
</table>
Research Question 3

The last question analyzed in this section: Is there a change in treatment burden and treatment burden’s antecedent factors from baseline in a skilled nursing facility to 30-days after discharge home in the adult population living with MCC? Paired sample T-tests comparing the difference between means in intrapersonal factors and treatment burden at baseline and the 30-day time point was used to analyze this research question in this study.

The results of the paired sample T-tests are found in Table 22. There was a significant difference in the scores for Intrapersonal antecedent factors except: self-rated health, the severity of MCC, and treatment burden, which demonstrated no statistically significant change. All of the antecedents that attained statistical significance improved over the 30-day period from baseline to discharge home (i.e. scores were lower, thus indicating lower symptoms).

Table 22
Dependent Sample T-Test Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Score</th>
<th>30-Day Score</th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
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<th>P value</th>
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<td>Depression</td>
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<td>6.96</td>
<td>0.41</td>
<td>1.23</td>
<td>2.84</td>
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Fatigue

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<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>12.41</td>
<td>10.97</td>
<td>1.36</td>
<td>2.22</td>
<td>5.29</td>
<td>73</td>
<td>&lt;.001</td>
</tr>
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</table>

Pain

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<thead>
<tr>
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<tbody>
<tr>
<td>5.50</td>
<td>3.89</td>
<td>1.51</td>
<td>2.18</td>
<td>5.98</td>
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Pain Interference

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<tr>
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</thead>
<tbody>
<tr>
<td>11.68</td>
<td>9.11</td>
<td>2.39</td>
<td>3.22</td>
<td>6.40</td>
<td>73</td>
<td>&lt;.001</td>
</tr>
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</table>

Physical Function

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</thead>
<tbody>
<tr>
<td>15.24</td>
<td>11.19</td>
<td>4.01</td>
<td>3.94</td>
<td>8.76</td>
<td>73</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Self-Rated Health

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>3.11</td>
<td>3.01</td>
<td>0.08</td>
<td>0.64</td>
<td>1.10</td>
<td>73</td>
<td>0.28</td>
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Severity MCC

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</thead>
<tbody>
<tr>
<td>19.17</td>
<td>18.26</td>
<td>0.81</td>
<td>6.72</td>
<td>1.04</td>
<td>73</td>
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Treatment Burden

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<table>
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</thead>
<tbody>
<tr>
<td>39.06</td>
<td>37.01</td>
<td>1.41</td>
<td>8.78</td>
<td>1.48</td>
<td>73</td>
<td>0.17</td>
</tr>
</tbody>
</table>

---

**Post-Hoc Power Analysis**

A post-hoc power analysis was run to answer test the adequacy of the study’s power using Cohen’s F method for the hierarchical multiple regression effect size (calculated as .51 for this study) and the G*Power program for the actual power analysis. The post-hoc G*Power analysis for this study demonstrated sufficient power at 0.99.

**Summary of Findings**

Treatment burden did not significantly change over time during the 30-day transition period from SNF to home. The antecedent factors, except for self-rated health,
improved from SNF discharge to 30 days. At 30 days, the IVPs fatigue, pain interference, the number of MCC, and the presence of a caregiver affected treatment burden with fatigue having the largest effect.

CHAPTER V

Discussion
This chapter focuses on the discussion of study findings, limitations of the study, and suggestions for future research.

**Study Findings**

**Treatment Burden in the Adults Living with MCC Transitioning for SNF to Home**

The first aim of the study was to describe and measure treatment burden in adults living with MCC transitioning for SNF to home. Results from this analysis of the TBQ-15 over two time points were the means and standard deviations stayed relatively stable over the 30-day transition period. Additionally, the mean of treatment burden decreased during the 30-day transition period but not significantly.

Tran et al., (2012) developed the TBQ-13 to test and measure treatment burden in the adult MCC population. Due to the use of the original TBQ-13, which was the non-adapted, French version, the different scores between Tran et al.’s (2012) study, using the TBQ-13, and this study, using TBQ-15, are not fully comparable. A partial comparison of results is worth exploring due to the lack of studies measuring treatment burden in the adult MCC population.

Tran et al. (2012) sample’s (n = 502) treatment burden was (M = 30.1; SD 25.3), with Tran et al.’s (2012) mean approximately 9 points lower than what was found in this study, though the SDs were similar. Tran et al. (2012) established cut-off points for treatment burden: low- M= 11.3; SD = 9.2, moderate- M = 34.6; SD = 11.1; high- M = 65.8; SD = 18.1. If Tran et al.’s (2012) unadjusted cut-off points were applied to the mean this study, this sample transitioning from SNF to home experienced a moderate amount of treatment burden.
Sav et al.’s (2016) study on adults with MCC used the TBQ-15 to measure treatment burden in English speaking adults with MCC in Australia. When comparing this current study’s treatment burden results to Sav et al.’s (2016) study, there is a noticeable difference between the means and standard deviations of the two studies, Sav et al. (2016) having a higher mean difference by approximately 18 points and a wider standard deviation of treatment burden than this study.

