

Factors Associated with Medication Adherence

In Frail Urban Older Adults:

A Descriptive and Explanatory Study

by

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ABSTRACT

The treatment of individuals with multiple chronic conditions represents the single largest driver of Medicare costs. The use of prescription drugs is a major component in the treatment/management of chronic disease in the United States. Medication nonadherence, however, is a common problem among older adults and leads to significant morbidity and mortality. Whereas, the problem of medication nonadherence has been a primary focus of research for the last thirty years, much is still unknown about which older adults are most at risk for medication nonadherence, as well as what are effective theory-based interventions to improve a person's medication self-management.

The purpose of this descriptive explanatory study was to better understand the self-management behavior, medication adherence, in a sample of frail urban older adults. The study used a combination of quantitative and qualitative methods to analyze data from a larger twelve-month study of a nurse care coordination intervention. Ryan and Sawin's (2009) Individual and Family Self-Management Theory served as the study's conceptual framework for identifying the context and processes involved in the older adults' medication self-management. Quantitative results found several individual- as well as family-level predictors for medication nonadherence. Qualitative analyses identified three overarching themes to describe the participants' struggles along the multistep process of medication adherence. Additionally, a cultural domain described the need for more information from participants to understand their nonadherence. Integration of the results further increased our understanding of medication-self management in these frail older adults, and offers direction for clinical practice and future research.

DEDICATION

To my Mom and Dad as well as the participants and caregivers in this study who have shared their stories. As Richard Castle (a.k.a. Rob Hanning, 2013) reminds us, “The story always matters...the story points us to the solution.” May this work help us to improve the health and well-being of cognitively impaired older adults and the families who care for them.

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CHAPTER 1

INTRODUCTION

With the largest cohort of Americans (i.e., the baby-boomer generation) entering into older adulthood, it is expected that by 2030, the number of Americans over the age of 65 will double to 88.5 million (Vincent & Velkoff, 2010), and will represent more than 20% of the U.S. population (Anderson, 2010). Among the most significant impacts of this aging cohort to our society will be their consumption of healthcare resources. Indeed, the Congressional Budget Office (CBO) (2009) estimates that Medicare expenditures alone will account for 8% of the nation's gross domestic product by 2035—a percentage comparable to what most industrialized countries incur for their entire population's healthcare. As Anderson (2010) notes, 31% of the healthcare dollars spent in the United States is on hospital care. These costs are forcing the Centers for Medicare and Medicaid (CMS) to reexamine relationships among patient, providers, healthcare systems and payers in order to reduce chronic disease complications and optimize health. The treatment of individuals with multiple chronic conditions represents the single largest driver of Medicare costs with 79% of all program dollars spent on those older adults with 5 or more chronic conditions (Anderson, 2010).

Background

The use of prescription drugs is a major component in the treatment/management of chronic disease in the United States. Because aging is significantly associated with the development of chronic disease, it is not surprising that older adults consume nearly 34% of prescription drugs in this country yet they only make up 13% of the population (Haynes, 2005). A recent update on Medicare's retail prescription drug expenditures

highlights the fiscal significance of this issue: In 2012, Medicare prescription drug coverage cost 68.2 billion dollars and accounted for 12% of the program's overall spending (CMS, 2014).

In addition to the direct costs associated with these filled prescriptions, however, are the indirect costs to the system when older adults do not take their medications as prescribed (i.e, medication nonadherence). Medication nonadherence can include both under- and over-dosing of one's prescribed medication and/or not taking it at all. The indirect costs of medication nonadherence in the older adult include increased risk for emergency department (ED) visits (Hope et al., 2004), hospital admissions (Ho et al., 2006a; Mojtabai & Olafson, 2003), and/or nursing home admissions (Lynch, 2006). Under-dosing can lead to both short term and long term consequences such as increased blood pressure, blood glucose levels, arrhythmias, myocardial infarction and stroke.

The cost of unintentional overdosing is also significant. Indeed a recent analysis of emergency hospitalizations for adverse drug events among older adults found that during 2007-2009, nearly two-thirds of the estimated 99,268 hospitalizations each year were due to unintentional overdosing (Budnitz, Lovegrove, Shehab, & Richards, 2011). Most importantly, research has also found that low adherers to drug therapy have a significantly higher risk of mortality than adequate adherers (Granger et al., 2009; Ho et al., 2006b; Ho et al., 2009; Simpson, 2006). Not surprisingly, medication nonadherence has been labeled by some researchers as a "silent epidemic" (Murdaugh & Insel, 2009).

