Examining the association of medication complexity with health-related quality of life in older adults receiving community-based long term services and supports

Claudia Ann Beck

Graduate Center, City University of New York

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EXAMINING THE ASSOCIATION OF MEDICATION COMPLEXITY WITH HEALTH-RELATED QUALITY OF LIFE IN OLDER ADULTS RECEIVING COMMUNITY-BASED LONG TERM SERVICES AND SUPPORTS

by

Claudia A. Beck

A dissertation submitted to the Graduate Faculty in Nursing in partial fulfillment of the requirements for the degree of Doctor of Philosophy, The City University of New York

2014
This manuscript has been read and accepted for the Graduate Faculty in Nursing in satisfaction of the dissertation requirement for the degree of Doctor of Philosophy.

Dr. Kathleen Nokes

____________________________

April 29, 2014

Date

Chair of Examining Committee

Dr. Donna Nickitas

____________________________

April 29, 2014

Date

Executive Officer

Dr. Keville Frederickson

Dr. Luisa Borrell

Dr. Arlene Farren

Dr. Katherine Abbott

Supervisory Committee

THE CITY UNIVERSITY OF NEW YORK
Abstract

EXAMINING THE ASSOCIATION OF MEDICATION COMPLEXITY WITH HEALTH-RELATED QUALITY OF LIFE IN OLDER ADULTS RECEIVING COMMUNITY-BASED LONG TERM SERVICES AND SUPPORTS

by

Claudia A. Beck

Adviser: Dr. Kathleen Nokes

While the complexity of a medication regimen is a concern for all individuals, it is of significant concern for community-dwelling older adults who often require multiple medications to treat chronic health problems. Health related quality of life (HRQoL) has been identified as a key quality outcome measure when assessing care of older adults, particularly those with long-term care needs. Although the use of multiple medications has been widely explored in the literature, there is a paucity of data regarding the combination of several medication-related factors (number of active medications, therapeutic drug class, and medication regimen complexity) and HRQoL in older adults. Wilson and Cleary's health-related quality of life conceptual model was the theoretical framework used to guide this study. This secondary analysis examined the relationship among the number of active medications, the number of therapeutic drug classes, and medication regimen complexity and HRQoL in community-dwelling older adults (68% Hispanic, 75% female) who were recent recipients of home and community-based services (H&CBS). The subjects in this study (N=123) were enrolled in a large, multi-site study (N=470) (R01-AG025524, PI, M. Naylor). Medication-related data were
obtained from medical charts, counted to include the active number of medications as all prescription and over the counter drugs ($mean = 9.3$), and a therapeutic drug class tool ($mean = 4.9$) measured the number of distinct therapeutic drug classes included in a medication regimen. Medication regimen complexity ($mean = 20.6$) was measured using the Medication Regimen Complexity Index (MRCI). The Medical Outcomes Study Short Form (MOS SF-12 v2) physical (PCS) and mental component scores (MCS) measured HRQoL. After controlling for age, gender, education, race, ethnicity, marital status and cognitive status, it was determined that the number of active medications ($\beta$ coefficient $- .497, p = .012$) was a key predictor of physical health-related quality of life, while therapeutic drug class and medication regimen complexity were not associated with either physical or mental health-related quality of life. The number of medications impacts on physical health-related quality of life but the directionality of that relationship is not clear; there were no significant effects on mental health-related-related quality of life and medication-related variables.

*Keywords:* Older adults, active medications, therapeutic drug class, medication regimen complexity, community-based long term services and supports.
Acknowledgements

It is with tremendous gratitude that I thank the many individuals who helped facilitate this endeavor. I have been blessed with so much love, support and guidance along the way from many folks who were or soon became a part of my life as a result of this journey.

None of this would have been possible without the support of my husband Kerry. I thank you for being ‘my rock upon which I stand.’ You never wavered as a constant source of love and encouragement (not to mention clean laundry, great meals, and a safe haven!). You walked beside me every step of the way. Hun, you deserve this sheepskin as much as I do.

To my Chair, Dr. Kathleen Nokes, thank you for helping to guide me through the curves in the road. Your generosity, patience and understanding through this process will forever be appreciated. To Dr. Keville Frederickson, thank you for providing a kind ear to listen and encourage and to guide and support from the very beginning. Your contributions have been invaluable. To Dr. Luisa Borrell, thank you for your insight, guidance and expertise. Your perspectives provided a catalyst that helped move this study forward. To Dr. Arlene Farren, thank you for your encouragement and support. I appreciate your expertise as a researcher and your input has been invaluable. To Dr. Katherine Abbott, thank you for lending your expertise in the area of health-related quality of life and older adults. You have been an inspiration and a constant source of encouragement.
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To Jeannie, you paved the way for the rest of us. Thank you for always being the true friend that you are and for making me laugh even when the going was tough, you’re the best. To Deb, thank you for always providing a refuge filled with great laughs, lots of love and huge dose of support (not to mention some pretty great Martinis!). To Steve, thank you for your calm guidance, your expertise in the process and for helping me remember to stay in the moment.

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To Anne Dowling, who became my first and most influential role model in nursing. Through the power of example, you demonstrated remarkable strength and excellence in everything you did.
Dedication

To my amazing mother, Helen, who believed in me every single day and continues to inspire me in infinite ways. I feel your radiance every day Mom. Love and miss you dearly.

PATIENCE, FORTITUDE, PERSEVERENCE
-SVH SON
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Chapter I

Research Objective

"What will this drug do for me?" asks the patient. "Well" replies the physician, "a rigorous systematic review of randomized trials shows that etidonate will improve measures in your bone density." "I'm not impressed," replies the patient, "unless those stronger bones improve my quality of life" (Guyatt et al. 2007, p.1232).

Background of the study

Medications are often used to cure and alleviate disease, improve quality of life, and lengthen life expectancy (Gelland, Grenard, & Marcum, 2011). The Institute of Medicine (IOM) (2013) has identified health-related quality of life as a national priority for older adults and it has emerged as an important and appropriate construct for older recipients of long-term services and supports. Health-related quality of life highlights aspects of the older adult's well-being affected by changes in their health status and the quality of their health care. Health-related quality of life is an individual's perception of the impact of a disease and its treatment on well being (Sousa & Kwok, 2006). Cella (1995) described health-related quality of life as “the extent to which one’s usual or expected physical, emotional and social well-being are affected by a medical condition or its treatment” (p.73).

The World Health Organization (WHO) defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (WHO, 1948). This conceptualization of health into physical, mental and social components has strongly shaped general health frameworks for more than 60 years.
(Fryback, 2010). In alignment with the WHO's definition of health, the theoretical framework of health-related quality of life is fundamentally based on a multidimensional view of health that includes physical, psychological, social functioning and well-being (Borglin, Jakobsson, Edberg, & Hallberg, 2005; Thompson, Zack, Krahn, Andresen, & Barile, 2012). The central components of health-related quality of life are required for an individual to meet the daily demands of life (Achat, Levine, Coakley, & Colditz, 1998) and have become an important outcome measurement in public health as well as in clinical research and practice (Moriarty, Zack, & Kobau, 2003). This is due in part to the advancement in treatment options and technology, particularly in the areas of chronic disease treatment and management in older adults (Chen, Li & Kochen, 2005).

As the leading causes of death shift from acute illness to chronic disease, health-related quality of life is a significant outcome measure when determining the impact and effectiveness of clinical interventions and treatment including medications (Chenet et al., 2005; Cleary & Howell, 2007; Francic & Jiang, 2006; Walters, Munro, & Brazier, 2001). This outcome is important because the goals of treatment in chronic disease is to improve function, slow disease progression, and reduce suffering. The aim is to reduce the negative impact on health-related quality of life arising from treatment in older adults rather than to achieve a cure (Degl'Innocente et al., 2002; Williams, 2002). As individuals age, there is a greater likelihood to experience multiple health symptoms such as pain and fatigue. These health complaints are relevant to nursing care through early assessment of health symptoms that potentially affect a decline in health-related quality of life (Borglin et al., 2005; Zubritsky et al., 2012).
At any given time four out of five American older adults will use multiple prescription medications, over-the-counter drugs or dietary supplements with 40% taking 5 to 9 medications and 18% taking 10 or more medications within eight or more therapeutic drug classes (Classen, Mann, Wu, & Tomita, 2004; Institute of Medicine (IOM), 2006; Slone Survey, 2006). In the United States, approximately 10,000 people turn age 65 every day and by 2030, approximately one out of every five Americans will be aged 65 years and older (Centers for Disease Control and Prevention, [CDC], 2011). As life expectancy continues to increase and more drugs become accessible to reduce the effects of chronic illness, the utilization of prescription medications will also increase (Masoodi, 2008) particularly in older adults living in the community.

Community-dwelling older adults are the largest consumers of medications today with approximately 20% actively taking ten or more different medications at a given time (LeCouteur, Ford, & McLachlan, 2010; Slone Survey, 2006; Steinman & Hanlon, 2010). The use of ten or more medications can easily be reached by following clinical practice guidelines for a small number of concurrent conditions such as diabetes, hypertension, chronic obstructive pulmonary disease and osteoarthritis (Boyd, et al., 2005; Slone Survey, 2006). Medication therapy is more complex in older adults due to age-associated physiologic changes, multiple co-morbidities, having numerous providers, using more than one filling pharmacy, multiple dosing frequencies (Elliot, O’Callaghan, Paul, & George, 2013; Planton & Edlund, 2009) using several forms of medications, for example tablets, inhalers or injections (Boparai & Korc-Grodzicki, 2011; Paquin et al., 2013).

The use of multiple medications, also known as polypharmacy, contributes to lower adherence, greater risk of falls (Tinetti et al., 2014), adverse drug events, increased
risk of medication errors, increased emergency room visits, hospitalizations, decline in cognitive status and nursing home admissions all of which result in increased health care costs (Boparai & Korc-Grodzicki, 2011; Francic & Jiang, 2006; Fulton & Allen, 2005; Jyrkka, Enlund, Korhonen, Sulkava, & Hartikainen, 2009; IOM, 1999; Preskorn, et al., 2005; Steinman & Hanlon, 2010). If medication-related problems were ranked as a disease by cause of death, it would be estimated to be the fifth leading cause of death in the United States, making medication management in older adults a significant concern (Ballentine, 2008; Slabaugh et al., 2010).

Despite the use of multiple medications being a significant concern in older adults, a commonly accepted definition or consistent cut-point for polypharmacy has yet to be established (Hajjar, Cafierio, & Hanlon, 2007; Slabaugh, Maio, Templin & Abouzaid, 2010). Although operational definitions of polypharmacy have varied significantly and gaining consensus on the definition is still lacking, a range of three to five drugs has been frequently used (Hanlon, Schmader, Ruby & Weinberger, 2001; Jyrkka, Enlund, Korhonen, Sulkava, & Hartikainen, 2009). However variation is seen, for example, Preskorn et al. (2005) defined polypharmacy to literally mean taking two or more prescription medications daily.

When evaluating polypharmacy, therapeutic drug classification is important to consider because of the potential for increased adverse drug events to occur (Hajjar, et al., 2007; Willson, Greer, & Weeks, 2014). A large national survey identified the most commonly used prescriptions medications in community-dwelling older adults in the cardiovascular, endocrine and antilipidemic drug classes (Kaufman, Kelly, Rosenberg, Anderson, & Mitchell, 2002). A study conducted by Gurwitz et al. (2003) found 1523
adverse drug events were associated with a wide range of different therapeutic drug classes with cardiovascular drugs most frequently cited (26%) followed by antibiotics (14.7%) and non-opioid analgesics (11.8%).

Along with the use of a wide range of therapeutic drug classes, older adults are frequently prescribed medications in varying doses, frequencies and routes of administration (Steinman, et al., 2006). As a result, the complexity of the medication regimen increases as the number of medications increase (George, Phun, Bailey, Kong & Stewart, 2004). The most frequent reasons for medication errors have been linked to the characteristics of complexity of an individual's medication regimen (administration, frequency of dosing, and symptoms prompting the need for medications) (George et al., 2004). Medication regimen characteristics have had significant impact on patient outcomes (Elliot, 2012; George, et al., 2004). A study by Wolf et al. (2011) found increased medication regimen complexity led to significant intrusion in patients' daily lives. Nurses can make a significant impact in reducing the effects of medication complexity in older adults and are in a unique position to modify the adverse consequences of complex medication regimens (Frazier, 2005; Liu, Manias, & Gerdtz, 2011).

Generally, the goals of medication therapy for older adults are to treat disease, diminish pain and suffering, avert life-threatening complications due to chronic illness, lengthen life expectancy and ultimately improve quality of life (Gelled, et al., 2011). To accomplish these goals, benefits and risks of optimal medication therapy must be balanced against health-related quality of life factors for older adults with chronic illness requiring long-term care needs (Cleary & Howell, 2007). Nurses often evaluate the
effectiveness of drug therapy through assessment of symptoms including physical or biochemical markers of disease activity (Griffiths, Johnson, Piper, & Langdon, 2004). These evaluation strategies however are not sufficient as they do not reflect the multiple determinants of health that could be revealed through health-related quality of life measurement (Degl'Innocenti et al., 2004).

An estimated six million older adults receive long term services and supports (LTSS) in their own homes, assisted living facilities or nursing homes (Abbott, Bettger, Hanlon, & Hirschman, 2012; Kaye, Harrington, & LaPlante, 2010). Older adults with chronic illness often require long-term care and the number of older adults who will be in need of long-term services and supports in the United States will more than double by 2030 (Knickman & Snell, 2002). A person in need of LTSS requires human assistance with activities such as bathing, dressing or eating or may need assistance with preparing a meal, shopping or using a telephone as a result of physical, mental, or emotional problems (Agency for Healthcare Research & Quality, [AHRQ], 2001). A wide range of services are offered and maintained over an extended period of time to people with chronic health care needs and functional deficits (Reinhard, Kassner, & Houser, 2011). Physical, functional and cognitive decline in combination with multiple co-morbidities underscore the importance of assessing health-related quality of life of individuals in LTSS (Zubritsky et al., 2012).

Statement of the Problem

Is there an association of the number of active medications, therapeutic drug class, and medication regimen complexity with health-related quality of life in community-
dwelling older adults receiving home and community-based long term services and supports in Washington Heights between 2007 and 2008? By examining three variables related to medication use, specifically the number of active medications, therapeutic drug class and medication regimen complexity, this study tested whether specific medication constructs were associated with health-related quality of life.

**Definition of Terms**

**Active medications.** Active medications were defined as the number of medications a subject was taking and included both prescription and over the counter medications. Active medications were measured according to the medication list in the electronic health record at the date of enrollment (see Appendix A) on the Health Related Quality of Life Chart Abstract Tool (Naylor, 2004).

**Cognitive status.** Any mental process that involves symbolic operations to include perception, memory, creation of imagery, and thinking and also includes awareness and judgment capacity (McGraw-Hill Concise Dictionary of Modern Medicine, 2002) and was measured by the Mini Mental State Exam (MMSE) (Folstein, Folstein, & McHugh, 1975). (see Appendix B).

**Community-dwelling.** Individuals who reside at home and are not in an assisted living facility or nursing home (Ganz et al., 2006) and was measured by the organization providing the home and community-based services (see Appendix C) (Naylor, 2004).

**Health-related quality of life.** Health related quality of life is a health-focused quality of life concept that includes characteristics of quality of life impacting health to include physical, mental and functional health and is viewed from the individual’s
perception of their physical and mental health (McHorney, 1999; Zubritsky et al., 2012). Health-related quality of life was measured by the Medical Outcomes Study Short Form (SF12 - v2) (see Appendix D) which provides a physical component summary (PCS) and a mental component summary (MCS) that measures self-reported physical and mental health ratings (Ware, Kosinski, & Keller, 1995).

**Long term services and supports (LTSS).** LTSS is a broad range of supportive services required by individuals who have reduced capacity for self-care as a result of physical, cognitive or mental disability or illness (Reinhard et al., 2011). Admission into an LTSS setting was measured by the classification (e.g. Home and Community-based {H&CBS}, Assisted Living Facility {ALF}, or Nursing Home {NH}) of the organization that enrolled the older adult (see Appendix C) in the Health Related Quality of Life Chart Abstract Tool (Naylor, 2004).

**Medication regimen complexity.** Medication regimen complexity is conceptually related, but not equal to the count of medications and takes into account several aspects of medication regimens to include dosage form (e.g. tablet, liquid), dosing frequency (e.g. once a day, twice a day), and additional directions (e.g. crush pill, take with food) (George et al., 2012) and was measured by the Medication Regimen Complexity Index (MRCI) (see Appendix E) (George et al., 2004).

**Therapeutic drug class.** Is the classification system of drugs into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties (World Health Organization Collaborating Center [WHOCC], 2011). Therapeutic drug class was measured by the number of distinct therapeutic drug classes present in the active medication list as defined by the 12
therapeutic drug classes (see Appendix F) categorized in *Drug Facts & Comparisons 2013.*

**Delimitations**

This study included adults who were:

1) enrolled in the primary study *Health Related Quality of Life: Elders in Long Term Care* (R01AG025524-01A2, PI, M. Naylor) during 2007 and 2008.