There are many potential reasons for this difference in treatment burden between samples. Demographic differences: Sav et al.’s (2016) study had 581 participants recruited from the general Australian population while this study had 82 US participants recruited from one SNF, thus there is potential that these populations inherently experience differing amounts of treatment burden. Additionally, Sav et al. (2016) used a much larger sample than this study, thus reducing potential sampling bias.

Another potential reason for the difference between the level of treatment burden between this study and Sav et al., (2016) is age. Sav et al.’s (2016) sample had a mean age of 57, while this study’s sample had an age of 75. Sav et al.’s (2016) sample mean age is considered still of working age, the present study’s participants mean age was far into retirement. This raises the possibility of treatment burden being higher in those individuals who are of working age, or who are currently working, versus those individuals who are of non-working age, or of retirement age. One explanation for this is that persons who are retired have more time for the “work” of self-management and do not see it as a burden.

Another potential reason for the difference in treatment burden between studies is the inclusion of individuals with only one chronic condition. In Sav et al.’s (2016)
sample, 18.2% only had one chronic condition, while this study was comprised of only participants with MCC.

Another potential reason for the difference in the mean treatment burden score between this study and Sav et al., (2016) is that treatment burden is temporal in nature. Corbin and Strauss (1985) discussed in their Chronic Illness Trajectory that individuals managing chronic conditions could reach a phase of acceptance and then stability in the management of the these chronic conditions. These phases of acceptance and stability in the management of chronic conditions could lessen the level of treatment burden in individuals who have successfully integrated the management of their MCC into their daily lives. This explanation was not able to be tested in either study as the length of participant’s being diagnosed with individual chronic conditions was not measured. However, this may still apply to the participants in the present study.

A final area to address in the description of treatment burden findings of this study is the PPT Index. This study established the PPT Index as an objective index of potential burdensome tasks prescribed by the provider. The PPT questions were chosen as an objective measure of corresponding TBQ-15 questions. This study used Cohen’s Kappa statistic to determine if there was statistically significant agreement between the corresponding questions. There was no statistical significance agreement between any of the four corresponding questions. This result was not unexpected, as the existence of a potentially burdensome task does not equate to that task causing treatment burden. For example, a participant could have multiple doctor’s appointments as part of the provided prescribed treatment plan but these appointments are not burdensome to the individual, thus the individual scores a 1 on the PPT Index, yet a 0 on the TBQ-15. While the
objective questions did not validate the TBQ-15, further study of the validity of the TBQ-
15 is in order.

Correlations of Factors Associated with Chronic Conditions and Treatment Burden

The second aim of this study was two-fold, with the first part exploring the association between variables associated with chronic conditions and treatment burden. The association between these independent factors and treatment burden had been previously unstudied, and thus a thorough review of MCC literature was conducted in Chapter II to these establish potential relationships. This section examines the study’s results as compared to results found in the current literature.

Demographics.

This study controlled for five patient demographics: age, education, income, race, and sex. Age was negatively correlated with treatment burden at baseline, thus as burden increased, so did the age of the participant. This negative correlation between age and treatment burden is supported by similar findings in Sav et al.’s (2016) sample. This negative correlation between age and treatment burden gives further support to the possibility of treatment burden being higher in working aged individuals versus retired, older adults. Education exhibited a small, positive correlation with treatment burden at the 30-day time point. This correlation states those individuals who had received high school degrees or greater have a greater degree of burden. This is a new finding in the current treatment burden literature and requires further testing.

Intrapersonal Factors.
The intrapersonal factors, or patient health characteristics, measured and correlated to treatment burden in this study are anxiety, depression, fatigue, pain interference, pain intensity, physical function, the diagnosed number of MCC, a severity index of MCC, and self-rated health. Since this was the first study to examine the majority of these relationships between intrapersonal factors and treatment burden, the only factor identified in the current literature is the number of MCC, which was found in Sav et al.’s (2016) study for comparison. This study found that as the number of MCC increased, so did the level of treatment burden, which Sav et al.’s (2016) study supported. This association indicates that as the number of MCC increases, so does the overall work the individual must do to manage the increasing number of MCC.

All interpersonal factors had statistically significant positive correlations with treatment burden, except self-rated health. Fatigue had the strongest positive correlation to treatment burden at both baseline and 30-day time points. Heckman et al., (2015) partially supports this finding; Heckman et al., (2015) hypothesized that high levels of treatment burden caused high levels of treatment fatigue. Additionally, Heckman et al. (2015) speculated that high levels of work needed to manage MCC caused high levels of associated fatigue. The present study hypothesized that individuals experiencing high levels of fatigue had higher levels of treatment burden as these individuals are unable to efficiently manage their MCC. Even though the studies differ in causal models, they do support the association of increasing levels of fatigue with increasing levels of treatment burden.

Another interpersonal factor of interest was self-rated health. Self-rated health demonstrated a large, significant negatively correlation with treatment burden, thus as the
rating of self-rated health decreased, the level of treatment burden increased. Self-rated health is an excellent predictor of morbidity and mortality, as well as a leading health indicator (Jylhä, 2010), thus those in poor health may be unable to effectively self-manage MCC.

The results of these intrapersonal factor correlations with treatment burden support the hypothesis that variables associated with chronic conditions would also be associated with treatment burden. The correlational analysis of these interpersonal factors and treatment burden validates the hypothesized relationship between these variables and significantly adds to the current state of the science.