Estimates are that more than half of older adults (53%) do not take their medications as prescribed (Roth & Ivey, 2005). Even though the problem of medication nonadherence has been a primary focus of research for the last thirty years, much is still

unknown about which older adults are most at risk for medication nonadherence, as well as what are effective interventions to improve a patient's medication self-management. Behavioral scientists argue that researchers need to deploy a diverse set of methodologies in order to not only increase the "quality and scientific power of data" but also to more fully understand complex health problems (Creswell, Klassen, Plano Clark, & Smith, 2011, p.2). Indeed, mixed methods research has emerged within the last decade as a promising methodological option to better understand chronic disease self-management in older adults (Bogner, Cahill, Frauenhoffer, & Barg, 2009; Gucciardi, DeMelo, Offenheim, & Stewart, 2008; Mayoh, Bond, & Todres, 2012). Following this charge, the proposed study examined the problem of medication adherence using quantitative and qualitative data collected during the original randomized controlled trial of a nurse care coordination intervention. As part of the original study, the intervention nurses collected extensive information on the participant's life context (i.e., demographics, health functioning, and living situation) through the use of standardized instruments (e.g., the Geriatric Depression Scale [GDS] (Yesavage et al., 1983), and the Mini-Mental Status Exam [MMSE] (Folstein, Folstein, & McHugh, 1975), and conducted bi-weekly pill counts to assess medication adherence. In addition, the nurses further explored the processes involved in medication adherence by asking participants at each pill count, the reason(s) why they had missed their medication(s). These data sets thus allowed for a mixed methods approach to examining the issue of medication self-management in frail urban older adults.

Purpose Statement

The purpose of this descriptive exploratory study was to better understand the contexts and processes involved in the health behavior of medication self-management. Findings from this study can inform the refinement of a nurse-led intervention to optimize medication self-management in older adults living with one or more chronic conditions. In order to more completely understand older adults' medication self-management, the study used a combination of quantitative as well as qualitative data from the larger study of a 12-month-long nurse care coordination intervention for the following purposes:

- (1) Identify significant risk and protective factors for medication adherence/nonadherence in frail urban older adults;
- (2) Describe the processes involved in older adults' medication self-management; and
- (3) Utilize the qualitative findings to enrich our understanding of the quantitative findings of the study.

Conceptual Framework

Several researchers have noted the complex set of actions involved in taking one's medication (Bergman-Evans, 2004; Russell, Ruppard, & Mattson, 2011). The process of medication taking begins with the client receiving a prescription from the provider which then assumes that, (1) the client has the ability to pick up the prescription, (2) has the money to buy the prescription, (3) can read the label/understand the medication directions, (4) can organize the medication by time and dose, (5) remembers to take the medication, (6) can recognize side effects and/or adverse reactions, (7) has the

opportunity to discuss with provider concerns about medications and/or desire to discontinue medications, and finally, (8) remembers to order refills. Much of the research assumes that older adults can navigate this multistep process of medication adherence, yet we know little about conceptual frameworks that can explain why or why not they are able to effectively master this health behavior. For example, Banning (2009) and Haynes (2008) argue that the effectiveness of medication adherence interventions to date has been limited by the lack of theories to adequately explain the process of medication adherence in older adults. Moreover, most research on medication adherence has used health behavior change theories that focus on individual-level factors (e.g., transtheoretical model, health belief model, theory of planned behavior, theory of reasoned action, self-regulation model) rather than use theories that are more multilevel focused (Johnson, 2002; Ruppap & Conn, 2011). The problem lies in the fact that leading experts in health behavior change posit that the adoption of a health behavior depends not only on an individual's knowledge, attitude, and motivation regarding the behavior, but also on the environmental context (or ecological system) in which one lives (Schneider & Stokols, 2009). These researchers thus propose that by conceptualizing human behavior within the context of a person's "ecology of health", researchers are better able to determine what are the "high impact leverage points" needed to develop effective health behavior interventions (Schneider & Stokols, 2009, p. 87).

Echoing this recommendation, Russell and colleagues (2011) in their review of medication adherence interventions also found that most studies focused on effecting change at the level of the individual, (i.e., education, counseling, and problem-solving skills) without recognizing the external factors that impact a person's ability to self-

manage their medications. In order to develop more effective interventions, the authors thus proposed a paradigm shift in medication adherence interventions from a focus on individual-level factors to a focus using a personal systems approach. According to the authors, the interventionist would use this approach to guide the client to move beyond personal level factors such as motivation and health beliefs by examining their life routines around medication taking, and then identifying the personal system changes that are needed to promote medication adherence. Preliminary findings from Russell and colleagues' work (2011) suggest that clients have found this approach both acceptable and engaging.