2) age 60 years and older

3) recently (within 60 days) recipient of community-based LTSS in New York, N.Y.

**Theoretical Rationale**

Most experts strongly recommend the use of a multidimensional conceptual model to guide the assessment of health-related quality of life (Ware, 1994; Wilson & Cleary, 1995). Wilson and Cleary (1995) developed a conceptual model (see Figure 1) of health-related quality of life that addresses patient outcomes that provided a linear depiction linking five domains of physiological variables, symptom status, function, general health perceptions, and health-related quality of life (Nokes et al., 2011; Wilson & Cleary, 1995). Prior to this conceptualization, there was little research that explored the relationship between clinical variables and measurement of the multidimensional concept of health-related quality of life (Chen et al., 2005; Wilson & Cleary, 1995). The model (see Figure 1.1) focuses on the relationships among several domains of health-related quality of life including: a) biological function and physiological factors; b) symptom status; c) functional status; d) general health perceptions; and e) overall quality of life.
There are two additional factors included in this model: a) characteristics of the individual, and b) characteristics of the environment which impact on all of the domains (Wilson & Cleary, 1995).


Individual characteristics can be defined as distinguishing traits of a human being to include measures of age, gender, education, race, ethnicity, marital status and cognitive status (Naylor, 2004; Wilson & Cleary, 1995). Environmental characteristics include interaction with providers, characteristics of the service delivery system, and the structural features of the physical environment. The characteristics of the individual and the environment are overarching factors that affect all of the five domains of overall
quality of life (Nokes, et al. 2000). For the purpose of this study individual characteristics included age, gender, education, race, ethnicity, marital status and cognitive status.

The intent of the health-related quality of life model was to unite the biomedical and social science paradigms to make the connection between the mind and body (Sousa & Kwok, 2006; Wilson & Cleary, 1995). The biomedical paradigm’s focal point relates to the causative and pathological factors with outcomes measured within the clinical aspects of biological and physiologic domains (Wilson & Cleary, 1995). The social science paradigm’s focal point relates to the domains of environment, functioning and overall well-being with the outcomes measuring intricate behaviors and feelings (Wilson & Cleary, 1995). The key goal of clinical care is to improve patient outcomes. Wilson and Cleary’s (1995) conceptual model of health-related quality of life links what is occurring on a biological, biomedical level to the impact on individual’s symptoms, functional status, general health perceptions and overall quality of life.

Biological function centers on cells, organs and organ systems. Examples include:

a) diagnoses such as inflammatory bowel disease or small cell lung cancer; b) laboratory values to include creatinine, blood urea nitrogen, glucose, and serum hemoglobin; c) measures of physiological function to include pulmonary function tests and physical examination findings such as splenomegaly or systolic ejection murmur; d) number and types of medications; e) height and weight; and f) medical conditions (Naylor, 2004; Wilson & Cleary, 1995). Medical conditions are often treated with medications and biological function was measured by the total number of active medications, therapeutic drug classes and medication regimen complexity (see Table 1.1) in this study since medications may impact on disorders of different biological systems.
Wilson and Cleary’s (1995) conceptual model of health-related quality of life has been useful in creating strategies and instruments that identify and measure variables associated with health-related quality of life and hence provide the opportunity to improve outcomes in this domain (Sousa & Kwok, 2006; Wilson & Cleary, 1995). Wilson and Cleary recommended assessing overall quality of life with general measures to determine how happy or satisfied a person is with their life as a whole (Sousa & Kwok, 2006). The Medical Outcomes Study Short Form (MOS SF-12 v2) (see Appendix D) provides an example of how assessment of health-related quality of life has been integrated as part of an overall health survey to measure and determine outcomes (Brazier & Roberts, 2004; Borglin et al., 2005; Gandhi et al., 2001; Jones, Jones & Miller, 2004; Larson, Schlundt, Patel, Beard, & Hargreaves, 2008; Montazeri et al., 2011; Sousa & Williamson, 2003).
Table 1.1
Conceptual-Theoretical-Empirical-Structure

<table>
<thead>
<tr>
<th>Wilson and Cleary's Health-related quality of life conceptual Model</th>
<th>Biological and physiological function</th>
<th>Health-related quality of life</th>
<th>Characteristics of the individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical Linkages</td>
<td>Active medications, therapeutic drug class and medication regimen complexity</td>
<td>Self reported mental and physical health scores</td>
<td>Age, gender, education, race, ethnicity, marital status, and cognitive status</td>
</tr>
<tr>
<td>Empirical Indicators</td>
<td>Number of active medications, Therapeutic Drug Classification</td>
<td>Medical Outcomes Study Short Form (SF-12 v2) Mental Component Score (MCS) and Physical Component Score (PCS)</td>
<td>1)Medical Record Abstract - Demographic data 2) Mini Mental State Exam (MMSE)</td>
</tr>
<tr>
<td>Medication Regimen Complexity Index tool (MRCI)</td>
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Research questions and hypotheses

**Research question 1.** Is there an association between the number of active medications and physical and mental health-related quality of life of older adults receiving community-based LTSS before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status?

**H1a:** The number of active medications will be associated with physical health-related quality of life in of older adults receiving community-based LTSS.
**H1b:** The number of active medications will be associated with mental health-related quality of life in older adults receiving community-based LTSS.

**Research question 2.** Is there an association between the number of therapeutic drug class and physical and mental health-related quality of life of older adults receiving community-based LTSS before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status?

**H2a:** The number of therapeutic drug classes will be associated with physical health-related quality of life in older adults receiving community-based LTSS.

**H2b:** The number of therapeutic drug class will be associated with mental health-related quality of life in older adults receiving community-based LTSS.

**Research question 3.** Is there an association between medication regimen complexity and physical and mental health-related quality of life in older adults receiving community-based LTSS before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status?

**H3a:** Medication regimen complexity will be associated with physical health-related quality of life in older adults receiving community-based LTSS.

**H3b:** Medication regimen complexity will be associated with mental health-related quality of life in older adults receiving community-based LTSS.

**Study Significance**

This study contributes: (a) to understand medication effects on health-related quality of life in a racially and ethnically diverse population of older adults, (b) to
advance knowledge of medication regimen complexity assessment, and (c) to the body of evidence in nursing science to improve health care health-related quality of life outcomes for older adults. Medications are vital to treat many chronic illnesses and maintain health and quality of life for older adults. However there are significant negative outcomes related to medication use. There is emerging evidence that older adults with multiple co-morbidities vary in the amount of value they place on health outcomes such as longer survival and prevention of specific disease events and the risk of medication-related adverse effects that they are willing to endure (Roth & Levy, 2005; Tinetti, Bogardus, & Agostini, 2004). Many efforts to evaluate the quality of medication use focuses on high-risk drugs, appropriate management of chronic disease or a set of pre-determined quality indicators of medications rather than the patient themselves (Cleary & Howell, 2007; Roth, Weinberger & Campbell, 2009). Nurses can provide comprehensive assessment and interventions to support older adults to safely and appropriately manage their medication regimens that provide cost-effective care and improvement in their health-related quality of life (Marek & Antle, 2008).

Older adults, and in particular those adults who are non-English speaking, have multiple co-morbidities, or cognitive impairments, are often excluded from evidence-generating research (Classen et al., 2005; Tinetti, Bogardus, & Agostini, 2004). In addition, the literature regarding health-related quality of life in community-dwelling older adults as it relates to medications factors (number of active medications, therapeutic drug class, and medication regimen complexity) is sparse. This study contributed to the evidence regarding medication-related factors and health-related quality of life in a small sample of predominately Hispanic older adults.
Chapter II

Review of Literature

The purpose of this study was to examine the relationships of medication-related factors (the number of active medications, the number of therapeutic drug classes, and medication regimen complexity) with health-related quality of life in older adults receiving home and community-based services (H&CBS). The following review of the literature represents the evidence relevant to this research study, namely, health-related quality of life, a health-related theoretical framework, health-related quality of life in older adults and Hispanics, multiple medication use in older adults, therapeutic drug class use, medication regimen complexity and health-related related quality of life and medication use.

Health-related quality of life

According to the WHO definition of quality of life, health is considered to be an important domain that contributes to the overall quality of life (Singh & Dixit, 2010). De Haes and van Knippenberg (1985) noted that the study of quality of life as it relates to health provides a greater understanding of a patient's response to a disease as well as to prescribed treatments. To better address this issue, the concept of quality of life in the context of health and illness is known as health-related quality of life. The term was intended to focus on the impact of health, illness and treatment on quality of life (Ferrans, Zerwic, Wilbur & Larson, 2005; Singh & Dixit, 2010). The concept of quality of life was originally used in cancer treatment by nurses and physicians to explain the distinction between the medical and technical components of care and other aspects of
patient care (De Haes & van Knippenberg, 1985). When confronted with the suffering of patients directly, they focused on paying more attention to supportive care or quality versus the duration of survival.

In the last 30 years, assessment of health-related quality of life has become more relevant in health care particularly in the realm of health and illness, with the patient considered to be an active participant in their care and their choice of treatment options (Ferrans, Zerwic, Wilbur & Larson, 2005). Research conducted on several chronic diseases has emphasized the relevance of evaluating health-related quality of life as part of clinical practice to determine the effects of medical and community-based interventions (Mickle et al., 2011; Singh & Dixit, 2010). Corace and Endler (2003) noted that assessment of health-related quality of life is significant for a number of reasons; specifically to provide clinicians with information related to the impact of disease and illness on an individual’s daily life, effects of treatments on their health-related quality of life and the ability to evaluate and measure the effects of interventions on health-related quality of life (Corace & Endler, 2003; Ferrans et al., 2005) from the patient’s perspective (Sousa & Kwok, 2006).

Theoretical Framework

Wilson and Cleary (1995) developed a conceptual model of health-related quality of life to address patient outcomes. The model has been widely used in different populations to include patients living with HIV/AIDS, Parkinson’s disease and cancer (Chrischilles, Rubenstein, Voelker, Wallace, & Rodnitzky, 2002; Nokes et al., 2000, 2011; Sousa & Williamson, 2003). Considerable work has been done to develop self-
administered health-related quality of life measures that can be scored through the use of subscales that encompass pertinent predictors. Archat et al. (1998) described the fundamental elements of health-related quality of life as functional status, general health and well-being, and proposed that these elements are required for a person to meet the daily demands of life and therefore satisfy their needs and desires. This description of health-related quality of life is compatible with the Medical Outcomes Study Short Form -12 (SF-12) (MOS SF-12) which aims to measure functioning, well being and general health status (Ware, Kosinski, & Keller, 1996).

The MOS SF-12 was used by Sousa & Williamson (2003) to study the relationship between symptom status and health-related quality of life utilizing the Wilson and Cleary conceptual model. The sample (n=99) included emergency room patients with a diagnosis of gastrointestinal bleeding with a mean age of 57.8 years with 62.6% being male. The Short Form 12 (SF-12) physical component scores (PCS) and mental component scores (MCS) were used to measure health-related quality of life along with a 15-item symptom checklist developed and validated for that study at baseline and one month follow-up. Regression analysis controlling for age, gender, hematocrit, and co-morbidities was used to examine the relationship between symptom status and health-related quality of life. Results showed that baseline symptom status contributed 20.2% ($R^2_{change} = .202, p=0.001$) of the variance explained in the baseline PCS score and 23.2% ($R^2_{change} = .232, p=0.001$) at one month follow-up. Symptoms status also explained variance in baseline and follow-up MCS scores ($R^2_{change} = .098, p=0.001$ and $R^2_{change} = .292, p=0.001$, respectively). This research suggested that symptom status was a key predictor to health-related quality of life.
Health-related quality of life in older adults

Predictors of health-related quality of life may be identifiable in older adults. This is of particular importance as the demographic profile in the United States shift towards old age with greater longevity, as adults over the age of 65 years comprise a growing proportion of the population with major use of health care (Walters, Munro, & Brazier, 2001). As a result of this shift assessing health-related quality of life in older adults has become an increasingly important component to address (Hickey, Barker, McGee, & O’Boyle, 2005). Older adults have a greater probability of having numerous co-morbidities and multiple health complaints that are not curable, and therefore greatly affect their health-related quality of life.

Similarly, Borglin et al. (2005) described how health complaints and selected characteristics of age, gender, living situation, marital status and socio-economic status predicted overall and health-related quality of life in older adults. The SF-12 was used to measure health-related quality of life with women reporting lower health-related quality of life. The SF-12 PCS mean ($p=0.03$) was 37.7 for females and 40.6 for male and a Mental Component Score (MCS) mean ($p=0.005$) of 51 for females and 54 for males. Self-reported health problems such as pain ($p=0.001$), mobility problems ($p=0.001$) and fatigue ($p=0.001$) significantly predicted lower physical health related quality of life. The findings indicate that many common health issues occurring at the same time can negatively impact older adults' health-related quality of life and may interact with each other rather than in isolation.
In addition, when compared to the general population, health-related quality of life in older adults can be a significant indicator of health status with prognostic implications (Otero-Rodriquez et al., 2010). Otero-Rodriguez et al., (2010) examined whether changes in health-related quality of life could predict ensuing mortality among a Spanish population aged 60 and older. The findings demonstrated that changes in health-related quality of life are predictive of mortality in older adults. The significance of decreased health-related quality of life in older adults should trigger awareness of a worsening prognosis and an assessment of possible causes of decline.

To further advance the assessment of health-related quality of life in older adults, Zubritsky et al. (2013) adapted the Wilson and Cleary model within the context of older adults who require long term services and supports (LTSS). To create a more rigorous model, functional status domain now includes cognition and LTSS use and behavior were added to environmental characteristics. The adaptation of this evolving model is more reflective and relevant to measure the characteristics of this population, particularly when cure is not the expected outcome, but rather the management of symptoms, chronic disease and cognitive decline (Zubritsky et al., 2013).

**Health-related quality of life and Hispanics**

While increased awareness of declining health-related quality of life is important for all older adults, few studies have examined health-related quality of life by race and ethnicity and most have focused on only one measure of health-related quality of life (Chowdhury, Balluz, & Strine, 2008). Many psychometric measures for health-related quality of life instruments were created utilizing ethnically homogeneous subjects,
making the suitability of administrating them to more ethnically diverse samples questionable (Corliss, Nicholas, & Nokes, 2001). Most attempts to adapt health-related quality of life measures, particularly the Short Form-36 (SF-36), across diverse minority groups have been through the utilization of language translation (Regidor, Barrio, de la Fuente, Domingo, Rodriguez, & Alonso, 1999; Tann, 2005). Hispanics are comprised of culturally diverse sub-groups which may influence views of illness and therefore, responses to questions related to health-related quality of life (Gonzalez-Burchard et al., 2005; Porter, Vijil, Unruh, Lora, & Lash, 2010).

In addition to being culturally diverse, Hispanics are the largest and fastest-growing minority population in the United States today (U.S. Census Bureau, 2011). In 2010, there were 50.5 million Hispanics in the United States (US Census Bureau, 2011). Hispanics comprised 16.3% of the population, and the largest Hispanic subgroup among this population consisted of Mexicans (63%) The second largest group was Puerto Rican, comprising 9.2%, Cubans account for 3.5% and Dominicans account for 2.8% of the total Hispanic population in the United States (Ennis & Albert, 2010). Yet there is a scarcity of data regarding health-related quality of life in minorities and in particular, in Hispanics (Porter et al., 2010).

Porter et al., (2010) highlighted certain issues in data collection that impact health-related quality of life results for Hispanics. For example one issue, item response bias, describes bias due to extreme response style with responses tending to collect toward the extreme choices. Population-based studies of health-related quality of life among people in the United States have found that Hispanics are more apt to report fair to
poor health-related quality of life when compared with whites (Zahran, Kobau, Moriaty, Zack, Holt, & Donehoo, 2005).

Likewise, Hayes et al. (2011) examined disparities in health-related quality of life among adults with self-reported coronary heart disease (CHD). Using data from the 2007 Behavioral Risk Factor Surveillance System, disparities in health-related quality of life were examined using the unhealthy days measurements for adults who self-reported coronary heart disease (6.1% of surveyed population). The study findings demonstrated that Hispanics were more apt than non-Hispanic whites to report fair or poor health status (Adjusted odds ratio[AOR], 1.5).

The literature regarding Hispanics and health-related quality of life measurement, although limited in volume, highlights the importance of selecting instruments that use unbiased terms that are culturally relevant to all Hispanic sub-groups. The sample for this secondary analysis was primarily recruited from a community in which the U.S. Census data reports that 71% are of Hispanic ethnicity (U.S Census, 2011).