**Interpersonal Factors.**

The interpersonal factors correlated to treatment burden in this study are the presence of a caregiver and the caregiver index, an index of the amount of care received by the participant. A negative correlation exists between the presence of a caregiver and treatment burden, thus, in the absence of a caregiver in this sample, the level of treatment burden is higher. This finding is contrary to the findings of Sav et al., (2016) which found that the presence of a caregiver increased the level of treatment burden. Sav et al., (2016) contributed this finding to the participants’ sense of guilt and shame in needing help from family of friends to maintain their health. Anecdotal comments given by participants during the data collection process supported this negative relationship between caregivers and treatment burden; participants stated how much caregivers decreased the amount of work they did managing their health needs on a daily basis. Corry, While, Neenan, & Smith, 2015, Kuluski et al., 2013, and Williams et al., 2016, articles cited in Chapter II, also support the negative correlation between caregivers and treatment burden.
**Organizational Factors.**

The organizational factors correlated with treatment burden in this study were: emergency department visits, home care, hospital admissions, outpatient therapy, the provider prescribed treatment index, and transitional care. Both the number of emergency department visits and the provider prescribed treatment index were positively correlated with treatment burden.

Treatment burden increases with the number of emergency department visits. A potential reason for this association between emergency department visits and treatment burden is the disruption the emergency department visit causes in the study participant’s life, which is supported by Demain et al. (2015), whose article examined the effects of treatment generated disruptions. Other potential reasons or this positive correlation between emergency department visits and treatment burden is the additional time, effort, and prescribed work need to manage the MCC due to the changing acuity that caused the emergency department visits.

Treatment burden also increases with the amount of provider prescribed work an individual needs to manage their MCC. The provider prescribed treatment (PPT) index, a four-question index, measured this amount of work prescribed by the participant’s provider. Sav et al. (2013) states that treatment burden can be objectively measured, thus the reason for establishing the PPT index. This study hypothesized that the PPT would be positively correlated with treatment burden, thus as the individual’s amount of work needed to manage MCC increased, so did the level of treatment burden. The positive correlation between the PPT and treatment burden confirmed this hypothesis.
Hierarchical Multiple Regression Analysis of Intrapersonal, Interpersonal, and Organization Factors Predicting Treatment Burden.

Four independent variables predicted treatment burden: fatigue, pain interference, the number of MCC, and caregivers. The predictive factors of fatigue, pain interference, and the number of MCC are defined as intrapersonal factors, or patient health characteristics. Since this is the first study examining these variables and their effect on treatment burden in a multiple regression, there is no study for comparison of the results. Despite the lack of comparative studies, the literature reviewed in Chapter II [Reyes-Gibby et al. (2006), Motl et al. (2010), and Liddy et al. (2014)] supports the clustering of fatigue and pain in individuals living with chronic conditions. Fatigue is the greatest predictor of treatment burden in this study in baseline and 30-day regressions; this finding is of importance as the impact of fatigue on treatment burden may be a variable of interest in futures studies in which reducing fatigue may have the greatest impact on reducing treatment burden in the MCC population.

Sav et al., (2016) found that the number of MCC and the presence of a caregiver, an intrapersonal factor, were significant predictors of treatment burden. The present study supported Sav et al.’s (2016) finding of the number of MCC predicting higher levels of treatment burden, but this study also contradicted the Sav et al.’s (2016) finding that having a caregiver increased the level of treatment burden in an individual living with MCC. As stated in the discussion of the correlation analysis of intrapersonal factors, this study finds that the presence of the caregiver decreases the amount of treatment burden in the adult population transitioning from SNF to home by assisting with the work needed to manage MCC in these individuals.
This study’s findings may contrast with the assumption that treatment burden is heavily influenced by delivery of care (May, Montori, and Mair, 2009). Instead, in the adult population transitioning from SNF to home, treatment burden may be driven by the intrapersonal factors, or patient health characteristics, interpersonal factors (e.g., the caregiver) than organizational factors, such as the complexity of the healthcare system or the delivery of fractured care (May, Montori, and Mair, 2009). Future research that focuses on reducing the impact of troublesome patient health characteristics, such as fatigue or pain interference, in order to reduce levels of treatment burden.

**Paired T-test between Intrapersonal Factors and Treatment Burden at Baseline and 30-Days**

The final aim of this study was to examine if the intrapersonal factors, or patient health characteristics, and the level of treatment burden, changed over the 30-day transition period from SNF to home. This aim intended to measure if the transition period lessened or intensified the mean values of these variables, thus did participant’s health characteristics improve or worsen and how did that correlate with the level of burden during the transition period. Anxiety, depression, fatigue, pain interference, pain intensity, and physical function mean scores were all lower or better (p < .05) at the 30-day time point as compared to baseline, indicating improvement of these health characteristic states. The level of treatment burden did not statistically change over the transition period, though the mean score was lower at the 30-day time point: 39.06 (baseline) versus 37.01 (30-day).

This finding may imply and support previously discussed explanation: that treatment burden is a temporal and adaptive process. The participants’ level of treatment
burden may be a floor effect, as the participants have adapted to living with chronic conditions. Additionally, adaptation for some participants may take longer than the 30-day period, thus explaining the lack of change in level of treatment burden in some individuals with new diagnoses, such as an acute stroke.