The Individual and Family Self-Management Theory (IFSMT) (Ryan & Sawin, 2009) is a systems-level framework that offers promise in informing the development of an effective medication intervention for older adults. Figure 1 illustrates the model.

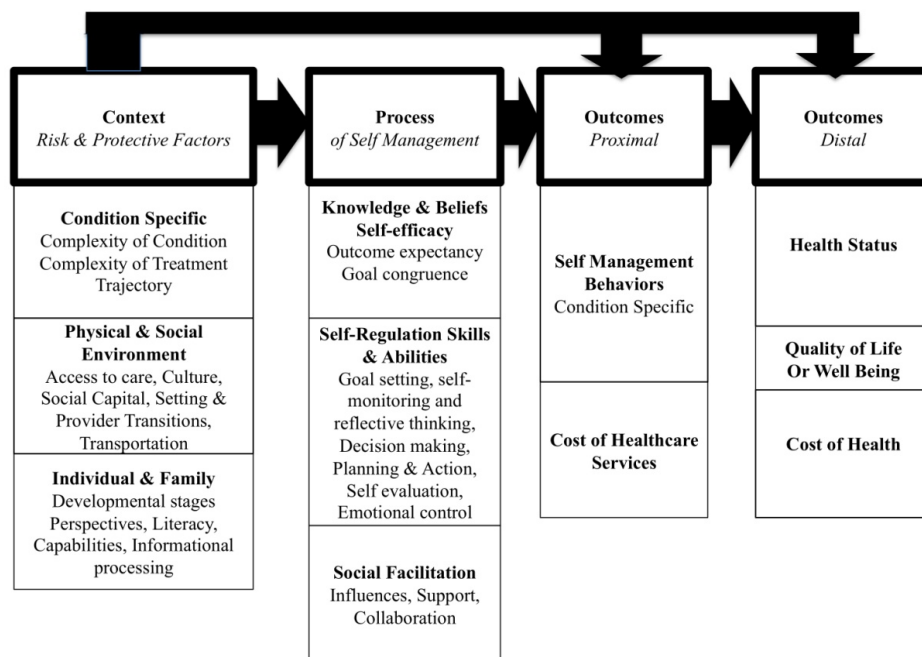


Figure 1. Model of the Individual and Family Self-Management Theory

The IFSMT recognizes that individuals, especially older adults with chronic conditions, often live with and rely on their family members to self-manage their health and healthcare needs. In this sense, medication adherence would then be conceptualized as a behavior in which both the individual and family are committed to adopting. In addition, the theory proposes that both contextual and process dimensions are involved in a patient's health behaviors such as medication self-management. In this theory, the context of a health behavior recognizes the importance of the ecology of one's health by considering the individual and family characteristics, the physical and social environment, and the individual's health condition(s). The conceptualization of self-management processes also utilizes a systems-based perspective of health behavior by not only considering the individual's knowledge, beliefs, and skills, but also the social facilitators that are involved in the behavior of interest.

Thus using the IFSMT as a framework, this study conceptualized an older adult's medication self-management as a health behavior that is influenced by both the context and processes of the person's life circumstances. While the study focused on the more proximal outcome of medication self-management (operationalized as medication adherence), there was the understanding that this proximal health behavior directly impacts the more distal outcomes of one's health status, quality of life or well being, and health cost as Ryan and Sawin (2009) conceptualize in their model. Figure 2 illustrates the conceptual framework of this study:

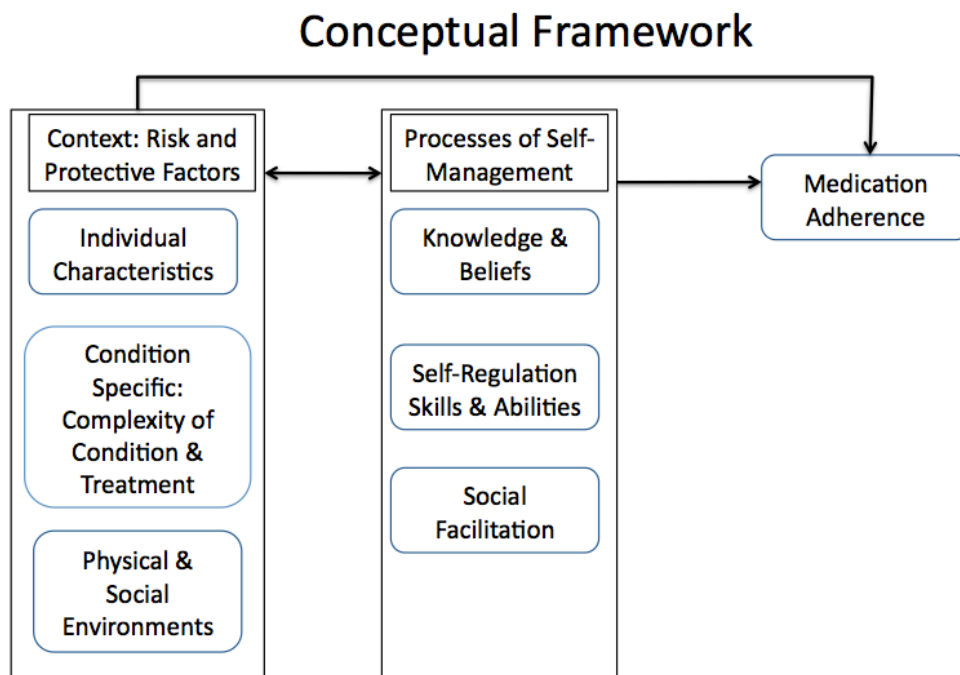


Figure 2. Conceptual Framework

Research Questions

The following research questions correspond to the three specific purposes of this dissertation study:

1. What are the context and/or process dimensions that emerge as significant risk and protective factors for medication adherence at Month 1 of the study?
2. What are the context and/or process dimensions that emerge as significant risk and protective factors for medication adherence over the course of the study?
3. What are the themes that describe the participants' medication self-management processes?
4. How do the qualitative data help explain the quantitative findings and contribute to a more complete understanding of the participants' medication adherence?

Assumptions

Researchers in health behavior change argue that in order to promote the adoption of health behaviors, clinicians and patients need to consider the “ecology” of a person’s health (Schneider & Stokols, 2009). “Ecology” can be conceptualized similarly to what Russell and colleagues (2011) call the personal systems of the individual. These systems include: interpersonal/social relationships; living situation; type of caregiver; the type of caregiving a person receives; the healthcare system; and health policy. This study assumes that both the participants’ contextual as well as processes dimensions are important determinants of a person’s medication self-management behavior (i.e., medication adherence). This study also includes an assumption from Ryan and Sawin’s IFSMT (2009) that, “Persons engage in behaviors for personally meaningful reasons that may or may not be directly related to optimizing health” (p. 21).

Definition of Variables

1. MD.2 machine: The MD.2 machine uses an audio/visual prompt to remind the participants when it is time to take their medication. The intervention nurse preloaded the MD.2 machine with the participant’s oral medications and then programmed the machine to dispense medications in a cup at the time the medications are due. The MD.2 machine uses a flashing light and a voice recorded reminder that goes off every three minutes for up to 45 minutes. If the client still has not taken the medication, the machine sends the medication to the missed dose compartment and attempts to reach a caregiver to notify them that the client has missed a dose.
2. Mediplanner: The mediplanner is a visual prompt for the participant to remember to take their medication. The planner is a plastic container with 28 individual compartments

that correspond to the day of the week and time of day. Each compartment can accommodate multiple pills.

3. Individual Characteristics: Age, gender, and race.

4. Condition Specific Characteristics: treatment complexity, cognitive function, physical function, psychosocial well-being, visual ability, and hearing ability.

5. Physical and Social Environment: Participant's living situation (alone or with someone); caregiver living in the home; assistance with activities of daily living (ADL) (e.g., bathing, dressing, toileting, bowel/bladder, eating/feeding); assistance with instrumental activities of daily living (IADL) (e.g., medications, meals, housekeeping, laundry, telephone, shopping, finances).

6. Medication Complexity Index: A calculation including the total number of medications taken each day as well as number of doses and other actions required to administer the medications. Used as a measure of the participant's treatment complexity.

7. Chronic Condition(s): Diagnosis of a disease or disease state that is ongoing.

8. Cognitive Prosthesis: The use of a pill organizer to aid in the process of medication self-management.

9. Medication Adherence: Percentage of the monthly doses taken. Determined by the taking the RN's monthly count of the missed prescribed pill doses and dividing it by the number of total monthly pill doses.