**Multiple medication use in older adults**

Medication-related problems are common, expensive and often avoidable in older adults and can lead to poor health outcomes (American Geriatric Society, 2012a). Polypharmacy, the concurrent taking of many medications, has been well documented in the United States (Fulton & Allen, 2005; Jyrkka et al., 2009) and can be a significant concern for improving quality of care for older adults. Medication therapy in older adults presents several challenges due to age-related physiologic changes, numerous co-morbidities, use of multiple medications to include prescription, over the counter and
herbal supplements, and multiple prescribing providers (Boparai & Korc-Grodzicki, 2011). Medications can play an essential role in maintaining the health of older adults who frequently experience the burden of multiple chronic diseases with acute episodes.

The burden of multiple chronic diseases often requires taking multiple medications concurrently, leading to an increase risk of an adverse drug event (LeCouteur, Ford, & McLachlan, 2010). This has been defined as "an injury resulting from the use of a drug" (Gurwitz et al., 2003, p.1109). In a study by Laroche et al. (2007) the risk of adverse drug events were shown to increase 3.4 fold when older adults took 4-6 medications, 4.6 fold when using 7-9 medications, and 5.9 fold when 10 or more medications were used. Delafuente (2003) reported an increase risk in the potential for drug to drug interactions as the number of prescribed medications increased, showing a probability of drug interactions rising to 50% with five drugs and as high as 100% with eight drugs.

Drug interactions become a higher risk when multiple medications are required to manage clinically complex individuals (Boyd, et al., 2005). As a result older adults are frequently at risk for medication- related issues (Foust, Naylor, Boling & Cappuzzo, 2005) with all medication having the potential to harm as well as benefit (Tinetti, Bogardus, & Agostini, 2004). And side effects, as a result of multiple medications, are often mistaken as a new onset of illness and treated with a new medication or simply accepted as a normal part of aging (Shrank, Polinski, & Avorn, 2007).

**Therapeutic Drug Class**
Increased risk for side effects can occur in older adults as a result of the significant differences in the way they metabolize medications (Hoskins, 2011). Physiological changes occur with advanced age to include decrease in renal function, decreased liver metabolism and alterations in the distribution of body water and fat that all impact on drug metabolism (Huisman-Baron et al., 2011). Slabaugh et al. (2010) reported older adults frequently used cardiovascular agents, antithrombotic agents and gastrointestinal agents. However there is a lack of clarity of how medication-related issues (therapeutic class of drug) relate to health-related quality in older adults (Classen, Mkanta, Walsh, & Mann, 2005). The Beers Criteria developed explicit criteria to identify potentially inappropriate medication (PIM) use by older adults (Beers, 1991).

The Beers Criteria published as original research in 1991, and revised in 2002 and 2012, identified a number of drugs and drug classes that were potentially inappropriate for the elderly. These drugs were found to have a risk for adverse drug events (ADE) that outweighed the potential for a therapeutic gain (American Geriatric Society, 2012a; Beers, 1997; Beers, Ouslander, Rollingher, Ruben, Brooks, & Beck, 1991; Swagerty & Brickley, 2005). The intention of the Beers Criteria was to reduce the use of potentially inappropriate medications (PIMs) in older adults and improve prescribing decisions by clinicians to reduce poor outcomes such as avoidable hospitalizations.

Budnitz et al. (2011) examined emergency hospitalizations in adults 65 years and older and found that four medication classes either alone or in combination were associated in 67% (95% CI, 60.0 to 74.1) of hospitalizations: warfarin (33.3%), insulins (13.9%), oral anti-platelet agents (13.3%), and oral hypoglycemic agents (10.7%). Almost 50% of hospitalizations for adverse drug events (ADEs) involved adults 80 years
and older. Likewise, Boparai (2011) found the most common drug classes implicated in ADEs in older adults included cardiovascular drugs, antibiotics, diuretics, steroids, anticholinergics, benzodiazepines and non-steroidal anti-inflammatory drugs.

Hospitalizations for ADEs are predicted to increase as adults live longer, experience increased numbers of chronic conditions and consume more medications (Budnitz, Lovegrove, Shehab, & Richards, 2011).

Similarly, Classen et al. (2005) compared medication drug classes and inappropriately prescribed medications to functional status and quality of life in frail home-based adults 65 years and older ($n=1099$) taking an average number of medications of 5.4 (SD ± 3.7). Cardiovascular medications were the most frequently (72%) used followed by gastrointestinal (41.3%), anti-inflammatory (41%) with cancer drugs having the lowest frequency (1.7%). Cardiovascular drugs were shown to have a positive association with motor performance ($p=0.00$) and cognition ($p=0.00$). These findings suggest that increased age, increased number of chronic conditions and decreased health-related quality of life are associated with greater number of medications.

The literature demonstrates that while there have been efforts to improve the quality of medication use in older adults targeted towards specific issues (avoidance of inappropriate drugs, drug classes and doses) have been important, they fail to include a more patient-centric focus related to health-related quality of life.

**Medication regimen complexity**

Several studies have found complexity of a medication regimen is a significant driver of poor medication adherence (Choudhry et al., 2011; Mansur, Weiss, &
Complex medication regimens are more likely to be error prone which may impact patient safety and quality of life (Paquin et al., 2013). In many situations the ability for an older adult to remain independent at home hinges on their capacity to manage a complex medication regimen, with non-adherence to regimens being a chief driver for nursing home placement (Marek & Antle, 2008). Medication regimen characteristics such as the number of medications, dosage frequency, drug route and administration directions contribute to medication complexity resulting in lower adherence and increased risk for adverse drug events (Corsonello et al., 2009; Elliot, O'Callaghan, Paul, & George, 2013; Ingersoll & Cohen, 2008).

Clinical awareness regarding medication complexity can help identify patients at higher risk for adverse outcomes. George et al. (2004) developed a 65 item medication regimen complexity index tool as a way to quantify several components of medication regimen complexity. Weights were assigned to dosage forms, frequency of doses, and additional directions. The tool was validated by an expert panel that subjectively ranked six regimens to confirm the tool's criterion-related validity demonstrating strong agreement (Kendall’s $W = .8$, $p = 0.001$). The value of the MRCI tool has gained recent interest as evidenced by the translation of the tool to other languages (Stange et al., 2012), additional studies further validating the tool (Mansur, Weiss, & Beloosesky, 2012; Paquin et al., 2013) and other studies that have explored integrating the MRCI as part of clinical decision making (Elliot, 2012; Elliot et al., 2013; Libby et al., 2013; McDonald et al., 2012; Rettig, Wood, & Hirsch, 2013).
McDonald et al. (2012) further applied the MRCI by adapting it for use in electronic health records (EHR) in a home-care setting. An automated process was developed to measure medication regimen complexity in a large population of post-acute discharged patients. The original paper-based MRCI (George et al., 2004) was adapted using an electronic algorithm that automatically calculates the MRCI score for medications entered into the EHR by a home care nurse. The number of total medications was highly associated with the total MRCI score and the greatest contributor to that score was dosing frequency (McDonald et al., 2012). This study provided the first comprehensive picture of medication regimen complexity in a large cohort of post-acute, community-dwelling patients characterized by multiple comorbidities and clinical complexity. The use of an automated MRCI tool may assist clinicians to identify patients with higher complexity with potential to improve medication management and overall outcomes for patients.

Cardone et al. (2011) examined medication regimen complexity and health-related quality of life in end-stage kidney disease patients (n=35) recently started on nocturnal home hemo-dialysis (NHHD) over a 24 month period. The SF-36 was used to measure health-related quality of life and the Medication Regimen Complexity Index (MRCI) was used to quantify regimen complexities. The MRCI scores increased significantly when patients were started on NHHD with a baseline mean score of 22.4 (SD±10.2) and increased to a mean score of 28.3 (SD±11.6) at 24 months (p<0.05). The researchers concluded that increases in the MRCI scores were most likely due to dialysate requirements once NHHD was begun. SF-36 scores improved significantly (p<0.05) from baseline through 24 months but MRCI scores were not significantly
related to the SF-36 score. Future studies are indicated to further explore the influence of different measures of medication regimen complexity and clinical outcomes such as health-related quality of life.

Wolf et al. (2011) explored whether patients inappropriately took multiple medications more frequently than prescribed due the regimen complexity. They assessed the accuracy and variability of how patients implemented a typical seven-drug regimen. The findings indicated that many patients took medications more frequently than indicated and those with inadequate literacy skills were a greatest risk for incorrect dosing. Furthermore, an increase in medication regimen complexity can at a minimum mean taking medication too often each day, causing adverse effects on overall health and intrusion in patients’ lives.

**Health-related quality of life and medication use**

There is a need to better understand the potential intrusion that medication regimen complexity may play in an older adult’s life. Ebrahim (1995) stated generic health-related quality of life measurements have a role in the evaluation of medication therapy where unforeseen adverse effects of therapy might otherwise go unnoticed. Youssef & Wong (2002) suggest there may be value to better understand the subjective feelings of patients along with clinical assessment of health care interventions that include medication regimens. This should also be evaluated according to its effect on the health and quality of life of the individual. Henderson (2006) found the number of medications were associated with lower SF-36 Physical Component Scores (PCS) and the
number of medications ($\beta = -0.91$, $p = 0.045$) to be predictive of lower health-related quality of life in older adults.

Holt et al. (2010) found that low health-related quality of life scores were associated with lower levels of anti-hypertensive medication adherence in adults over the age of 65 years old. Those with low physical and mental component summary scores on the Short Form (SF) 36 tool were 1.33 (95% CI 1.01, 1.74) and 2.26 (95% CI 1.74, 2.97) times more likely, respectively, to have lower medication adherence than those with higher PCS and MCS scores.

Older adults have a greater likelihood to experience multiple health issues that will require the use of multiple medications, resulting in a potential decline in health-related quality of life (Cleary & Howell, 2007). Community-based older adults reported an increase use of all medications with advancing age with the highest occurrence of drug use in females 65 years and older with 12% taking 10 or more medications (Kaufman, Kelly, Rosenberg, Anderson & Mitchell, 2002). Cleary & Howell (2007) examined health-related quality of life and prescription medication use in a study sample of adults aged 65 years and older ($n=46$) living in a rural region of the United States. The Short Form-36 version 2 (SF-36 v2) was used to measure health-related quality of life. Differences between subjects SF-36v2 physical component summary (PCS) and mental component (MCS) scores were compared based on gender and age and showed the mean PCS score for women was slightly better than men with a trend toward significance ($p = 0.06$). This study supported the perception that health-related quality of life declines with age but did not find an association with prescription medication use. Of note, the average number of medication used (3.3) of the study subjects was lower than the national
average for older adults (4-5). The implications of these findings as they relate to the current study are: 1) the mean number of medications in the current study will be expected to be higher; 2) the subjects are from an urban area; 3) there is greater racial and ethnic diversity; and 4) the sample size will be larger (n=123).

Likewise, Henderson et al. (2006) examined the association of health-related quality of life and polypharmacy to determine the influence of demographic and clinical characteristics on this relationship among a group of older American Indians. An in-home interview and survey were conducted on a convenience sample \((n = 63)\) of community-dwelling American Indians. The independent variables included total number of all prescription and nonprescription medications, age, education, annual income, health insurance, perceived health and medical history. The Medical Outcomes Short Form-36 (SF-36) was used to measure health-related quality of life. Increased use of medications were significantly associated with poorer self-reported health with the mean PCS score of 36.5, \((r=.30, p=.02)\). The study will build upon the literature in the following ways: (a) the subjects reside in an urban area; (b) larger sample size, and 3) majority are Hispanic older adults.

While there have been efforts to improve the quality of medication use in older adults targeted towards specific issues to include avoidance of inappropriate drugs, specific drug classes and doses (Beers, 1991; Budnitz et al., 2011) have been important, they fail to include a more patient-centric focus related to health-related quality of life. Identifying outcome measures specific to health-related quality of life continues to pose challenges for nursing. Traditional measures, for example morbidity and mortality, do not provide adequate information concerning health-related quality of life. Yet clinicians may
remain unconvinced concerning the clinical significance of health-related quality of life, possibly because there is a paucity of research linking health-related quality of life to nursing-sensitive indicators (Sousa & Williamson, 2003).

**Summary**

While the literature pertaining to health-related quality of life has emerged as a significant clinical indicator for older adults with chronic health problems, the evidence linking the use of multiple medications, therapeutic drug class, and medication regimen complexity, and health-related quality of life in older adults is lacking, and in particular in ethnically diverse older adults. Although the use of multiple medications has been widely explored in the literature, this literature review highlights the gaps regarding whether specific medication-related factors (number of active medications, number of therapeutic drug classes, medication regimen complexity) are related to health-related quality of life in older adults. The findings from this study explored whether key medication-related factors had a significant impact on health-related quality of life.
Chapter III

The Method

The primary goal of this study was to examine the relationships of medication-related factors (the number of active medications, the number of therapeutic drug classes, and medication regimen complexity) with health-related quality of life in older adults receiving home and community-based services. The methodology used to test the research questions and hypotheses is presented in this chapter which is organized into six sections: a) overview of the primary study, b) study design, c) study sample and setting, d) data collection, e) instrumentation, and f) data analysis.

Primary Study Overview

The data for this secondary analysis came from the baseline interviews and electronic health record abstractions of a large multi-site, longitudinal study investigating health-related quality of life in older adults recently transitioned to long term support services (LTSS). The primary study, *Health Related Quality of Life: Elders in Long Term Care* (R01-AG025524, PI, M. Naylor) was designed to examine the natural history of changes in health-related quality of life among older adults in three distinct settings to include nursing homes (NH), assisted living facilities (ALF) and home and community-based services (H&CBS) and compare patterns of change in each of the multiple domains of health-related quality of life across long-term care settings by examining patterns among matched samples of older adults who remained in their setting for at least one year. Eligibility criteria included adults age 60 years and older who were newly admitted (within 60 days) to one of the LTSS options; able to communicate verbally in
English or Spanish. Exclusion criteria included severe cognitive impairment (MMSE score of less than 12 at baseline), active psychiatric disorders, terminal illness, or admission to a LTC option for post-acute services with an expected plan for discharge from the LTC site. The primary study site locations took place at two visiting nurse agencies (H&CBS) providing in-home LTSS (one was located in New York, NY); nine NHs; nine ALFs and two Program for All Inclusive Care of Elderly (PACE) programs. With the exception of the New York-based home and community-based agency, all study sites were located in the Philadelphia area. Subject recruitment for the primary study was conducted at each study site based on eligibility criteria. Designated site staff approached eligible potential subjects to describe the study. The names of subjects who were interested in learning more were then provided to study project staff who explained the study, administered the MMSE and sought informed consent. Those subjects with MMSE scores of 12 or below were excluded and subjects with a score between 13-22 required additional consent from their legally authorized representative. The primary study commenced in 2007 (Hirschman, Abbott, Hanlon, Bettger, & Naylor. 2012) and data collection was completed in 2012.

Design

This study was a secondary data analysis using baseline data collected by the primary study (R01AG025524-01A2, Principal Investigator, M. Naylor).

Study Sample and Setting

As part of the multi-site primary study, Visiting Nurse Service of New York (VNSNY) CHOICE Health Plan was asked to recruit eligible older adults recently
admitted to their program to receive community-based LTSS. A review of the VNSNY CHOICE member census identified the Washington Heights and Inwood neighborhoods as having potentially eligible research subjects. Washington Heights and Inwood have a higher proportion (71%) of Hispanic residents than other areas in Manhattan (27%) and NYC overall (27%) (U.S Census, 2011). According to Bergad (2008), beginning in the 1980s, the upper Manhattan neighborhoods of Washington Heights and Inwood have become home to a large Hispanic population, making up 73% of the population by 2005 with Dominicans representing the most prominent ethnic group.

The sample for this study consisted of community-dwelling older adults (n =123) who were enrolled during 2007 and 2008 in the primary study (N = 470) previously described (R01-AG025524, PI, M. Naylor). Inclusion criteria for this study included individuals who were: 1) enrolled in the primary study, 2) aged 60 years and older, and 3) were recent recipients (within 60 days) of home and community-based services in New York City. Exclusion criteria for this study excluded any subject who did not reside in the community at time of enrollment. The initial baseline sample (n = 124) included all recruited subjects from the VNSNY site. One subject lived in an assisted living facility (ALF) and was therefore excluded.

**Human Subjects Protection**

The policies and procedures of the Graduate Center of City University of New York and the Visiting Nurse Service of New York (which participated in the primary study and where this researcher was employed) were followed to seek and receive approval from their internal review boards (IRBs). The primary study had already been
approved by the Visiting Nurse Service of New York and the University of Pennsylvania IRBs. Certain medication-related factors were not collected as part of the baseline data by the primary study researchers. Therefore, additional medication-related factors including dosage form/route (e.g. tablet, injection) and additional directions (take with food, crush pill) required access to the subjects’ electronic health record for the additional data. VNSNY IRB approval was sought and obtained to re-identify subjects to facilitate access of the electronic health records to attain medication information. IRB approval was also received from Hunter College, CUNY in accordance with Graduate Center policies.