**Implications**

The majority of implications are research directed and are discussed in the suggestions for future research section of this chapter, since treatment burden research is still in a beginning stage of scientific development. Despite this early stage of development in treatment burden research, this study does raise implications for changes in policy and for health providers.

**Policy Implications**

CMS (2016) in 2012, launched a Comprehensive Primary Care (CPC) initiative, which is a four year, multi-payer initiative design strengthen primary care. The CPC’s aim was to improve health outcomes and cost savings by focusing on primary, preventative care and coordination of health services/resources (CMS, 2016). This initiative was based around five core functions: (1) Risk-stratified Care Management; (2) Access and Continuity; (3) Planned Care for Chronic Conditions and Preventive Care; (4) Patient and Caregiver Engagement; and (5) Coordination of Care across the Medical Neighborhood (CMS 2016). The potential use of the TBQ-15 as a screening tool in the primary care setting touches on all five of these core functions. In terms of risk-stratified care management, it identifies persons with high treatment burden, thus those with high risk of poor treatment adherence and management of MCC, and specific domains of high treatment burden risk, such as medication burden, or financial burden. Care managers and
social workers to could assist patients in managing MCC through support and resources allocated to areas of need by identifying global or specific treatment burden issues. This identification of treatment burden improves access to care, support and resources (core function 2) for these individuals, improves planned care of MCC (core function 3), and increases patient and caregiver engagement (core function 4) through identifying and working through the patient’s care needs. Additionally, allocating and connecting patients with the correct resources to reduce treatment burden and increase adherence of the treatment plan and management of MCC, would improve effective coordination across the medical community, or medical neighborhood, while reducing cost through impactful, directed care.

**Healthcare Provider Implications**

The use of the TBQ-15 as a screening tool for treatment burden could be beneficial to individuals living with MCC beyond just the implementation in the primary care settings. As demonstrated in this study, treatment burden exists in the SNF population and the use of the TBQ-15 to identify global and specific domains of treatment burden could potentially improve health outcomes in these individuals. Coleman et al., (2006), Naylor (2000), and Jack et al. (2009) all advocate for the use of transitional care in home going patients with chronic conditions to improve health outcomes. Part of this transitional care is providing the needed resources to help individuals transition to home; the TBQ-15 identifies areas of deficiency in the management of chronic conditions mitigating treatment burden with increased resource allocation. Social workers in the SNF settings could better provide resources based on the needs of the patient by understanding areas of treatment burden after administering the
TBQ-15, such as financial assistance or a need for transportation services. Healthcare providers in the SNF could also spend more time on education or connect patients with effective educational resources, identifying areas of management of MCC, such as medication management or high burden in engaging in increase physical exercise or diet management, thus mitigating treatment burden. Even nutritionists in the SNF setting could be working with patients that may need help planning how to eat healthy when returning home, or physical therapists could assist in devising a manageable exercise plan at home with attainable goals for the individual.

Home care as another setting measured in this study, with 81% of the study participants receiving some type of nursing directed home care. Home care nurses could measure treatment burden using the TBQ-15 at different time points and compare these results to baseline scores to identify a global increase in burden, or specific areas of high burden, that potentially lead to poor health outcomes. Identifying high global or areas of specific treatment burden would allow a home care nurse to intervene, reducing burden by allocating the needed resources to the area of high treatment burden, thus averting non-adherence in an area of the prescribed treatment.

In summary, the TBQ-15 used a screening tool for global and domains of specific treatment burden has vast clinical applications in improving adherence, management of MCC, and health outcomes in individuals with MCC. It is a simple tool, easily administered, that is not cumbersome to the practitioner or the patient, but has the potential to yield highly effective results.
Limitations

Treatment burden is a newly developed and sparsely tested phenomenon as evident in the review of literature. A limitation of this study was the lack of prior quantitative research on treatment burden. This study measured treatment burden in a two previously untested populations, a homogenous US population and the adult population living with MCC transitioning from SNF to home. Due to the lack of quantitative literature, comparisons of current findings to validate or challenge this study’s results were very limited, making drawing conclusions about the study’s results difficult. This study tested many variables not tested in previous studies, which contributed to the limited discussion of the results in this study.

Sav et al.’s (2013) conceptual model of treatment burden lacked through testing in the current literature, which proved to be a limitation in the design of this study’s conceptual framework. Since the definitions of Sav et al.’s (2013) were not tested, this study choose to use an adapted version of the Socio-Ecological Model, a more robustly tested model. Additionally, treatment burden potentially aligns with the concept of self-management, especially in the areas of self-efficacy (Bandura 1979, Maddux 1995) and patient activation (Hibbard et al., 2004). Further research is needed to examine this alignment of concepts in order to better understand the complexity and impact of living and effectively managing MCC.

Another limitation rising the untested conceptual framework of treatment burden is that certain concepts had no established, psychometrically tested measures. Thus, the use of untested indices (Severity of MCC Index, PPT Index, and the Caregiver Index) to measure variables in the study further complicated the interpretation of the study’s
results. Since these indices are not psychometrically tested, measures of validity and reliability are lacking, thus the contribution of the indices to the science of treatment burden are unclear. Further development and testing of ways to measure concepts associated with treatment burden is needed before conclusive statistical results can be inferred using these indices.