**Data Collection**

Data for this secondary analysis were collected by the primary study as part of the baseline face to face interviews conducted at the time of enrollment and by retrieving data from electronic health records. Following IRB approval, the VNSNY baseline data set was re-identified and the additional medication-related data were obtained from the subject’s electronic health record (EHR) by this researcher. Following retrieval of all medication data from the subject’s EHR data were de-identified and recorded on Microsoft excel spreadsheets using a password-protected computer with access limited to this researcher only. To ensure all study data were examined at the same time point, the date of enrollment (see Appendix B) was used to retrieve the additional medication-related data from the subject’s EHR.

**Instruments and Data Collection Procedures**

**Demographic data measurement**
Baseline demographic data included age, gender, education, race, ethnicity, marital status and cognitive status. This data was obtained during the initial in-home interviews. These data were collected by the primary study on the demographic questionnaire (see Appendix G) as part of the Health Related Quality of Life Baseline Subject Interview developed and used in the primary study.

**Baseline HRQoL Chart Abstract Tool with Medication Data**

The baseline HRQoL chart abstract tool (see Appendix C) collected the date of enrollment in the primary study. The tool was designed by the primary study to abstract data from the study subject’s electronic health record to include their active medication list (see Appendix A). The baseline medication information initially collected by the primary study at baseline only included the name, dosage and frequency for each medication. The dosage form (tablet, injection) and additional directions (take with food, take at bedtime) were not included and were required to measure medication regimen complexity scores and were collected by this researcher.

**Cognitive Status**

The Mini Mental State Exam (MMSE) was used in the primary study to measure cognitive status. The MMSE is a widely used global cognitive assessment tool that measures orientation to time and place, recalls ability, short-term memory and arithmetic ability in older adults (Folstein, Folstein, & McHugh, 1975). It consists of 20 questions, divided into two sections (see Appendix B). The first section requires verbal responses to orientation, memory, and attention questions, and the second section requires reading and writing and covers the ability to name, follow verbal and written commands, write a
sentence, and copy a polygon. The MMSE total score ranges from 0 to 30 and reflects the number of correct responses. Older adults scoring 24 or higher are considered to be cognitively intact, those with scores of 23-20 are mildly impaired and older adults with scores of 19-12 are moderately impaired (Pangman, Sloan, & Guse, 2000). For the purposes of regression analysis this variable was recoded to dichotomize cognitive status into cognitively intact (MMSE score ≥ 24) and cognitively impaired (MMSE ≤ 23).

**Medical Outcomes Study Short Form (SF-12v2)**

Health-related quality of life was measured using the Medical Outcome Study (MOS) Short Form (SF-12v2) which is a multi-purpose generic measurement of health-status (Ware, Kosinski, & Keller, 1996). The MOS SF-12v2 (see Appendix D) is a psychometrically rigorous instrument frequently used by clinicians and researchers to measure and assess health-related quality of life in a variety of patient populations (Brazier & Roberts, 2004; Borglin et al., 2004; Gandhi et al., 2001; Larson et al., 2008; Montazeri et al., 2011; Resnick & Nahm, 2001; Sousa & Williamson, 2003;). The SF12-v2 contains 12 items, with a range of 3 to 5 response levels that measure eight aspects of general health to include physical functioning, role limitations due to physical health issues, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health (Ware et al., 1996). The instrument uses a Likert scale of 1 to 3 for physical function items; 1 to 5 for bodily pain, social function and general health perception items; 1 to 5 for vitality and mental health; and a dichotomous scale (yes/no) for the presence of role function items (Ware, Kosinski, & Keller, 1996).
The purpose of the MOS SF-12v2 in this study was to measure both physical and mental health-related quality of life using the physical component score (PCS-12) and mental component score (MCS-12) respectively. The sample ($N=123$) mean ($M$) and range results are noted for each item for both component scores (see Table 4.6). Higher scores indicate better self-perceptions of health.

PCS-12 and MCS-12 scores can range between 0 to 100, with 0 indicating the lowest level of health and 100 indicating the highest level of health (Ware, Kosinski, & Keller, 1996). Scoring of the SF-12 v2 PCS-12 and MCS-12 were created using norm-based methods that standardized the scores to a mean of 50 and a standard deviation of 10. Norm-based scoring facilitates comparison of sample scores against the general population (Resnick & Nahm, 2001). The test-retest reliability for the PCS-12 was .89 and the reliability coefficient of .76 was observed for MCS-12 in the general U.S. population (Ware et al., 1996, p.29).

Based on reliability estimates, the MOS SF-12v2 performed adequately in this study sample ($N=123$). Internal consistency for the SF 12 v.2 instrument for this sample was determined using the Cronbach's alpha coefficient. The results for this study ($N=123$) showed Cronbach's alpha coefficient for the physical component score approached 0.70 ($\alpha$ for PCS-12 was .662) and the mental component score exceeded 0.70 ($\alpha$ for MCS-12 was .765).

**Active Medication Data Collection Procedure**

Active medications, created as a continuous variable, were defined as the number of medications a subject was taking and included both prescription and over the counter
medications. Data for active medications comprised a total of 1138 medications for the sample ($N=123$) with subjects taking an average of 9.3 medications (range 2-19) (see Table 4.2). Medication data was obtained from the medication list documented by a registered nurse in subject’s electronic health record (EHR). Medication data included the medication name, form or route (e.g. tablet, injection), frequency (e.g. once a day) and additional directions (e.g. take with food, crush tablet) and were routinely entered and documented in the subject’s EHR by home care nurses using tablet computers as part of usual care (personal communication, M. McDonald November 11, 2013). In addition to prescription medications, over the counter medications were included in the EHR medication list as part of usual practice as they often play a vital role in a patient’s treatment plan and have potential to interact with prescription medications (McDonald et al., 2012). All medication data retrieved from the subject’s EHR were de-identified and recorded on Microsoft excel spreadsheets stored in a password-protected computer with access limited to this researcher only.

**Therapeutic Drug Class Measurement Tool**

To enhance the precision of data about medication-related factors, this researcher developed a therapeutic drug class tool (see Appendix F) to measure the number of individual therapeutic drug classes represented in the subject’s medication regimen. Each medication that shared the same therapeutic class was matched according to one of the 12 pre-determined therapeutic drug classifications in the established drug reference, *Drug Facts and Comparisons 2013*. A 13th drug classification labeled "Other" was created to capture any medications that did not fit into any of the established drug classifications (e.g. Fish oil, Glucosamine). Each medication was assigned a therapeutic drug class (e.g.
MEDICATION COMPLEXITY AND HRQOL

cardiovascular, central nervous system, respiratory). Unique therapeutic drug classes were only counted once for each medication regimen. For example, a study subject taking two cardio-vascular medications and two gastrointestinal medications would have a total of two therapeutic drug classes (cardiovascular, gastrointestinal) counted in their regimen. The average number of therapeutic drug classes represented in the study sample was 4.89 with a range of 2-8 and was analyzed as a continuous variable (see Table 4.3).

**Medication Regimen Complexity Index**

Medication regimen complexity was measured using the Medication Regimen Complexity Index (MRCI) (George et al., 2004). The MRCI is a valid and reliable instrument with strong inter-rater and test-retest reliabilities ≥0.9 (Elliot et al., 2013; George at el., 2004) The MRCI is a 65-item tool designed to quantify prescription medication in three components of medication regimen complexity. For the purpose of this study, over the counter medications were also included in addition to prescription medications. MRCI component "A" measures dosage form/route (e.g. tablets, eye drops, injections). Each dosage form/route is counted only once within a regimen. For example, if a patient's regimen consists of four tablets that are taken orally, their MRCI component “A” sub-score would be one. The MRCI component "B" measures dosing frequency (e.g. once a day, every 12 hours, alternate days) for each medication. A weight is given to each medication frequency, with higher weights assigned to greater frequencies. For example, if a patient is taking six medications with a frequency of once a day for each medication, the MRCI component B subscore would be six. The third MRCI component “C” measures additional directions (e.g. crush pill, take with food, taper dose). A weight is given for each instruction per medication. For example, if a patient is on a single
medication that needs to be crushed and taken with meals, the component C score for that medication is two. The Medication Regimen Complexity Index is a summary score of all three components. There is no limitation to the number of medications or special directions that may be prescribed for a patient, and as a result the MRCI is an open index without upper limitations for ranging scores with higher scores indicating greater complexity (George et al., 2004). The range of total MRCI scores for this study sample ranged from 3 to 69, with a mean total score of 20.6 and was analyzed as a continuous variable (see Table 4.2).

The paper-based MRCI tool was adapted for electronic use in a study conducted in a large home and community-based organization (McDonald et al., 2012), the setting for the study sample used in this secondary analysis (and where this researcher was employed). McDonald et al. (2012) analyzed medication regimen complexity from electronic health records (EHR) of a large sample (N=89,645) of elderly home-care patients to develop and test the translation of the original MRCI components into an automated algorithm tool within the EHR. Scores for MRCI components A and B were calculated by directly mapping to electronic fields that contained this information. Certain regimens were abstracted and manually scored to ensure the programming was working correctly.

Once all data were available to compute the MRCI score for each study subject, this researcher completed a paper-based MRCI tool and calculated component and total scores for each subject's medication regimen. The MRCI results were then analyzed using SPSS Version 21. Inter-rater reliability between the paper-based MRCI scores computed by this researcher and MRCI scores computed using the electronic algorithm
(EA) method previously described was tested. After receiving IRB approval, a researcher familiar with the development of the electronic MRCI algorithm scored 100% of the study sample (T. Peng, personal communication, July 13, 2013). Strong, positive statistically significant correlations were found for the total number of medications ($r = .995, p \leq .01$) (see Table 3.1) and for all three MRCI components (dose forms, dosing frequencies, additional directions), demonstrating high degree of agreement between paper-based and electronic scores. The electronic algorithm (EA) MRCI scores were strongly and positively correlated with the researcher’s paper-based (PB) MRCI scores, specifically dosage form (MRCI A) ($r = .954, p \leq .01$), dosing frequency (MRCI B) ($r = .991, p \leq .01$), additional directions (MRCI C) ($r = .895, p \leq .01$) and MRCI total scores ($r = .984, p \leq .01$).

Table 3.1

Inter-rater Reliability for Medication Regimen Complexity Index (MRCI) tool: VNSNY Electronic Algorithm (EA) and Paper-based (PB) MRCI

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total Active Medications (EA)</th>
<th>MRCI A (EA)</th>
<th>MRCI B (EA)</th>
<th>MRCI C (EA)</th>
<th>MRCI Total (EA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Active</td>
<td>.995**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRCI A (PB)</td>
<td></td>
<td>.954**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRCI B (PB)</td>
<td></td>
<td></td>
<td></td>
<td>.991**</td>
<td></td>
</tr>
<tr>
<td>MRCI C (PB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.895**</td>
</tr>
<tr>
<td>MRCI Total (PB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.984**</td>
</tr>
</tbody>
</table>

*Note.* **$p \leq .001$
Data Analysis

This study utilized a quantitative methodology for data collection and analysis. Prior to analyses, data were examined for accuracy and missing items. It was determined the health-related quality of life instrument, MOS SF-12 v2, had 4.8% \( (n=6) \) missing data. The missing data is just below the 5% missing data criterion recommended by Tabachnick and Fidell (2007). The total count of active medications, Therapeutic Drug Class and MRCI tool instruments had no missing data. To address the missing data, cases with missing data were excluded pair-wise which excludes the cases only if they are missing data required for the specific analysis (Tabachnick & Fidell, 2007).

The study covariates age, gender, race, ethnicity, education, marital status, and cognitive status were originally collected by the primary study. For regression analysis, certain variables were recoded as new dummy or dichotomized variables. Age was kept as a continuous variable. Gender recoded as (0= female/ 1= male). Cognitive status was dichotomized (no impairment = 0 [MMSE >12 <23] / impaired =1 [MMSE ≥23]). Marital status was dichotomized (married = 0/ not married =1). Ethnicity was dichotomized and recoded (Hispanic = 1/ not Hispanic =0).

Normality of variables was assessed using statistical and graphical methods to include histograms to identify outliers and the shape of distributions were examined for evidence of normal distribution. Descriptive statistics to include measures of central tendency were computed for study variables and for appropriate demographic data. The researcher examined the relationship between the number of active medications and the dependent variable (physical health-related quality of life) using Pearson’s product-
moment correlation. Partial correlations were computed to control co-variants (age, gender, education, race, ethnicity, marital status, and cognitive status). Full model multiple regressions were conducted for all covariates and physical and mental health-related quality of life. The 0.5 alpha level was the criteria used for statistical significance in all analyses. Data were analyzed using the Statistical Packages for the Social Sciences (SPSS) Version 21.0 for Windows program to run statistical tests.

Linear regression analyses was the analytical approach conducted to test all six research hypotheses to determine: (a) if the number of active medications predicted physical and mental health-related quality of life, (b) if the number of therapeutic drug classes predicted physical and mental health-related quality of life, and finally (c) if medication regimen complexity predicted physical and mental health-related quality of life.
Chapter IV

The Results

This chapter presents the results of the statistical data analysis. The statistical findings of study are presented in three main sections: (a) descriptive statistics of sample characteristics and study variables, (b) main analysis to include linear regression models, for the six study hypotheses and (c) ancillary analysis. Presentation of the findings was summarized in narrative format and depicted in table format.

Descriptive Statistics

Sample Characteristics

The study sample was comprised of 123 older adults who recently began receiving home and community-based services provided by a home and community-based agency. Overall subjects were 79 years old on average, the majority were female (75%), and Hispanic (68%). Fifty-nine percent only had an 8th grade education (see Table 4.1). The majority of subjects (84%) had a mean MMSE score of 24.7 and almost half (42%) were widowed. Over one third (35%) of the sample were Black or African American. Of note, 37% \((n = 46)\) chose the "Other" category for race (see Appendix G).
Table 4.1
Sample characteristics of older adults receiving H&CBS in Washington Heights and Inwood, NY, during 2007-2008 (N = 123)

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>%</th>
<th>n</th>
<th>Mean (SD)</th>
<th>Range (Min - Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>123</td>
<td>79 yrs (7.7)</td>
<td>34 (63-97)</td>
</tr>
<tr>
<td>≤ 75 years</td>
<td>36</td>
<td>44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>76 - 83 years</td>
<td>31</td>
<td>38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 84 years</td>
<td>33</td>
<td>41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>75</td>
<td>92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25</td>
<td>31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td>8 yrs (4.5)</td>
<td>21 (0 - 21)</td>
</tr>
<tr>
<td>≤ 8th grade</td>
<td>59</td>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 - 12 years</td>
<td>28</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 12 years</td>
<td>13</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>28</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or AA</td>
<td>35</td>
<td>41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian Pacific</td>
<td>1.6</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>37</td>
<td>46</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>68</td>
<td>84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>24</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>42</td>
<td>52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>10</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/Separated</td>
<td>24</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive Status</td>
<td></td>
<td>122</td>
<td>24.7 (2.94)</td>
<td>16 (14-30)</td>
</tr>
<tr>
<td>Impaired (MMSE &gt;12 &lt;23)</td>
<td>16</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Impaired (MMSE ≥23)</td>
<td>84</td>
<td>102</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. H&CBS = Home and Community-Based Services. MMSE = Mini Mental State Exam. AA = African American
Medication-related Factors

Active medications. The average total number of active medications was 9.3 (SD 3.6) with a range of 2-19 (see Table 4.2).

Table 4.2

<table>
<thead>
<tr>
<th>Medication Variables</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Active Medications*</td>
<td>9.3 (3.6)</td>
<td>17 (2 - 19)</td>
</tr>
<tr>
<td>MRCI A (dosage forms)</td>
<td>4.8 (4.3)</td>
<td>21 (1 - 22)</td>
</tr>
<tr>
<td>MRCI B (frequency)</td>
<td>13.7 (6.7)</td>
<td>26 (2 - 38)</td>
</tr>
<tr>
<td>MRCI C (directions)</td>
<td>2.1 (2.2)</td>
<td>12 (0 - 12)</td>
</tr>
<tr>
<td>MRCI Total Score</td>
<td>20.6 (11.6)</td>
<td>66 (3 - 69)</td>
</tr>
</tbody>
</table>

Note. * Includes prescription and over the counter medications. MRCI = Medication Regimen Complexity Index

Medication regimen complexity. MRCI total scores ranged from 3 to 69 (see Table 4.2) with a mean average of 20.6 (SD 11.6). The greatest contributor to the MRCI total score was dosing frequency (MRCI B) with a mean score of 13.7 (SD 6.7) with a range from 2 to 38, thus representing multiple medications and multiple dosing patterns. There was a strong correlation between the number of medications and the MRCI total score ($r=.839$, $p \leq 0.001$) (see Table 4.7).

There was wide variance of MRCI total scores found within regimens containing the same number of medications as noted in the two sample medication regimens (see
Tables 6 and 7). To illustrate this point, the MRCI total scores for 2 study subjects taking 9 medications a day were compared to demonstrate the wide variance of medication regimen complexity. The MRCI total score computed in Regimen “A” was 25 and the MRCI score computed in Regimen “B” was 11 (see Figure 4.1).

![Figure 4.1](image)

*Figure 4.1.* Scatterplot of medication regimen complexity (MRCI) and total active medications with example regimens for 2 subjects taking 9 medications.

The first medication regimen example (see Table 4.3) was more complex with a MRCI total score of 25, which is approximately 25% higher than study sample average (20.6). The higher complexity was attributable to 1) multiple routes/forms (tablet and two forms of inhaled medications), 2) frequencies ranging from once daily up to every four hours as needed and 3) two additional directions (taking medication at a specific time (bedtime) and the using of multiple units (2 puffs) at one time).
Table 4.3

Medication Regimen Example A: Older adult receiving H&CBS in Washington Heights and Inwood, NY, during 2007-2008 (n=1)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Form / Route (MRCI A)</th>
<th>Frequency (MRCI B)</th>
<th>Directions (MRCI C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singular</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>Take a bedtime</td>
</tr>
<tr>
<td>Motrin</td>
<td>Tablet / Oral</td>
<td>Every 4 hours prn</td>
<td>-</td>
</tr>
<tr>
<td>HTCZ</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Micardis</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Amlodipine</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Calcium</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Advair Diskus</td>
<td>Inhalation / Aerolizer</td>
<td>Twice a day</td>
<td>Multiple units (2 puffs)</td>
</tr>
<tr>
<td>Spiriva</td>
<td>Inhalation / Accuhaler</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Ferrous Sulfate</td>
<td>Tablet / Oral</td>
<td>Every 8 hours</td>
<td>-</td>
</tr>
</tbody>
</table>

*Note. HCTZ = Hydrochlorothiazide. MRCI = Medication Regimen Complexity Index. PRN = take as needed*

The medication regimen in the second example (see Table 4.4) was less complex than was typical for patients taking nine medications. The MRCI score of 11 was approximately 49% lower than study sample average (20.6). The lower complexity in this example was attributable to using only one route/form (oral/tablet/capsule) with a once a day frequency for eight out of nine medications with no additional directions indicated.

Table 4.4

Medication Regimen Example B: Older adult receiving H&CBS in Washington Heights and Inwood, NY, during 2007-2008 (n=1)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Form / Route (MRCI A)</th>
<th>Frequency (MRCI B)</th>
<th>Directions (MRCI C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avandia</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Omega 3</td>
<td>Capsule / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Glimepiride</td>
<td>Tablet / Oral</td>
<td>Twice a day</td>
<td>-</td>
</tr>
<tr>
<td>Prevacid</td>
<td>Capsule / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Allopurinol</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>Tablet / Oral</td>
<td>Once a day</td>
<td>-</td>
</tr>
</tbody>
</table>
**Therapeutic drug class.** On average, the medication regimens of the subjects were comprised of five unique therapeutic drug classes with a range from two to eight classes. The five most prevalent therapeutic drug classes (see Table 4.5) were cardiovascular agents (97%), central nervous system agents (94%), nutrients and nutritional agents (63%), gastrointestinal agents (60%), and endocrine and metabolic agents (59%). Systemic anti-infective agents (6%) and biologic and immunologic agents (4%) had the lowest frequency of use.

Table 4.5

Characteristics of Therapeutic Drug Class (TDC) of older adults receiving H&CBS in Washington Heights and Inwood, NY, during 2007-2008 (N =123)

<table>
<thead>
<tr>
<th>Therapeutic Drug Class</th>
<th>%</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique TDC per regimen</td>
<td></td>
<td>123</td>
<td>4.89 (1.5)</td>
<td>6 (2-8)</td>
</tr>
<tr>
<td>TDC Frequencies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>97</td>
<td>119</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>94</td>
<td>116</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutrients &amp; Nutritional</td>
<td>63</td>
<td>78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>60</td>
<td>74</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocrine &amp; Metabolic</td>
<td>59</td>
<td>73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>35</td>
<td>43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematological</td>
<td>20</td>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal &amp; Genitourinary</td>
<td>16</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmic &amp; Otic</td>
<td>13</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermatological</td>
<td>11</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic Anti-infective</td>
<td>6</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biologic &amp; Immunologic</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note. TDC = Therapeutic Drug Class*
Health related quality of life

Health-related quality of life was measured using the Medical Outcomes Study Short Form (SF-12v2) (see Table 4.6). The SF-12v2 produces two component scores (physical component score [PCS-12] and mental component score [MCS-12]) with higher scores indicating better health-related quality of life (Ware et al., 2002). The results for the six items in the PCS-12 were in the lower range, measuring physical functioning ($M=1.28$) (range 1-3), role limitations due to physical health problems to include limited stair climbing ($M=1.28$) (range 1-3), accomplishing less ($M=2.8$) (range 1-5), limited work or activities ($M=2.77$) (range 1-5), bodily pain ($M=3.18$) (range 1-5) and general health ($M=(range 1-5)$. Physical health-related quality of life for the study sample indicated lower than average physical health ratings. The mean PCS-12 score of 31.2 ($SD=7.66$) for the sample which is well below the average norm-based PCS-12 score of 50 (Resnick & Nahm, 2001).

The results for the six items in the MCS-12 were higher range measuring vitality (energy) ($M=2.58$) (range 1-5), social functioning ($M=3.24$) (range 1–5), role emotion (accomplished less) ($M=3.46$) (range 1-5), role emotion (not careful) ($M=3.76$) (range 1-5), mental health (felt calm & peaceful) ($M=3.43$) (range 1-5), mental health (downhearted and depressed) ($M=3.24$) (range 1-5). The average MCS-12 was higher than the PCS-12 with a mean score of 47.3 ($SD=10.5$) which is closer to the norm-based average of 50 (Resnick & Nahm, 2001). The study subjects on average had higher mental component scores when compared to their physical component scores (PCS-12).
Table 4.6

Characteristics of Health related Quality of Life of older adults receiving H&CBS in Washington Heights and Inwood, NY, during 2007-2008 (N =117)

<table>
<thead>
<tr>
<th>MOS SF-12v2</th>
<th>Mean (SD)</th>
<th>Range (Min-Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical HRQoL (PCS-12)</td>
<td>31.2 (7.66)</td>
<td>37 (14-51)</td>
</tr>
<tr>
<td>Mental HRQoL (MCS-12)</td>
<td>47.3 (10.5)</td>
<td>56 (14-70)</td>
</tr>
</tbody>
</table>

Note. MOS SF-12v2 = Medical Outcomes Study Short Form (SF-12 v2). PCS-12 = Physical Component Score. MCS-12 = Mental Component Score.

Main Analysis

Main analysis examined the relationships between the dependent variables, physical and mental health-related quality of life, and the independent variables: number of active medications, number of therapeutic drug classes, and medication regimen complexity. The correlation matrix for the study variable is reported on Table 10. Cohen’s (1988) guidelines for evaluating correlational results for the behavioral sciences were used to interpret the strength of the correlations. The study sample size (N = 123) met the required number of minimum cases recommended when using multiple regression. Preliminary analyses were conducted to determine there were no violation of assumptions of normality, linearity, outliers, multicollinearity and homoscedasticity (Tabachnick & Fidell, 2007). The Normal Probability Plots (P-P) suggested no deviation from normality. The scatterplot of the standardized residuals supported homoscedasticity and indicated no visible patterns or outliers. Collinearity diagnostics for the independent
variable (VIF = 1.0, Tolerance = 1.0) did not violate the assumption of multicollinearity. The maximum value for Cook’s Distance was .28 suggesting no major issues of undue influence on the results. Scores larger than 1.00 are most likely due to outliers (Tabachnick & Fidell, 2007).

Table 4.7
Correlation Matrix of Associations Among Main Study Variables (N = 123)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Physical HRQoL (PCS-12)</th>
<th>Mental HRQoL (MCS-12)</th>
<th>Total Active Medications</th>
<th>Therapeutic Drug Class</th>
<th>MRCI Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical HRQoL (PCS-12)</td>
<td>-.117</td>
<td>-.185*</td>
<td>-.046</td>
<td>-.081</td>
<td></td>
</tr>
<tr>
<td>Mental HRQoL (MCS-12)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Total Active Medications</td>
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<td></td>
<td></td>
<td>.720**</td>
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<tr>
<td>Therapeutic Drug Class</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.839**</td>
</tr>
</tbody>
</table>

Note. **p ≤ .001, one tailed. *p ≤ .05. HRQoL = Health-related quality of life. PCS-12 = Physical Component Score. MCS-12 = Mental Component Score. MRCI = Medication Regimen Complexity Score.

Testing the Research Hypotheses

Research question 1. Is there an association between the number of active medications and health-related quality of life in older adults receiving community-based LTSS before and after controlling for age, gender, education, race, ethnicity, marital and cognitive status?
**H1a:** The number of active medications will be associated with physical health-related quality of life in older adults receiving community-based LTSS.

A Pearson product-moment correlation was calculated to explore the relationship between the number of active medications ($M = 9.3$) and physical health-related quality of life (measured by PCS-12) ($M = 31.2$). Before controlling for age, gender, education, race, ethnicity, marital and cognitive status, this analysis was found $r = -.185$, indicating a small negative relationship between the total number of active medications and physical health-related quality of life.

Partial correlation was used to explore if the relationship between physical health-related quality of life and the total number of active medications while controlling for age, gender, education, race, ethnicity, marital and cognitive status. There was a small, negative partial correlation between physical health-related quality of life and the total number of active medications controlling for age, $r = -.194, p < .05$, education, $r = -.185, p < .05$, race $r = -.184, p < .05$, ethnicity, $r = -.185, p < .05$, marital status, $r = -.188, p < .05$, and cognitive status, $r = -.193, p < .05$. An inspection of the zero order correlation ($r = -.185$) suggested that controlling for age, education, race, ethnicity, marital and cognitive status had very little effect on the strength of the relationship between the two variables. There was a small decrease in the strength of the correlation (from -.185 to -.171) when controlling for gender, $r = -.171, p = .06$.

A simple linear regression was performed (see Table 4.8). It was found that the total number of medications significantly predicted physical health-related quality of life ($\beta = -.185, p = .046$). A multiple regression was then conducted adjusting for age, gender,
education, race, ethnicity, marital status and cognitive status. After adjusting for the covariates, the predictive power of total number of active medications on physical health-related quality of life was reduced ($\beta = -.186$, $p = .062$) (see Table 4.8). These results indicated that for every unit increase in medication, physical health-related quality of life decreases by .5, interpreted to mean that people taking more medications will have a decrease in physical health-related quality of life.

**H1b:** The number of active medications will be associated with mental health-related quality of life in older adults receiving community-based LTSS.

A Pearson product-moment correlation was calculated to explore the relationship between the number of active medications ($M = 9.3$) and mental health-related quality of life (MCS-12) ($M = 47.3$). This analysis found that there was a non-significant correlation, $r = -.101$, $p > .05$, between the number of active medications and mental health-related quality of life.

A simple linear regression was performed before adjusting for age, gender, education, race, ethnicity, marital status and cognitive status (see Table 4.9). The total number of active medications did not predict mental health-related quality of life ($\beta = -.101$, $p = .279$). A multiple regression was then conducted adjusting for age, gender, education, race, ethnicity, marital status and cognitive status. After adjusting for the covariates, the total number of active medications did not predict mental health-related quality of life ($\beta = -.041$, $p = .676$).
Research Question 2

Research question 2. Is there an association between the number of therapeutic drug class and health-related quality of life of older adults receiving community-based LTSS before and after controlling for age, gender, education, race, ethnicity, marital and cognitive status?

**H2a:** The number of therapeutic drug classes will be associated with physical health-related quality of life in older adults receiving community-based LTSS.

A Pearson product-moment correlation was calculated to explore the relationship between the number of therapeutic drug classes ($M = 4.9$) and physical health-related quality of life (PCS-12) ($M = 31.2$). This analysis found that there was a non-significant correlation, $r = -.046$, $p > .05$, between the number of therapeutic drug classes and physical health-related quality of life.

A simple linear regression was performed before adjusting for age, gender, education, race, ethnicity, marital status and cognitive status (see Table 4.8) The number of therapeutic drug classes did not predict physical health-related quality of life ($\beta = -.046$, $p = .623$). A multiple regression was then conducted adjusting for age, gender, education, race, ethnicity, marital status and cognitive status. The results of the regression indicated that the number of therapeutic drug classes did not predict physical health-related quality of life ($\beta = -.044$, $p = .651$) (see Table 4.8).

**H2b:** The number of therapeutic drug class will be associated with mental health-related quality of life in older adults receiving community-based LTSS.
A Pearson product-moment correlation was calculated to explore the relationship between the number of therapeutic drug class ($M = 4.9$) and mental health-related quality of life (MCS-12) ($M = 31.2$). Before controlling for gender, age, education, marital status, ethnicity, race, and cognitive function, this analysis found that there was a non-significant correlation, $r = -.091, p > .05$, between the number of therapeutic drug classes and mental health-related quality of life.

A simple linear regression was performed before adjusting for age, gender, education, race, ethnicity, marital status and cognitive status (see Table 4.9). The total number of therapeutic drug classes did not predict mental health-related quality of life ($\beta = -.157, p = .091$). A multiple regression was then conducted adjusting for age, gender, education, race, ethnicity, marital status and cognitive status. After adjusting for the covariates, the number of therapeutic drug classes did not predict mental health-related quality of life ($\beta = -.114, p = .230$) (see Table 4.9).

**Research Question 3**

**Research question 3.** Is there an association between medication regimen complexity and health-related quality of life in older adults receiving community-based LTSS before and after controlling for gender, age, number of years of education, marital status, ethnicity, race, and cognitive status?

**H3a:** Medication regimen complexity will be associated with physical health-related quality of life in older adults receiving community-based LTSS.

A Pearson product-moment correlation was calculated to explore the relationship between medication regimen complexity ($M = 20.6$) and physical health-related quality of life.
life (PCS-12) \( (M = 31.2) \). This analysis found that there was a non-significant correlation, \( r = -.081, p > .05 \), between the medication regimen complexity and physical health-related quality of life.

A simple linear regression was performed before adjusting for age, gender, education, race, ethnicity, marital status and cognitive status (see Table 4.8) Medication regimen complexity did not predict physical health-related quality of life \( (\beta = -.081, p = .387) \). A multiple regression was then conducted adjusting for age, gender, education, race, ethnicity, marital status and cognitive status. After adjusting for the covariates, medication regimen complexity did not predict physical health-related quality of life \( (\beta = -.074, p = .458) \) (see Table 4.8).

**H3b:** Medication regimen complexity will be associated with mental health-related quality of life in older adults receiving community-based LTSS.

A Pearson product-moment correlation was calculated to explore the relationship between medication regimen complexity \( (M = 20.6) \) and mental health-related quality of life (MCS-12) \( (M = 47.3) \). This analysis found that there was a non-significant correlation, \( r = -.076, p > .05 \), between the medication regimen complexity and mental health-related quality of life.

A simple linear regression was performed before adjusting for age, gender, education, race, ethnicity, marital status and cognitive status. Medication regimen complexity did not predict mental health-related quality of life \( (\beta = -.076, p = .416) \). A multiple regression was then conducted adjusting for age, gender, education, race,
ethnicity, marital status and cognitive status. Medication regimen complexity did not predict mental health-related quality of life ($\beta = -.008, p = .938$) (see Table 4.9).

**Ancillary Analysis**

**Medication-related variables and Health-related quality of life**

To further explore the relationships among the independent variables (total number of active medications, number of therapeutic drug classes, and medication regimen complexity) the study covariates (age, gender, education, race, ethnicity, marital status and cognitive status) and the dependent variables (physical and mental health-related quality of life) multiple regression, using a fully adjusted model, was conducted for physical (see Table 4.8) and mental health-related quality of life (see Table 4.9).

**Physical Health-related quality of life.** A summary of the regression coefficients is presented in Table 11 and indicated that the number of total active medications remained significant in predicting physical health-related quality of life ($\beta = -.497, p = .012$), while the number of therapeutic drug classes ($\beta = .156, p = .266$) and medication regimen complexity ($\beta = .234, p = .189$) were not associated with physical health-related quality of life after controlling for age, gender, education, race, ethnicity, marital status and cognitive status.

**Mental health-related quality of life.** Regression results (see Table 12) indicate the overall model was not significant, $F(10,105) = 1.182, p = .311$. A summary of the regression coefficients is presented in Table 12 and indicates the total number of active medications ($\beta = .001, p = .996$), the number of therapeutic drug classes ($\beta = -.190, p = .172$) and medication regimen complexity ($\beta = .118, p = .504$) were not associated with
mental health-related quality of life after adjusting for age, gender, education, race, ethnicity, marital status and cognitive status.