Another limitation of this study is the potential for sampling bias. The study was susceptible to sampling bias due to the small sample collected from a single SNF. A larger sample collected from multiple SNFs would have reduced the chance for sampling bias. This was evident demographically, as the sample was majority white, thus not enabling the results to be representative of non-white populations. Additionally, the sample was primarily female, thus age, with specific focus on the resiliency/coping of women when faced with health related challenges, potentially contributed to the low levels of treatment burden.

The age of onset of each MCC as well as the duration of diagnosis and living with MCC was not measured. This limited the ability to measure the effects of early disability and the trajectory of MCC/ incurred treatment burden versus the impact of late disability. As the number of MCC is expected to rise with age, older adults expect to develop MCC and this may influence the level of perceived burden.

An additional limitation is the attrition rate of ten percent. Though relatively low as compared to attrition rates in other studies sampling older adult populations (Chatfield et al., 2005), the potential for these eight participants experiencing high treatment burden following discharge home from the SNF is a possibility.
A final limitation was the exclusion of 17 potential participants with a BIMS score of less than eight due to the complexity of including individuals with cognitive deficits in a dissertation. Not measuring treatment burden and the antecedent factors of treatment burden in the population living with MCC and extreme cognitive impairment limited the scope of impact of the study. This study lacked the expertise in designing and implementing the measurement of treatment burden in adults living with MCC with severe cognitive impairment.

**Suggestions for Future Research**

This section discusses suggestions for future research studies stemming from the outcomes of this current study.

**A Qualitative Study focusing on Treatment Burden in Adults Transitioning from SNF to Home**

This study hypothesized that treatment burden would be higher in the population transitioning from SNF to home due to its prevalence of MCC, this population’s high level of medical complexity, and the added transitional complications of returning home after an extended clinical stay. The level of treatment burden was significantly lower in this population as compared to another population of working adults (Sav et al., 2016), thus burden may be conceptualized and realized much differently in this population than what is reported currently in the treatment burden literature. A qualitative study using phenomenology would provide robust qualitative data and a greater conceptual understanding of what treatment burden is like in the population of adults living with MCC transitioning from SNF to home.
A Revised Study with Increased Sample Size

There is the need for a larger sample size. This study established the need for creating indices to explore the conceptual framework of treatment burden, such as the Provider Prescribed Treatment Index. A step in establishing the psychometric properties of new instruments is to test their construct validity through exploratory factor analysis, a method of structural equation modeling, which requires a minimum sample size of 200 participants (Boomsma, 1982).

Instrument Development

A second suggestion for future research is the development and the psychometric testing of two of this study’s indices: the Severity of MCC and the Patient Prescribed Treatment Index. The development of these indices into psychometrically tested instruments would allow a more precise measurement of variables associated with treatment burden as well as other concepts that could benefit from the use of these measurements.

Exploring the Potential Temporal Nature of Treatment Burden

A third suggestion for future research is to explore the potential nature of treatment burden, if and how the level of burden changes across the continuum of living and managing chronic conditions. Applying Corbin and Strauss’s (1985) illness trajectory, levels of treatment burden may vary during acute changes in an individual living with MCC’s trajectory due to acute or chronic health or life events, thus increasing treatment burden, and at other times, treatment burden may be low due to the individual’s adaptation to the chronic illness and/or appropriate management of MCC. Exploring this potential facet in the phenomenon of treatment burden would further explain the concept,
but could help researchers, healthcare providers, and individual themselves reduce treatment burden and improve health outcomes.

**Comparison of Treatment Burden in Retired Adults versus Working Adults**

Sav et al.’s (2016) sample of adults living with MCC reported higher levels of treatment burden than the sample in this study. As stated in Chapter 5, a potential reason for this difference is working aged adults may have higher levels of burden due to outside demands, such as work and supporting a family, interfering with appropriate management of MCC as compared to retired adults. By exploring this difference, this study could potential identify a more at risk population for high treatment burden, explore differences between populations, as well as add to the state of treatment burden science.

**Treatment Burden and Fatigue**

The results of this study determined that fatigue was the best predictor of treatment burden in the context of this study’s conceptual framework. This finding directs future studies to further explore the relationship between these two variables, with an understanding that if fatigue remains the best predictor of treatment burden in certain populations with MCC, interventions focused on reducing treatment burden would focus on reducing fatigue in that population.

Further research into the relationship between fatigue and treatment burden would also clarify differing hypotheses. Heckman et al., (2015) posited that high levels of treatment burden caused high levels of fatigue, while this study posited that high level of fatigue were associated with high level of treatment burden. The use of cross-lagged correlation analysis could determine the correct temporal ordering of fatigue and treatment burden in a predictive model.
Treatment Burden, Treatment Adherence, and Health Outcomes

This study aimed to explore the associations of antecedents of treatment burden and the level of treatment burden in an adult population transitioning from SNF to home. This study did not measure the association of treatment burden with treatment adherence or health outcomes in this population. A study focusing on these relationships would explore the proximal and distal outcomes of treatment burden in adults living with MCC transitioning from SNF to home, measuring the impact of burden on treatment adherence and subsequent health outcomes, such as readmission rates, quality of life, morbidity, and mortality.