**Study Variables and the Demographic Data**

As a final step, attention was focused on the role of the demographic data in relation to the study variables. Differences in the means were examined for demographic characteristics and the study variables. The demographic factors included age, gender, education, race, ethnicity, marital and cognitive status. Both significant and non-significant results were reported for selected variables.

**Health-related quality of life and age.** A one-way between-groups analysis of variance (ANOVA) was conducted to explore the impact of age on health-related quality of life based on the mean scores for physical (PCS-12) and mental (MCS-12) (see Table 9). Subjects were divided into three approximately equal groups according to their age (Group 1: ≤75 yrs, n = 41, Group 2: 76-83 yrs, n = 37, Group 3: ≥84 yrs, n = 39). Equal variances, as noted by non-significant (p > .05) Levene’s test of Homogeneity were present for both PCS-12 and MCS-12 analysis. There was no statistically significant differences in the PCS-12 mean scores across the three age groups: \( F(2, 114) = .074, p > .05 \). In addition, there was no statistically significant difference in the mean MCS-12 scores: \( F(2, 114) = 2.81, p > .05 \).

**Health-related quality of life and gender.** An independent-samples t-test was conducted to compare health-related quality of life physical (PCS-12) and mental (MCS-12) scores for females and males in the study subjects. There was no significant difference in PCS-12 scores for females (\( M= 30.8, S.D = 7.6 \)) and males (\( M= 32.6, S.D = \))
7.6; \( t(115) = -1.1, p = .27, \) two-tailed). The magnitude of the differences in the means
(mean difference = -1.78, 95% CI: -4.99 to 1.42) was small (eta squared = .01) according
to Cohen's (1988) guidelines. There was no significant difference in the MCS-12 scores
for females (\( M = 46.9, S.D = 10.5 \)) and males (\( M = 48.3, S.D = 10.54; \) \( t(115) = -.608, p = \)
.54, two-tailed). The magnitude of the differences in the means (mean difference = -1.3,
95% CI: -5.7 to 3.07) was very small (eta squared = .003).

**Health-related quality of life and ethnicity.** An independent-samples t-test was
conducted to compare health-related quality of life physical (PCS-12) and mental (MCS-
12) scores for Hispanic and non-Hispanic study subjects. There was no significant
difference in PCS-12 scores for Hispanics (\( M = 31.2, S.D = 7.1 \)) and non-Hispanics (\( M =
31.2, S.D = 9.1; \) \( t(115) = -.019, p = .98, \) two-tailed). The magnitude of the differences in
the means (mean difference = -.021, 95% CI: -3.13 to 3.07) was very small (eta squared =
.001) according to Cohen's (1988) guidelines. There was no significant difference in
MCS-12 scores for Hispanics (\( M = 47.6, S.D = 10.4 \)) and non-Hispanics (\( M = 46.6, S.D =
10.9; \) \( t(115) = .468, p = .64, \) two-tailed). The magnitude of the differences in the means
(mean difference = 1.0, 95% CI: -3.2 to 5.2) was very small (eta squared = .003).

**Medication-Related Variables and Age**

**Medication Regimen Complexity Index and Age.** An ANOVA was conducted
to explore the impact of age on medication regimen complexity as measured by the
MRCI tool. Subjects were divided into three groups according to age (Group 1: ≤75 yrs,
\( n = 41 \), Group 2: 76-83 yrs, \( n = 37 \), Group 3: ≥84 yrs, \( n = 39 \)). The results revealed
statistically significant mean differences in medication complexity based on age, \( F(2, \)
120) = 3.419, \( p = .036 \). All groups were close to but not equal in numbers and ranged from \( n = 37 \) (76 – 83 yrs) to \( n = 41 \) (≤ 75 years). When cell size are unequal, at test of homogeneity should be confirmed (Polit & Beck, 2012). Equal variances, as noted by non-significant \( (p > .068) \) Levene’s test of Homogeneity of Variances were present. The difference in the mean scores approached a moderate effect based on Cohen’s (1988) classification terms of effect size. The effect size, calculated using eta squared, was .05. Post hoc comparisons (Tukey) indicated that the mean score for Group 1 \( (M = 22.9, S.D = 10.5) \) was statistically significantly different \( (p < .05) \) from Group 3 \( (M = 16.9, S.D = 8.2) \). Group 2 \( (M = 22.2, S.D = 14.8) \) did not differ significantly from either Group 1 or 3.

**Summary of Results**

In this chapter, a demographic analysis of the sample characteristics and descriptive statistics for all independent and dependent study variables were discussed. Main analysis of the research hypotheses revealed that the total number of medications was predictive of physical health-related quality of life. This finding indicates that for every unit increase in medication, physical health-related quality of life decreases by .5, interpreted to mean that people taking more medications will have a decrease in physical health-related quality of life. Simple regression analyses revealed that therapeutic drug class and medication regimen complexity were not associated with physical health-related quality of life. In addition, multiple regression analysis revealed that the total number of active medications, therapeutic drug class and medication complexity were not associated with mental health related quality of life.
Analysis of variance (ANOVA) revealed that mean medication regimen complexity scores were significantly different based on age. Younger adults (aged 75 years or younger) had higher mean medication complexity scores on the MRCI than adults aged 84 years and older.
Table 4.8 Regression of Total Number of Active Medications, Number of Therapeutic Drug Classes, and Medication Regimen Complexity Index on Physical Health-Related Quality of Life in older adults receiving H&CBS in Washington Heights and Inwood, NY, 2007-2008.

<table>
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<th>Adjusted*</th>
<th></th>
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<td></td>
<td>ß Coefficient</td>
<td>P value</td>
<td>ß Coefficient</td>
<td>P value</td>
</tr>
<tr>
<td>Total Active Medications</td>
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<td>0.046</td>
<td>-0.186</td>
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<td>Age, years</td>
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<td>0.694</td>
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<td>Gender, Female</td>
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<td>Number of Therapeutic Drug Class (TDC)</td>
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<tr>
<td>Medication Regimen Complexity Index (MRCI)</td>
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<td>0.387</td>
<td>-0.074</td>
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<td>Total Active Medications, Total Number of TDC, MRCI</td>
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<td>TDC</td>
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Note. * Adjusted for all variables listed. TDC = Therapeutic Drug Class. MRCI = Medication Regimen Complexity Index
### Table 4.9 Regression of Total Number of Active Medications, Number of Therapeutic Drug Class, and Medication Regimen Complexity Index on Mental Health-Related Quality of Life in older adults receiving H&CBS in Washington Heights and Inwood, NY, 2007-2008.

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<th>Adjusted*</th>
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<td>ß Coefficient</td>
<td>P value</td>
<td>ß Coefficient</td>
<td>P value</td>
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<tr>
<td><strong>Total Number of Active Medications</strong></td>
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<tr>
<td>Total Active Meds</td>
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<td>.279</td>
<td>-.041</td>
<td>.676</td>
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<tr>
<td>Age, years</td>
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<td>.012</td>
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<td>Gender, Female</td>
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<td>Education, years</td>
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<td>Race, White</td>
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*Note.* *Adjusted for all variables listed. TDC = Therapeutic Drug Class. MRCI = Medication Regimen Complexity Index.*
Chapter V

Discussion

This chapter discussed the results of this study based on: (a) the six research hypotheses within the context of findings and related literature, (b) integration of the theoretical rationale, (c) study sample characteristics, (d) ancillary findings, and (e) a review of the strengths and limitations of the research.

Overview of the Study

Medication regimens for each subject were examined in detail. Regression analysis, controlling for age, gender, education, race, ethnicity, marital status and cognitive status, determined that the number of active medications was a key predictor of physical health-related quality of life but was not associated with mental health-related quality of life. Therapeutic drug class and medication regimen complexity were not associated with either physical or mental health-related quality of life. This was the first study that explored these medication-related independent variables together in the context of health-related quality of life within a community-dwelling, minority older adult population receiving long-term services and supports.

First Hypotheses (H1a and H1b)

This study hypothesized that the number of active medications would be associated with physical and mental health-related quality of life before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status. The data from the study determined that the number of active medications predicted physical health-related quality of life before controlling for the covariates and remained
significant in a fully adjusted model. For every unit increase in the number of active medications, physical health-related quality of life decreases by 0.5. In other words, older adults who take more medications have a decrease in physical health-related quality of life. The number of active medications was not associated with mental health-related quality of life before or after controlling for covariates.

The National Center for Health Statistics (NCHS) (2010) reported trends in prescription drug use continue to increase among older adults (aged 60 and over) with 88% using at least one prescription drug per day. More than 76% use two or more prescription drugs and 37% use five or more. 17% of men and 19% of women use at least ten medications on a regular basis (Slone Survey, 2006). Overall women use more prescription drugs than men and non-Hispanic whites have the highest prescription drug use when compared the Mexican-American population who have the lowest utilization (NCHS, 2010). Comparatively, the data from this study indicated the average number of medications was 9.3 with a range from 2 to 19. Females used an average of 9.6 medications and males used an average of 8.2. Hispanics used an average of 9.2 medications and non-Hispanics used an average of 9.3. The results indicate a higher degree of medication use when compared to the national data for age, gender and ethnicity.

The use of multiple medications, also known as polypharmacy, in older adults has been widely recognized in several studies to increase drug related problems affecting patient safety (Elliot et al., 2013; Institute of Medicine [IOM], 2006; Liu, Manias, & Gerdtz, 2010), quality of care (American Geriatrics Society [AGS], 2012a; AGS, 2012b;
Roth et al., 2009), decline in functional status, avoidable hospitalizations and increased health-care costs (Budnitz et al., 2011; Slabaugh et al., 2010; Tinetti et al., 2014). Yet gaps exist as few studies have explored the relationships of multiple medication use and health-related quality of life in community-dwelling older adults. There were no studies found that examined medication regimens of community-dwelling minority older adults to the level of detail conducted in this study. The findings of the current study support others showing that the number of medications used in older adults was a significant predictor of physical health-related quality of life.

Francic & Jiang (2006) investigated the relationship between potentially inappropriate medication use and two generic health-related quality of life measures, the SF-12 and EuroQol’s EQ-5D. Using a longitudinal retrospective cohort design, the researchers conducted secondary analysis of adults 65 years of age and older who were part of the national 1996 Medical Expenditure Panel Survey (MEPS). The study found that the number of drugs prescribed was a significant predictor of health-related quality of life for PCS-12 ($r = -.237$) and EQ-5D VAS ($r = -.361$) which indicated that a higher number of prescribed medications predicted poor physical health-related quality of life.

Additionally, a large study ($N = 1099$) using secondary analysis from the Consumer Assessment Study included frail community-based older adults with an age range from 60 to 106 years of age, 73% female and 80% White (Classen, Mann, Wu, & Tomita, 2004). The study examined the relationship between the number of medications and functional status, and health-related quality of life. The average number of medications was 5.4 (S.D 3.8) from 13 different drug classes. Two global self-rated quality of life questions were asked, but were lacking validity or reliability measurement
data. The findings indicate that increased age, increase number of chronic diseases and decrease in health were all associated with higher numbers of medications. The lack of psychometric properties for the health and quality of life questions were of concern in this study. The average number of medications was lower (5.4) compared to the current study (9.3).

In two smaller cross-sectional studies, findings indicated significant associations between polypharmacy and physical health-related quality of life. Sorensen et al. (2005) reported poor patient outcomes to include decrease in physical health-related quality of life in community-based study of older adults ($N=204$) living in Australia. The sample average age was 72.4 years and 61% female. Patients self-reported taking on average of 9.9 medications during office visits. When home visits were conducted by clinicians, the average number of medications found in the home increased to 14.7. Medication-related risk factors identified included the total number of medications, having no established routine for medication administration, recent reports of adverse drug events (ADE), therapeutic duplications, hoarding medications, and lack of knowledge regarding brand name versus generic. The medication-related factors related to decrease in physical health-related quality of life (measured by the SF-36 PCS) and severity of illness included an increased in number of medications ($p<.001$), recent ADEs and therapeutic duplications.

Likewise, Henderson et al. (2006) examined the association of polypharmacy and health-related quality of life in a small sample ($N=63$) of community-dwelling American Indians aged 50 years and older. The average number of medications was 9.8 for males and 10 for females with a range from 4 to 19. Health related quality of life was measured
by the MOS SF-36 PCS and MCS scores. The PCS score ($r = -.91, p = .045$) was associated with the degree of polypharmacy before and after controlling for age, gender and chronic disease. The current study is similar in the average number and range of medications, although the demographic characteristics differ in age and ethnicity.

Cleary & Howell (2007) examined prescription drug use and health-related quality of life in rural adults aged 65 years and older ($N = 43$). The sample was 98% White with an average age of 78 years. The mean number of medications was 3.6 Health related quality of life was measured by the SF-36 PCS and MCS scores. The study found no significant association between PCS and MCS and the number of medications.

The existing research suggests that older adults who take more medication have a decrease in physical health-related quality of life. Research specifically examining the relationships between medication use and health-related quality of life among predominately Hispanic older adults has not been widely studied. The findings of this study support current evidence and expand the demographics with the inclusion of an ethnic population (68% Hispanic). This study strengthens the evidence regarding the potential negative impact of multiple medication use can have in older adults.

**Second Hypotheses (H2a and H2b)**

It was hypothesized that the number of therapeutic drug classes would be associated with physical and mental health-related quality of life before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status. The data suggested that the number of therapeutic drug classes was not associated with either physical or mental health-related quality of life before and after controlling for the covariates.
The majority of literature investigating therapeutic drug classes is related to the risk of adverse drug events as a result of specific drug classes. Several studies support the contribution of specific drug classes to increase risk of falls (Tinetti et al., 2014), confusion, and adverse drug events (AGS, 2012a; Choudry et al., 2011). Many preventable adverse drug events are associated with cardiovascular drugs, non-opioid analgesics, hypoglycemic agents, anticoagulants, and opioids (Bopari & Korc-Grodzicki, 2011; Gurwitz et al., 2003). Budnitz et al. (2011) found adults aged 65 years and older were admitted for emergency hospitalizations as result of four common medications and medication classes taken either alone or combination: warfarin (33.3%), insulins (13.9%) oral anti-platelet agents (13.3%) and oral hypoglycemic agents (10.7%). Hospitalizations resulting from hematologic agents were for acute hemorrhages (71.3%) and almost all hospitalizations due endocrine agents were a result of hypoglycemia (94.6%).

Some studies have explored the relationship of specific drugs or drug classes and health related quality of life in community-dwelling older adults aged 65 years and older including: treatment of high cholesterol with cholesterol lowering drugs (Carlsson, Papcke-Benson, Carnes, McBride, & Stein, 2002), and older and younger adults with insulin-treated diabetes (Trief, Wade, Pine, & Weinstock, 2003). Carlsson et al. (2002) used a double-blind RCT design in a small sample (N=41) and measured the Global Health Perception Question. Findings determined health-related quality of life scores did not change after 12 months of therapy with cholesterol lower agents. Trief et al. (2003) examined health-related quality of life measured by the SF-36 PCS and MCS scores and found when compared to a younger cohort, older adults with insulin-treated diabetes encountered more decline in physical health-related quality of life, but revealed higher
mental health-related quality of life with better coping and social supports that may account for reduced levels of distress related to diabetes.

Holt et al. (2010) examined health-related quality of life and antihypertensive medication adherence in a large cohort (N = 2,180) of community-dwelling older adults aged 65 and older. The average age of the participants was aged 75 years, 70% were white, 58.5% were women and 14% had low medication adherence. Health-related quality of life was measured using the MOS SF-36 tool. Lower physical and mental health-related quality of life was associated with decreased antihypertensive adherence.

The most frequently prescribed medications used by American older adults, aged 60 and over, are cardiovascular agents to treat high blood pressure, heart disease and high cholesterol including: (a) diuretics 19.9%, (b) beta-blockers 26.4%, and (c) cholesterol-lowering drugs 44.9% (NCHS, 2010). The fact that close to 40% of older Americans use five or more medications a day reflects the degree of co-morbidity that regularly occurs in this age group. Qato et al. (2008) determined community-dwelling older adults are the largest consumers of prescription and over the counter medications along with dietary supplements, which are often all used concurrently. As a result, an estimated 1 in 25 older adults are at risk for significant drug to drug interactions.

This study determined the average number of therapeutic drug classes was 4.89 with a range from 2 to 8. The five most frequently used drug classes were: cardiovascular agents (97%), central nervous system agents (94%), nutrients and nutritional agents (63%), gastrointestinal (60%) and endocrine and metabolic agents (59%). These findings are similar to what is described in the literature and expands the types of therapeutic drug.
classes most frequently used in older adults receiving home and community-based services.