Treatment Burden and the Caregiver

This study examined the presence or absence of the caregiver and the impact of the caregiver had on treatment burden in this population. This study also used an index to estimate the impact of the work the caregiver did for the participant and that potential impact on treatment burden. For future research, exploring the impact of the caregiver’s health status on treatment burden in this population is of interest. Understanding how the health status of the caregiver interacts with caregiving and treatment burden is an area of importance, as caregivers in poor health could potentially add to a participant’s treatment burden.

Additionally, the self-efficacy of the caregiver is another area of future research. Self-efficacy is an important concept in adapting and dealing with challenging situations (Bandura 1979, Maddux 1995), thus caregivers with higher self-efficacy are capable of delivering more effective care, thus potentially reducing treatment burden more effectively than caregivers with lower self-efficacy.
Finally, an examination of the social support literature concerning caregivers and their recipients is another avenue of future research. The impact of concepts, such as social capital (Kawachi, Subramanian, & Kim, 2012) on treatment burden is an area of research that is currently unexplored.

**Treatment Burden, Self-Efficacy, and Self-Management**

As stated in the limitation section, the intersection of treatment burden, self-efficacy, and self-management has not been explored. There are robust areas of literature on both concepts, and the definition and conceptual model of treatment burden shares many similarities with self-efficacy and the broad umbrella of self-management. A concept analysis of treatment burden and self-management is needed to explore the relationship between these two overlapping concepts, whereas treatment burden may be a part of self-management. Additionally, measuring the impact of self-efficacy (Bandura 1979, Maddux 1995) on treatment burden is a priority, as individuals who display higher self-efficacy hypothetically should have lower treatment burden, as they can better deal with less than ideal situations and life challenges. A factor analysis between psychometrically tested measures of each latent construct can be analyzed to determine if unique properties exist in each construct or whether constructs mimic/reflect one another. The conceptual alignment between these three concepts is an area that may define the study of treatment burden in the future.

**Summary of the Discussion**

This study measured treatment burden before and 30 days after discharge from a SNF, the association treatment burden and the antecedent factors of treatment burden, and the improvement in the antecedent factors of treatment burden over a 30-day period
in adults transitioning from SNF to home. Discussion of results were supported by some literature current treatment burden literature (e.g. the number of MCC predicting treatment burden) and contradicted in others (e.g. caregiver and the temporal ordering of fatigue). The study also contributed to the conceptual understanding of treatment burden, including testing of Sav et al.’s (2013) conceptual model by establishing antecedent factors of treatment burden.

Implications of the study centered around the use of the TBQ-15 as a potential screening tool to identify treatment burden in many healthcare settings, including a policy recommendation to add the TBQ-15 screening to CMS’s Comprehensive Primary Care initiative. This study disclosed its limitations, and though the limitations are extensive, the study did answer its proposed research questions.

Based off the robust discussion and limitations of the study, suggestions for future studies took on many diverging paths in advancing the state of treatment burden science. These future studies ranged from instrument development to exploring treatment burden in potentially more at risk populations. In conclusion, this study met its research aims, adequately filled the intended gaps in the treatment burden literature, raised more questions concerning the nature of treatment burden, and definitively added to the state of treatment burden science.
Appendix A

Instruments in Facility
PROMIS MEASURES

PHYSICAL FUNCTION

1. Are you able to do chores such as vacuuming or yard work?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do
2. Are you able to go up and down stairs at a normal pace?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do
3. Are you able to go for a walk of at least 15 minutes?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do
4. Are you able to run errands and shop?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do

ANXIETY

In the past 7 days

1. I felt fearful
   o Never
   o Rarely
   o Sometime
   o Often
   o Always
2. I found it hard to focus on anything other than my anxiety
   o Never
   o Rarely
   o Sometime
   o Often
   o Always
3. My worries overwhelmed me
DEPRESSION

In the past 7 days

1. I felt worthless
   - Never
   - Rarely
   - Sometime
   - Often
   - Always

2. I felt helpless
   - Never
   - Rarely
   - Sometime
   - Often
   - Always

3. I felt depressed
   - Never
   - Rarely
   - Sometime
   - Often
   - Always

4. I felt hopeless
   - Never
   - Rarely
   - Sometime
   - Often
   - Always
FATIGUE

During the past 7 days

1. I feel fatigued
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

2. I have trouble starting things because I am tired
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

In the past 7 days

3. How run-down did you feel on average?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

In the past 7 days

4. How fatigued were you on average?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

PAIN INTERFERENCE

In the past 7 days

1. How much did pain interfere with your day to day activities?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

2. How much did pain interfere with work around the home?
3. How much did pain interfere with your ability to participate in social activities?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

4. How much did pain interfere with your household chores?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

**PAIN INTENSITY**

*In the past 7 days*

1. How would you rate your pain on average?
   - 0 (no pain)
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10 (worst pain imaginable)

**SELF-RATED HEALTH**

1. How would you rate your overall health?
   - 1 (very poor)
   - 2 (poor)
   - 3 (average)
   - 4 (good)
SEVERITY OF CHRONIC ILLNESS

For each chronic illness: How severe is the illness on your overall health and well-being?

- 1 (no impact on health and well-being)
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10 (severe impact on health and well-being)

TREATMENT BURDEN QUESTIONNAIRE 15 (TBQ-15)

Each question is prefaced with: “How much treatment burden is caused by:”

All questions are answered on a 0 (no burden) to 10 (high burden)

1. The taste, shape or size of your tablets and/or the annoyances caused by your injections (e.g., pain, bleeding, bruising or scars)?
2. The number of times you should take your medication daily?
3. The efforts you make not to forget to take your medications (e.g., managing your treatment when you are away from home, preparing and using pillboxes)?
4. The necessary precautions when taking your medication (e.g., taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down)?
5. Lab tests and other exams (e.g., blood tests or radiology): frequency, time spent and associated nuisances or inconveniences?
6. Self-monitoring (e.g., taking your blood pressure or checking your blood sugar): frequency, time spent and associated nuisances or inconveniences?
7. Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers?
8. The difficulties you could have in your relationships with healthcare providers (e.g., feeling not listened to enough or not taken seriously)?
9. Arranging medical appointments and/or transportation (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments?
10. The administrative burden related to healthcare (e.g., all you have to do for hospitalizations, insurance reimbursements and/or obtaining social services)?

11. The financial burden associated with your healthcare (e.g., out-of-pocket expenses or expenses not covered by insurance)?

12. The burden related to dietary changes (e.g., avoiding certain foods or alcohol, having to quit smoking)?

13. The burden related to doctors' recommendations to practice physical activity (e.g., walking, jogging, swimming)?

14. How does your healthcare impact your relationships with others (e.g., being dependent on others and feeling like a burden to them, being embarrassed to take your medications in public)?

15. The need for medical healthcare on a regular basis reminds me of my health problems?

DEMOGRAPHICS

1. What is your current age in years?

2. What is the race you identify with?
   - White American
   - African American
   - Native American and Alaska Native
   - Asian American
   - Native Hawaiian and Other Pacific Islander

3. What is your sex?
   - Male
   - Female

4. What is the highest level of education completed?
   - (0) No formal education
   - (1-11) Grades 1-11
   - (12) High School
   - (13-15) Some College
   - (16) College Graduate
   - (17) Post-College (+17 years)

5. What is your current income?
   - (1) $5,000 or less
   - (2) $10,000 or less
   - (3) $25,000 or less
   - (4) $50,000 or less
   - (5) $99,999 or less
   - (6) $100,000 or more
Appendix B

Instruments At Home
PROMIS MEASURES

PHYSICAL FUNCTION

5. Are you able to do chores such as vacuuming or yard work?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do

6. Are you able to go up and down stairs at a normal pace?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do

7. Are you able to go for a walk of at least 15 minutes?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do

8. Are you able to run errands and shop?
   o Without any difficulty
   o With a little difficulty
   o With some difficulty
   o With much difficulty
   o Unable to do

ANXIETY

In the past 7 days

5. I felt fearful
   o Never
   o Rarely
   o Sometime
   o Often
   o Always

6. I found it hard to focus on anything other than my anxiety
   o Never
   o Rarely
   o Sometime
   o Often
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**DEPRESSION**

**In the past 7 days**

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FATIGUE

During the past 7 days

5. I feel fatigued
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

6. I have trouble starting things because I am tired
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

In the past 7 days

7. How run-down did you feel on average?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

In the past 7 days

8. How fatigued were you on average?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

PAIN INTERFERENCE

In the past 7 days

5. How much did pain interfere with your day to day activities?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

6. How much did pain interfere with work around the home?
7. How much did pain interfere with your ability to participate in social activities?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

8. How much did pain interfere with your household chores?
   - Not at all
   - A little bit
   - Somewhat
   - Quite a bit
   - Very much

**PAIN INTENSITY**

**In the past 7 days**

2. How would you rate your pain on average?
   - 0 (no pain)
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
   - 7
   - 8
   - 9
   - 10 (worst pain imaginable)

**SELF-RATED HEALTH**

2. How would you rate your overall health?
   - 1 (very poor)
   - 2 (poor)
   - 3 (average)
   - 4 (good)
SEVERITY OF CHRONIC ILLNESS

For each chronic illness: How severe is the illness on your overall health and well-being?

- 1 (no impact on health and well-being)
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10 (severe impact on health and well-being)

CARE GIVER

1. Do you have a care giver assist you in daily activities? (If yes, go to question 2)
   - 0 (no)
   - 1 (yes)

2. Who is your care giver?
   - 1 (spouse)
   - 2 (family member)
   - 3 (employed professional)

3. For each questions, what level of assistance does your care giver provide?
   a. ADL assistance (transfer/ambulation, bathing, dressing, toileting, eating/feeding)
      - 0 (no assistance)
      - 1 (minimal assistance)
      - 2 (moderate assistance)
      - 3 (maximum assistance)
   b. IADL assistance (meals, housekeeping, laundry, telephone, shopping, finances)
      - 0 (no assistance)
      - 1 (minimal assistance)
      - 2 (moderate assistance)
      - 3 (maximum assistance)
   c. Medication Administration
      - 0 (no assistance)
4. Do you think your caregiver has increased or decreased your level of treatment burden and why?