**Third Hypotheses (H3a and H3b)**

It was hypothesized that medication regimen complexity would be associated with physical and mental health-related quality of life before and after controlling for age, gender, education, race, ethnicity, marital status and cognitive status. The data suggested that medication regimen complexity was not associated with either physical or mental health-related quality of life before and after controlling for the covariates. Medication regimen complexity data revealed an average total score of 20.6 with a range from 3 to 69. The greatest contributor to the MRCI total score was dosing frequency with an average score of 13.4 and a range from 2 to 38. The results support similar findings for mean MRCI scores in a similar population (McDonald, et al., 2012).

Medication regimen complexity measurement is an emerging area of interest and research including: predictive risk for hospitalization and readmission (Elliott, O’Callaghan, Paul, & George, 2013; Willson, Greer, & Weeks, 2014), chronic disease management (Libby et al., 2013; Rettig, Wood, & Hirsch, 2013), medication adherence (Choudry et al., 2011; Witticke, Seidling, Lohmann, Send, & Haefeli, 2013), patient preference (Witticke, Seidling, Klimm, & Haefeli, 2012), and decision support technology (McDonald et al., 2012).

Although medication regimen complexity was not associated with either physical or mental health-related quality of life, this study advances the use of MRCI tool in community-dwelling older adults, which has not been widely studied in home care populations. In addition to assessing the total number of medications, quantifying the
medication regimen provides a more nuanced way of determining potential challenges and risks associated with complex regimens in community-dwelling older adults (McDonald et al., 2012).

**Theoretical Rationale**

Wilson and Cleary’s (1995) health-related quality of life conceptual model provided the theoretical framework for this interpretation (see Figure 1). This study examined components of health-related quality of life by testing Wilson and Cleary’s model in community-dwelling older adults who were receiving long-term services and supports. According to the Wilson and Cleary model, measures of health exist along a continuum moving from biological measures at one end of the continuum to overall quality of life at the other, and theorizes bidirectional relationships among the domains. The Wilson and Cleary model distinguishes components of health-related quality of life from a conceptual standpoint within five domains (biological and physiological factors, symptom status, functional status, general health perceptions, and overall quality of life). Moving in the model from left to right, the domains of each level become more complex for the clinician to determine and measure. The “inputs” as the model progresses, are often not within the control of the clinician or health care system (patient preference, role of emotional or psychological factors) (Wilson & Cleary, 1995, p.63). The characteristics of the individual and the environment are overarching factors that affect all five domains. Individual characteristics commonly associated with illness are age, gender, race, ethnicity and marital status (Ferrans et al., 2005). This study proposed to test the theoretical linkages of the model components to include: biological and physiological factors (medication-related factors: number of medications, number of therapeutic
classes, and medication regimen complexity) and overall quality of life (MOS SF-12 PCS-12 and MCS-12). Individual characteristics selected for inclusion were: (a) age, (b) gender, (c) education, (d) race, (e) ethnicity, (f) marital status and (g) cognitive status. Regression analysis determined that the number of active medications were predictive of physical health-related quality of life before and after controlling for individual characteristics (age, gender, education, race, ethnicity, marital status and cognitive status). Individuals who take more medications have a decrease in physical health-related quality of life. None of the medication-related factors were associated with mental health-related quality of life before or after controlling for individual characteristics (age, gender, education, race, ethnicity, marital status and cognitive status).

### Study Sample Characteristics

Significant risk factors, based on demographic characteristics, have been associated with medication safety in older adults who are aged 65 years and older, have less than a high school education, a minority, non-English speaking, have low incomes or are unemployed (Health Research & Education Trust, Institute for Safe Medication Practices, and Medical Management Association [HRET, ISMP, & MGMA], 2008; Lindenberg, 2010). The study sample reflected several of these risk factors to include: (a) an average age of 79 years, with a range from 63 to 97 years, (b) 59% eighth grade education or less ($n = 72$), (c) 68% ($n = 84$) Hispanic, 35% Black or African American ($n = 35$).

### Ancillary Analysis

Differences in the level of medication complexity based on age were reported. Older adults aged 84 years and older demonstrated less medication complexity when
compared with adults aged 75 years and younger. These differences may be as a result of having chronic illness at a younger age with greater severity of illness that requires more medications. In addition, goals of care may shift from aggressive, curative management towards an approach of comfort and palliation interventions requiring decreased medication use.

Additional analysis was conducted to determine whether there were significant differences in demographic data related to the main study variables. There were no significant differences in either physical or mental health-related quality for age, gender or ethnicity. There were no significant differences in the total number of medications, therapeutic drug classes, or medication complexity for gender and ethnicity.

**Strengths and Limitations of this Study**

This was the first study to examine three medication-related variables, the number of active medications, the number of therapeutic drug classes, and medication regimen complexity and the association of health-related quality of life in a population at risk for potential medication-related issues. The findings from this study contributed to health-related quality of life research in older adults with long-term health needs. In addition, it expanded the growing body of research related to medication regimen complexity measurement with strong inter-rater reliability and relevance to clinical practice for patients receiving home-based care. The use of secondary data facilitates the generation of new knowledge maximizing existing data and is both economical and efficient.

**Limitations**
The sample size was small, predominately female (75%), Hispanic (68%), in one urban setting which makes it difficult to generalize the findings. Use of secondary analysis presents limitations because variables and instruments are defined by the primary study. Additional collection of medication data required re-identification of the dataset. Cross sectional design allows measurement of variables at a single point in time but does not allow for analysis of direction of associations or changes over time.
Chapter VI

Implications, Recommendations and Conclusions

Evidence is limited to date linking medication-related variables to include taking multiple medications, using multiple therapeutic drug classes and complex medication regimens in older adults. There is scant research regarding these characteristics and their relationship to health-related quality of life. Findings from this study determined that the use of multiple medications was associated with a decreased physical health-related quality of life in older adults receiving home and community-based services. Several studies have identified community-based older adults as the highest consumers of medications and as a result are at higher risk for poor health outcomes that are medication-related. Community health nurses can play a significant role in helping patients manage complex medication regimens, and reduce potential drug related problems to include simplifying medications. Home visits are critical when determining specific medication related risk factors may be exist that are not apparent based on patient self–reporting alone (Sorensen et al., 2005).

Implications

The findings from this study generated several implications for nursing practice and education. Additionally, recommendations in the arenas of public policy and future research are elucidated from this research.

Nursing Practice Implications

Health plays a central role in nursing and is one of the key metaparadigm components (Sousa & Williamson, 2003). Evaluating health-related quality of life in
older adults should be embedded as a standard of nursing practice. Identifying the health needs of older adults improves understanding of their responses to disease states as well as to prescribed treatments including medications and the impact that disease and medical treatments have on daily life activities from the perspective of the individual, rather than the nurse. Incorporating health-related quality of life assessment into clinical practice provides greater understanding of patients' responses and their self-perception of health to include the impact of taking multiple medications (Borglin et al., 2005; Guyatt, et al., 2007; Singh & Dixit, 2010; Sousa & Williamson, 2003).

**Community Health Nursing.** Plain and simple, caring for older adults who wish to remain in their own home, but require long term services and supports (LTSS) to do so, is complex and challenging on several levels. Understanding the current LTSS landscape and future growth and demand for these services (as a result of the “Baby Boomer” generation growing older), is a call to action for nursing, but significantly so for nurses who provide and manage care for older adults in community-based settings. The fact that 89% of Americans aged 50 years and older want to remain in their own homes for as long as possible and an estimated 5 million older adults are in need of this level of care (AARP Public Policy Institute, 2011) posits nursing care in communities in a crucial position. Community health nurses (CHNs) can develop, provide and improve care that is patient-centric, high quality and cost efficient for older adults who often have complex clinical and psychosocially needs often compounded by polypharmacy and medication regimen complexity.

Community health nurses (CHNs) play a significant role in helping patients manage complex medication regimens, and in particular those patients with chronic long-
term needs that require long term service and supports who wish to remain at home (IOM, 2010). A key driver for nursing home admissions is the often the inability to self manage complex medication regimens.

There are several implications for CHNs that may reduce medication complexity and decrease the risk for adverse drug events with the potential to improve a patient’s health related quality to include:

- A first step in reducing medication regimen complexity is to identify patients with medication complexity. The ability for clinicians to easily identify complex medication regimens through the use clinical support tools such as the MRCI tool has not been widely studied in home-based settings. This study advanced the use of MRCI tool in home care setting looking at older adults with chronic illness
- The use of a paper-based MRCI tool is not pragmatic in a community-based setting; the development of an electronic MRCI tool would be optimal for practice settings (McDonald et al., 2012)
- Employ the use of medication simplification using a stepwise approach. This process involves a thoughtful approach to reducing and simplifying medications to include: a) using long-acting forms of medication, b) use of one pharmacy provider, c) discard old or discontinued medications, d) provide alternatives to medication therapy, e) decrease the use of multiple drug treatment for a single condition, f) discontinue or reduce medication whenever possible, and g) schedule medications times with daily routines (e.g. brushing teeth, eating a meal) (Home Health Quality Improvement Campaign, 2007)
- Fostering inter-professional partnerships with multiple disciplines to include medical providers, community pharmacists, social workers, nutritionists, physical therapists with a focus for improved communication regarding medication management and best practice
- Consideration and assessment of older adults preference for treatment choice, in particular those patients with multiple conditions (co-morbidities); identify the patient’s goals of care and align treatment accordingly
- Explore patient experiences regarding their medication regimens. Providing an environment to allow patients to share their perceptions about their medications enhances a patient-centered approach to care from the patient’s perspective
- Identify and administer a health-related quality of life measurement tool as part of nursing assessment at regular intervals to measure change over time and determine precipitating event of decline

**Advanced Practice Nursing.** Home-based primary care services provided to community-dwelling older adults by Nurse Practitioners (NPs) is an area with significant potential to improve care. By assessing health-related quality of life and medication use, NPs practicing in full scope can work with older adults to establish patient-centric plans of care that reflect optimum use of therapeutic agents while minimizing harm and improving health-related quality of life. NPs can ‘unpack’ the different complex layers of medication regimens by using a comprehensive approach when assessing the quality of medication use in community-dwelling older adults. By using evidence-based practice, NPs ensure the rational use of medications that are appropriate based on individual
clinical needs in doses that are therapeutic and by simplifying the medication regimen to minimize risk and reduce adverse events and ultimately improve health-related quality of life outcomes (George & Jacobs, 2011; Lindenberg, 2010; World Health Organization, 2010). NPs are well situated to better understand the burden an older adult may experience when taking multiple medications at varied times with different requirements and how this burden affects their day-to-day routine such as increased urination, bothersome side effects and the overall impact on their health-related quality of life. Identifying ways to develop and support greater access to NP-led primary care for this population needs enhancement. Since the number of active medications was the only predictor of physical health-related quality of life, it is imperative to ensure that older adults are the taking the absolute minimum number of medications needed to maintain health.

**Enhancing Patient-Centered Care.** Understanding the patient’s perspective and their preferences regarding medication-related factors to include the number of medications and the frequency they require is an important implication from this study. The use of medication should begin with shared-decision making process between the patient and the prescriber based on the individual’s preferences and goals of care. Nurses practicing in home and community-based settings have an ideal opportunity to educate and empower patients to become active participants in their care to include reducing the number of medications at less frequent intervals.

**Public Policy Implications**
**Long Term Services and Supports.** The cost of LTSS is expensive for all levels of care to include nursing homes, assisted living facilities, and home community-based care services (HCBS) (Kaiser Commission on Medicaid & the Uninsured, 2013). LTSS is primarily funded by Medicaid with 73% of the costs spent on LTSS provided in nursing homes, the most expensive level of LTSS, while only 27% is spent in HCBS, which is the least expensive level of LTSS (AARP Public Policy Institute, 2009). Public policy reform need to continue to support the expansion HCBS LTSS options that provide patient-centric quality care that is cost efficient.

**Future Research Recommendations**

As a result of advances in medical science, many older Americans are living longer with chronic conditions including heart disease, diabetes and asthma. Many chronic conditions require long-term medication management and as a result, the focus on health-related quality of life will become an increasingly important outcome measure. Determining predictors of health-related quality of life, and in particular identifying predictors that may be modifiable (e.g. reducing the number of daily medications) to improve health-related quality of life need further investigation. Further research is required to identify methods to translate health-related quality of life measures into useful clinical decision support tools to include a focus on the patient’s perceptions of treatment. The recommendations for future research are as follows:

- Conduct a qualitative study to explore patient preference for medication regimen characteristics in a sample with characteristics similar to this study sample. The aim would be to explore how patients relate their health and use of medication to
include the use of alternative treatments to include folk medicine and complementary and alternative medicine (CAM).

- Develop clinical guidelines for older adults with multiple co-morbidities particularly in the presence of cognitive impairment aimed at simplifying regimens rather than complicating them (American Geriatrics Society, 2012a; 2012b; Boyd et al., 2005)

- Hold providers accountable to practice rationale prescribing. Use of rational prescribing (Crigger & Holcomb, 2008; Lindenberg, 2010) guides clinicians to provide individuals with the appropriate medications to meet their clinical needs, at the minimal required doses for the shortest duration possible, provided at the lowest costs available

- Develop automated MRCI and health-related quality of life clinical decision support tools that can be standardized for use across multiple health-care settings shared among multiple providers

**Conclusions**

Evaluation of medication use is evolving from simply counting the number of drugs to more precise medication-related factors such as therapeutic drug class, evidence of therapeutic effects and the degree of regimen complexity (Gnjidic et al., 2013). Older adults experience significantly higher rates of adverse drug events (ADRs) and as a result experience higher rates adverse outcomes to include falls, hospitalizations, delirium, and functional decline (Tinetti et al., 2014). As a result, health-related quality will often decline as well (Henderson et al., 2005; Sorensen et al., 2005). This study contributed to the evidence of medication use and health-related quality of life in older adults.
APPENDICES
Appendix A

Active Medication List

<table>
<thead>
<tr>
<th>Med Name</th>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Appendix B

HRQoL Subject Information Form

HRQoL Subject Information Form - VNSNY

Interviewer ID: [ ]
Subject ID: [ ]

Contact Date: [ ] / [ ] / [ ]
Entry/Admission Date or Start of Service Date: [ ] / [ ] / [ ]

Sex: O Male O Female
Age: [ ]
Years of Education: [ ]
Speaks English and/or Spanish: O Yes O No

Race: O White
O Black or African American
O Asian
O Native Hawaiian or Pacific Islander
O American Indian or Alaskan Native
O Other: [ ]
O No Response

Hispanic/Latino: O Yes O No (not asked)

Did respondent correctly repeat all three words (apple-table-penny): O Yes O No (not asked)
1. What year is this?
2. What month is this?
3. What is the day of the week?
4. Apple
5. Table
6. Penny

# Correct [ ] [only score items #1-6]

WMSE Score: [ ] (VNSNY Completed)

Is subject eligible? O No O Yes
Does subject wish to participate? O No O Yes

If yes to both questions, when is the best time to be visited?

If no, why? (Please explain reason for refusal. For example: lack of interest, too busy, too ill, etc.)

Pertinent subject information (for example: macular degeneration, call before ringing doorbell):

Subject signed consent form? O Yes O No
Responsible party signed consent form? O Yes O No O N/A
Responsible party gave verbal consent? O Yes O No O N/A
MMSE

Now, I would like to ask you some questions to check your memory and concentration. Some of them may be easy and some of them may be hard.

1. What is the year?  O Correct  O Incorrect  O Not Assessed
2. What is the season?  O Correct  O Incorrect  O Not Assessed
3. What day of the week is it?  O Correct  O Incorrect  O Not Assessed
4. What is today's date?  O Correct  O Incorrect  O Not Assessed
5. What month is it?  O Correct  O Incorrect  O Not Assessed
6. What city are we in?  O Correct  O Incorrect  O Not Assessed
7. What state are we in?  O Correct  O Incorrect  O Not Assessed
8. What building is this?  O Correct  O Incorrect  O Not Assessed
9. What floor are we on?  O Correct  O Incorrect  O Not Assessed
10. What county are we in?  O Correct  O Incorrect  O Not Assessed

11. I am going to name 3 objects. After I have said them I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Allow one second between speaking each one. Then ask the subject to name all 3 objects after you have said them. Give one point for each correct answer. Repeat as needed, count trials and record the number. Up to 3 trials considered correct. After 5 trials, move on to next question.

   # of TRIALS:  [Blank]

   HAT  O Correct  O Incorrect  O Not Assessed
   CAR  O Correct  O Incorrect  O Not Assessed
   TREE  O Correct  O Incorrect  O Not Assessed

12. Now I am going to ask you to spell the word WORLD backwards. [Repeat if necessary, and help subject spell word forward, if necessary.]

   Spell the word WORLD backwards:  [Blank] (3 points)  TOTAL:  [Blank]

13. Now what were the 3 objects I asked you to remember?

   HAT  O Correct  O Incorrect  O Not Assessed
   CAR  O Correct  O Incorrect  O Not Assessed
   TREE  O Correct  O Incorrect  O Not Assessed
14. (Show WRIST WATCH) What is this called? □ Correct □ Incorrect □ Not Assessed
   (Show PENCIL) What is this called? □ Correct □ Incorrect □ Not Assessed

[Interviewer note: if you do not have the items listed above, you can substitute eyeglasses, a chair, keys, or other common objects. Please note what was substituted in the text box below.]