TRANSITIONAL CARE

1. Have you received a home visit from a physician or nurse practitioner in the last 30 days? (If yes, continue to question “a” below)
   o 0 (no)
   o 1 (yes)
   a. How many home visits from a physician or nurse practitioner in the past 30 days?

2. Have you received a phone call from your physician and/or nurse practitioner discussing your health in the past 30 days? (If yes, continue to question “a” below)
   o 0 (no)
   o 1 (yes)
a. How many phone calls from your physician and/or nurse practitioner have you received in the past 30 days?

3. Have you had a scheduled transitional care visit in your primary care physician’s office in the past 30 days? (If yes, continue to question “a” below)
   o 0 (no)
   o 1 (yes)

   a. How many scheduled transitional care visit in your primary care physician’s office in the past 30 days?

4. Do you think transitional care increased or decreased your level of treatment burden and why?

5. Do you think that the timing of the first transitional care visit after your discharge to home increased or decreased your level of treatment burden and why?”

**HOME CARE**

1. Have you received any in-home care from a healthcare provider other than your physician or nurse practitioner in the last 30 days? (If yes, continue to question “a” below)
   o 0 (no)
   o 1 (yes)

   a. How many in-home care interactions did you receive in the past 30 days?

2. Have you been using any technology-related monitoring of your health status in the last 30 days?
   o 0 (no)
   o 1 (yes)

   a. How many home care interactions using any technology-related monitoring of your health status have you received in the past 30 days?

3. Do you think home care increased or decreased your level of treatment burden and why?

4. Do you think that the timing of the first home care visit after your discharge to home increased or decreased your level of treatment burden and why?

**HOSPITAL ADMISSIONS**

1. Were you admitted to the hospital in the past 30 days? (If yes, continue to question 2)
   o 0 (no)
   o 1 (yes)

2. How many hospital admissions occurred in the past 30 days?
3. Do you think hospital admissions increased or decreased your level of treatment and why?

**EMERGENCY DEPARTMENT VISITS**

1. Have you received care in the ED in the past 30 days? (If yes, continue to question 2)
   - 0 (no)
   - 1 (yes)
2. How many emergency department visits occurred in the past 30 days?
3. Do you think visiting the emergency department increased or decreased your level of treatment burden and why?

**OUTPATIENT THERAPY**

1. Have you received outpatient therapy in the past 30 days? (If yes, continue to question 2)
   - 0 (no)
   - 1 (yes)
2. How many outpatient therapy interactions they received in the past 30 days?
3. Do you think having outpatient therapy increased or decreased your level of treatment burden and why?

**PROVIDER PRESCRIBED TREATMENT (PPT) INDEX**

1. How many times a day do you take your medications? (verify with Discharge Summary and EMR)
2. How many lab tests or radiology exams have you had in the past 30 days? (verify with Discharge Summary and EMR)
3. How many times do you perform self-monitoring activities (e.g., blood pressure, blood glucose, weight) a day? (verify with Discharge Summary)
4. How many doctor or other health care professional visits have you had in the past 30 days? (Verify with Discharge Summary and EMR)

**TREATMENT BURDEN**

**TREATMENT BURDEN QUESTIONNAIRE (TBQ-15)**

Each question is prefaced with: “How much treatment burden is caused by:”

All questions are answered on a 0 (no burden) to 10 (high burden scale)

1. The taste, shape or size of your tablets and/or the annoyances caused by your injections (e.g., pain, bleeding, bruising or scars)?
2. The number of times you should take your medication daily?
3. The efforts you make not to forget to take your medications (e.g., managing your treatment when you are away from home, preparing and using pillboxes)?
4. The necessary precautions when taking your medication (e.g., taking them at specific times of the day or meals, not being able to do certain things after taking medications such as driving or lying down)?
5. Lab tests and other exams (e.g., blood tests or radiology): frequency, time spent and associated nuisances or inconveniences?
6. Self-monitoring (e.g., taking your blood pressure or checking your blood sugar): frequency, time spent and associated nuisances or inconveniences?
7. Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers?
8. The difficulties you could have in your relationships with healthcare providers (e.g., feeling not listened to enough or not taken seriously)?
9. Arranging medical appointments and/or transportation (doctors visits, lab tests and other exams) and reorganizing your schedule around these appointments?
10. The administrative burden related to healthcare (e.g., all you have to do for hospitalizations, insurance reimbursements and/or obtaining social services)?
11. The financial burden associated with your healthcare (e.g., out-of-pocket expenses or expenses not covered by insurance)?
12. The burden related to dietary changes (e.g., avoiding certain foods or alcohol, having to quit smoking)?
13. The burden related to doctors' recommendations to practice physical activity (e.g., walking, jogging, swimming)?
14. How does your healthcare impact your relationships with others (e.g., being dependent on others and feeling like a burden to them, being embarrassed to take your medications in public)?
15. The need for medical healthcare on a regular basis reminds me of my health problems?
REFERENCES


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