15. I would like you to repeat a phrase after me: "NO IF'S, AND'S OR BUT'S" [Allow only one trial] □ Correct □ Incorrect □ Not Assessed

15. Next, I am going to give you a piece of paper, when I do I would like you to take it in your right hand, fold the paper in half and place it in your lap. [Hand over piece of paper, do not coach.]
   RIGHT HAND: □ Correct □ Incorrect □ Not Assessed
   FOLDS IN HALF: □ Correct □ Incorrect □ Not Assessed
   PLACES IN LAP: □ Correct □ Incorrect □ Not Assessed

17. Read the words on this page, then do what it says. Interviewer note: the paper reads: "CLOSE YOUR EYES." Code correct if subject closes eyes. Do not coach and do not read what it says. □ Correct □ Incorrect □ Not Assessed

18. Please write a sentence. □ Correct □ Incorrect □ Not Assessed

19. Please copy the design. □ Correct □ Incorrect □ Not Assessed

TOTAL Score: □

If a question is marked Not Assessed, please explain below:

____________________________________________________________________________________
____________________________________________________________________________________
# Baseline

**Health Related Quality of Life Chart Abstraction Tool**

Date of Enrollment in Service to Date of Enrollment in Study

<table>
<thead>
<tr>
<th>Abstraction Date</th>
<th>Date of Admission</th>
<th>Date of Enrollment</th>
<th>abstractor ID</th>
<th>Time to complete abstraction in minutes</th>
</tr>
</thead>
</table>

**Type of Insurance**

- O No  O Yes Medicaid
- O No  O Yes Medicare Plan A only (hospitalization)
- O No  O Yes Medicare Plan A and B (hospitalization and doctor's bills)
- O No  O Yes Other Insurance - specify

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
<th>Year</th>
</tr>
</thead>
</table>

**Biological Status**

Collect the data from the most recent assessment - or closest to the specific baseline/follow up date

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
<th>Blood Pressure</th>
<th>Blood Sugar (fasting)</th>
<th>Blood Sugar (other, if avail.)</th>
<th>Hemoglobin A1C (diabetes)</th>
<th>BUN (Blood Urea)</th>
<th>Cre (Creatinine)</th>
<th>Alb (Albumin)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ft</td>
<td>lbs</td>
<td>mmHg</td>
<td>mg/dL</td>
<td>mg/dL</td>
<td>HgbA1C</td>
<td>g/dL</td>
<td>g/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

O Not Available
Appendix D

Medical Outcomes Study Short Form (SF-12 v.2)

Page 1

Medical Outcome Study - Short Form (SF-12 v.2)

For this section of the interview I am going to ask you some questions about how your health affects some of your daily activities.

[Read each question aloud and read the responses aloud. Instruct patient to choose a response. Fill in the corresponding response. For patients that have difficulty understanding questions, break questions into two parts.]

Part One: YES/NO QUESTIONS (e.g. During the past week have you been limited in the kind of work or regular daily activities you do as a result of your physical health?)

Part Two: HOW MUCH QUESTIONS (e.g. How much has this happened in the past week)

1. In general, would you say your health is: [Key p. 15]
   - O Excellent
   - O Very good
   - O Good
   - O Fair
   - O Poor

The following questions are about activities you might do during a typical day.

2a. Does your health now limit you in performing moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? Does your health now limit you a lot, limit you a little, or does not limit you at all? [Probe: if respondent says he/she does not do activity ask "Is that because of your health?" Key p. 16]

   - O Yes, limited a lot
   - O Yes, limited a little
   - O No, not limited at all

2b. Does your health now limit you from climbing several flights of stairs? Does you health now limit you a lot, limit you a little, or does not limit you at all? [Probe: If respondent says he/she does not do activity ask if that because of your health?]

   - O Yes, limited a lot
   - O Yes, limited a little
   - O No, not limited at all

3a. During the past week, how much of the time have you accomplished less than you would like as a result of your physical health? [Key p. 17]

   - O All of the time
   - O Most of the time
   - O Some of the time
   - O A little of the time
   - O None of the time

3b. During the past week how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health?

   - O All of the time
   - O Most of the time
   - O Some of the time
   - O A little of the time
   - O None of the time
4a. During the past week how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

4b. During the past week how much of the time did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

5. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)? [Key p. 18]
   - Not at all
   - A little bit
   - Moderately
   - Quite a bit
   - Extremely

6a. How much of the time during the past week have you felt calm and peaceful? [Key p. 19]
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

6b. How much of the time during the past week did you have a lot of energy?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

6c. How much of the time during the past week have you felt downhearted and depressed?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

7. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time
### Appendix E

**Medication Regimen Complexity Index**

**Page 1**

#### Table: Medication Regimen Complexity Index

<table>
<thead>
<tr>
<th>Dosage Forms</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>Capsules/Lozenges</td>
<td>1</td>
</tr>
<tr>
<td>Capsules/Suppositories</td>
<td>2</td>
</tr>
<tr>
<td>Capsules/Liquids</td>
<td>2</td>
</tr>
<tr>
<td>Tablets/Granules</td>
<td>2</td>
</tr>
<tr>
<td>Sublingual/Transdermal</td>
<td>2</td>
</tr>
<tr>
<td>INHALATION</td>
<td></td>
</tr>
<tr>
<td>Metered dose inhalers</td>
<td>4</td>
</tr>
<tr>
<td>Nebulizer</td>
<td>3</td>
</tr>
<tr>
<td>Oxygen Concentrators</td>
<td>3</td>
</tr>
<tr>
<td>Syrups</td>
<td>3</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
<tr>
<td>Syringes</td>
<td>2</td>
</tr>
<tr>
<td>Ears, eyes &amp; nose</td>
<td></td>
</tr>
<tr>
<td>Ear drops/concurrents</td>
<td>3</td>
</tr>
<tr>
<td>Eye drops/concurrents</td>
<td>3</td>
</tr>
<tr>
<td>Nal-decongestant</td>
<td>3</td>
</tr>
<tr>
<td>Nose spray</td>
<td>2</td>
</tr>
<tr>
<td>Oral overlap</td>
<td></td>
</tr>
</tbody>
</table>

A) Circle the weighting corresponding to each dosage form (ONCE ONLY) present in the regimen.

**Notes:**
- ORAL = Oral
- INHALATION = Inhalation
- INJECTION = Injection
- OTHERS = Others

CNH = dry-powder inhaler, MDI = metered dose inhaler.

(continued on page 1375)
Medication Regimen Complexity Index

Appendix II. Medication Regimen Complexity Index (MRCI) (continued)

B) For each medication in the regimen tick a box [✓] corresponding to the dosing frequency. Then, add the no. of [✓] in each category and multiply by the assigned weighting. In cases where there is no exact option, choose the best option.

<table>
<thead>
<tr>
<th>Dosing Frequency</th>
<th>Medications</th>
<th>Total No. of Medications</th>
<th>Weighting</th>
<th>Total Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once daily</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once daily pm</td>
<td></td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twice daily</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twice daily pm</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three times daily</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three times daily pm</td>
<td></td>
<td>1.5</td>
<td></td>
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</tr>
<tr>
<td>Four times daily</td>
<td></td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four times daily pm</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 1/2h</td>
<td></td>
<td>2.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 1/2h pm</td>
<td></td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 3h</td>
<td></td>
<td>3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 4h</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 6h</td>
<td></td>
<td>4.5</td>
<td></td>
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</tr>
<tr>
<td>q 8h</td>
<td></td>
<td>2.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 12h</td>
<td></td>
<td>6.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 24h</td>
<td></td>
<td>3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>q 48h</td>
<td></td>
<td>12.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prn/as</td>
<td></td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On alternate days or less frequently</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen pm</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen &lt;5Shs</td>
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<td>Oxygen ≥5Shs</td>
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<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total for Section B

C) Tick a box [✓] corresponding to the additional directions, if present in the regimen. Then, add the no. of [✓] in each category and multiply by the assigned weighting.

<table>
<thead>
<tr>
<th>Additional Directions</th>
<th>Medications</th>
<th>Total</th>
<th>Weighting</th>
<th>Total Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Break or crush tablet</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disolve table/powder</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple units at one time (e.g. 2 tabs, 2 puffs)</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variable dose (e.g. 1-2 cups, 2-3 puffs)</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take/has at specified times (e.g. morn, night, 9 AM)</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Related to food (e.g. prn, ac, with food)</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take with specific fluid</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take/has as directed</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tapering/maintaining dose</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alternating dose (e.g. one morning &amp; two nights, one two on alternate days)</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total for Section C

Medication Regimen Complexity = Total (A) + Total (B) + Total (C)
### Therapeutic Drug Classification Tool

<table>
<thead>
<tr>
<th>Therapeutic Drug Class</th>
<th>Medication Name (Brand)</th>
<th>Medication Name (Generic)</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cardiovascular</td>
<td>Digoxin</td>
<td>Lanoxin</td>
<td></td>
</tr>
<tr>
<td>2. Central Nervous System</td>
<td>Amitriptyline</td>
<td>Elavil</td>
<td></td>
</tr>
<tr>
<td>3. Endocrine &amp; Metabolic</td>
<td>Metformin</td>
<td>Glucophage</td>
<td></td>
</tr>
<tr>
<td>4. Systemic Anti-Infective</td>
<td>Levofloxacin</td>
<td>Levaquin</td>
<td></td>
</tr>
<tr>
<td>5. Respiratory</td>
<td>Albuterol</td>
<td>Proventil</td>
<td></td>
</tr>
<tr>
<td>6. Hematologic</td>
<td>Clopidogrel</td>
<td>Plavix</td>
<td></td>
</tr>
<tr>
<td>7. Gastrointestinal</td>
<td>Ranitidine</td>
<td>Zantac</td>
<td></td>
</tr>
<tr>
<td>8. Renal &amp; Genitourinary</td>
<td>Spironolactone</td>
<td>Aldactone</td>
<td></td>
</tr>
<tr>
<td>9. Dermatologic</td>
<td>Hydrocortisone</td>
<td>Hydrocort</td>
<td></td>
</tr>
<tr>
<td>10. Ophthalmic &amp; Otic</td>
<td>Timolol 0.5%</td>
<td>Timoptic 0.5%</td>
<td></td>
</tr>
<tr>
<td>11. Biologic &amp; Immunologic</td>
<td>Methotrexate</td>
<td>Rheumatrex</td>
<td></td>
</tr>
<tr>
<td>12. Nutrients &amp; Nutritional</td>
<td>Calcium</td>
<td>Citracel</td>
<td></td>
</tr>
<tr>
<td>13. Other</td>
<td>Glucosamine Sulfate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix G
Demographic Questionnaire

Demographics

These next questions are about you.

1. Sex of participant  ○ Male  ○ Female

2. What is your date of birth?  
   M    M    D    D    Year

2a. Age [Interviewer calculates.]  

3. In what country were you born?  

4. How many years of school did you complete (or highest degree attained)? [Convert degree to years.]  

5. Are you single, married, separated, divorced, widowed?
   [PROBE: If they answer single, ask if they have ever been married.] [Key p. 1]
   ○ Single (never married)  ○ Married  ○ Widowed  ○ Divorced  ○ Separated  ○ Refused

6. Are you Hispanic?  ○ Yes  ○ No

7. What race do you consider yourself? [Key p. 2]
   ○ White
   ○ Black or African American
   ○ Asian
   ○ Native Hawaiian or Pacific Islander
   ○ American Indian or Alaskan Native
   ○ Other  
   ○ No Response

7a. Do you consider yourself part of any particular ethnic group?  ○ Yes  ○ No

7b. If yes, which group? 

8. Do you identify with any particular religion? [Key p. 3]
   ○ None
   ○ Protestant
   ○ Catholic
   ○ Jewish
   ○ Muslim
   ○ Other, please specify  
   ○ Refused
Appendix H

Letter of Permission Dr. M. Naylor

January 7, 2013

Claudia A. Beck, MS, ANP-BC
Director, Clinical Support Services and Education
VNSNY CHOICE Health Plans
1250 Broadway, 3rd Floor
New York, NY 10001

RE: Project title: Examining the association of medication complexity with health-related quality of life in older adults receiving community-based long term services and supports (VNSNY: E07-001)

Dear Claudia,

As the principal investigator of the Health Related Quality of Life: Elders in Long-Term Care (HRQoL) [National Institutes of Health, R01AG025524] research study, I am formally approving your use of this data set for your dissertation work. I understand that you will be conducting a secondary analysis of the VNSNY baseline data set.

It has been a pleasure to work with you and we look forward to hearing about your results and next steps. If you need anything further, please do not hesitate to contact me at any time.

Sincerely,

Mary D. Naylor, PhD, FAAN, RN
Marian S. Ware Professor in Gerontology
Director, NewCourtland Center for Transitions and Health
Direct Tele: (215) 898-6088
Email: naylor@nursing.upenn.edu
Appendix I

Letter of Permission Dr. J. George

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**RE: Permission to use MRCI tool for dissertation**

Johnson George [Johnson.George@monash.edu]

Sent: Monday, March 03, 2014 9:23 PM

To: Claudia A. Beck

Hi Claudia,

Thank you for your interest in using the MRCI.

I am happy to give you permission to use the MRCI in your study with due acknowledgement.

Wish you all the best in your research project.

Best wishes,

Johnson

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**From:** Claudia A. Beck [mailto:CLAUDIA.BECK@vsnv.org]

**Sent:** Tuesday, 4 March 2014 7:10 AM

**To:** Johnson George

**Subject:** Permission to use MRCI tool for dissertation

Good afternoon Dr. George,

My name is Claudia Beck and I am PhD Nursing student at the Graduate Center, City University of New York.

I am writing to ask your permission to use the Medication Regimen Complexity Index (MRCI) tool in my study.

My dissertation research is examining medication factors to include medication regimen complexity with health-related quality of life in older adults.

I look forward to hearing from you and appreciate your support in advance.

Sincerely,

Claudia A. Beck

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https://secure.vnsv.org/owa/DanAInfo=owa.vnsv.org_SSL+?ae=Item&tie=1PM.Note&id=R... 3/7/2014
Appendix J

IRB Approval Hunter College (CUNY)

DATE: March 12, 2013
TO: Claudia Beck, MS, ANP, BC
FROM: Hunter College (CUNY) HRPP Office
PROJECT TITLE: [367338-2] Examining the association of medication complexity with health-related quality of life in older adults receiving community-based long-term services and supports
SUBMISSION TYPE: Revision to New Project
ACTION: APPROVED
APPROVAL DATE: March 11, 2013
EXPIRATION DATE: March 10, 2014
RISK LEVEL: Minimal Risk
REVIEW TYPE: Expedited Review
REVIEW CATEGORY: Expedited review category 47

Thank you for your submission of Revision materials for this project. The University Integrated IRB has APPROVED your research. This approval is based on an appropriate risk-benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Please remember that informed consent is a process beginning with a description of the project and assurance of the participants understanding, followed by a signed consent form(s). Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

- HIPAA Authorization was waived or altered only for the participants from the first phase of the study.

Please note that any modifications/changes to the approved materials must be approved by this IRB prior to implementation. Please use the appropriate form for this request.

All UNANTICIPATED PROBLEMS (UUPS) involving risks to subjects or others, NON-COMPLIANCE issues, and SUBJECT COMPLAINTS must be reported promptly to the office. All sponsor reporting requirements must also be followed. Please use the appropriate form for this report.

This research must receive continuing review and final IRB approval before the expiration date of March 10, 2014. Your documentation for continuing review must be reviewed with sufficient time for the IRB to conduct its review and obtain final IRB approval by that expiration date. Please use the appropriate form for this procedure. PLEASE NOTE: The regulations do not allow for any grace period or extension of approvals.

If you have any questions, please contact the HRPP office at (212) 650-3053 or hrpp@hunter.cuny.edu. Please include your project title and reference number in all correspondence with this committee.
Appendix K

IRB Approval Visiting Nurse of New York

DATE:    February 27, 2013
TO:      Mary Naylor, PhD
FROM:    Visiting Nurse Service of New York Institutional Review Board (IRB)
STUDY TITLE: [212462-6] Health Related Quality of Life: Elders in Long-Term Care
IRB REFERENCE #: E07-001
SUBMISSION TYPE: Amendment/Modification
ACTION: APPROVED
APPROVAL DATE: February 27, 2013
EXPIRATION DATE: February 26, 2014
REVIEW TYPE: Expedited Review
REVIEW CATEGORY: Minimal Risk

Thank you for your submission of Amendment/Modification materials for this research study. Visiting Nurse Service of New York Institutional Review Board (IRB) has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.
References


doi:10.1093/ageing/30.4.337