Significance of Medication Adherence

As previously noted, aging is significantly associated with an increased risk for developing one or more chronic conditions. There are several theories of aging that seek to explain this risk (Carey, 2003; Miller, 2003), as well as an established body of research

on how to prevent and/or delay the risk of developing a chronic condition (World Health Organization, [WHO], 2005). Despite advances in the diagnosis and treatment of chronic disease, however, the management of these conditions has been unsatisfactory. For example, while the percentage of hypertensive older adults with controlled blood pressure has significantly increased over the last decade, the majority of adults over the age of 60 still do not have their blood pressure under control (Yoon, Ostchega, & Louis. 2010). Similarly, older adults with diabetes mellitus (DM) often fail to meet targeted clinical outcomes for blood pressure, HbA1c, and cholesterol levels, thus reflecting suboptimal management of their chronic conditions (Cheung et al. 2009).

Both health complications and health system costs tend to increase when older adults with one or more chronic conditions fail to meet targeted clinical goals. For example, diabetes mellitus is one of the most common chronic conditions as well as one of the most expensive to our healthcare system. Currently over one quarter of adults 65 years of age and over (10.9 million) has diabetes mellitus and another 50% is prediabetic (CDC, 2011). More importantly, adults aged 65 years and older account for approximately 56% of \$116 billion dollars spent annually on diabetes related care (ADA, 2008). Medication management is a critical component of this chronic disease, and thus not surprisingly, a significant predictor of healthcare costs for the older adult with diabetes. Indeed, in their five-year longitudinal study of Medicare Advantage patients diagnosed with diabetes, Balkrishnan and colleagues (2003) found that medication adherence was the most significant predictor of healthcare utilization. Given that the average medical expenditures for diabetic patients are more than twice the nondiabetic

patients (CDC, 2011), optimal management of chronic disease is critical to reducing overall health expenditures in the US.

In addition to the costs associated with older adults not taking their medications, are the costs associated with an unintentional overdose (i.e, when the older adults takes more than their prescribed dosage). Indeed, older adults are not only among the highest risk groups for experiencing an adverse drug event (ADE) from their prescription drugs, but are also nearly seven times more likely to be hospitalized for an ADE than younger adults (Budnitz, et al., 2006). A more recent study by Budnitz and colleagues (2011) estimated that annually there were over 265,000 emergency department visits and over 99,000 hospitalizations due to ADEs in older adults. Two-thirds of the ADE hospitalizations (65.7%) were due to unintentional overdose. The authors also found that our oldest old, (ages 85 and older) were three and a half times more likely than younger Medicare patients (aged 65-69 years old) to be hospitalized (1.3/1000 persons vs. 4.6/1,000) and that rates of hospitalization were also significantly higher for those patients taking five or more medications versus those taking one to four medications (54.8% vs. 39.9%). It also appears that older adults in the United States are in need of additional teaching on medication self-management given that 95% of the hospitalizations involving warfarin, insulin, and oral hypoglycemic ADEs were due to unintentional overdose.

Optimal medication self-management for multiple chronic conditions, however, poses a particular challenge to the older adult for myriad reasons. First, many chronic conditions require specialists for consultation and/or management of the patient's treatment plan. Cardiologists often manage patients with CHF and CVD, neurologists for

dementia, psychiatrists for depression and other mental health conditions, and endocrinologists for diabetes. Indeed, more than half (55%) of older adults with serious chronic conditions have 3 or more physicians involved in their care (Anderson, 2010). When multiple providers are engaged in prescribing medications, there is a risk of unintended drug-drug interactions due to poor communication between prescribing providers, as well as between provider and patient about the prescribed medications. A second barrier to effective medication self-management is the dilemma of what to do when there is a medication interaction between medications prescribed by more than one provider. The patient then has to coordinate between prescribers to decide which medication to take and which one to stop and/or the options for taking a different medication.

Another common reason many older adults give for not taking their medications is the out-of-pocket expense, and the effects of this problem are significant. Mojtabai and Olafson (2003), for example, examined the effects of cost-related nonadherence (CRNA) on health and healthcare utilization over a two-year period in 10,413 Medicare recipient and found that 7% of the adults reported taking less medication than prescribed due to cost (CRNA). The authors extrapolated that this would represent nearly 2 million Medicare beneficiaries. The authors also found that CRNA was significantly associated with several adverse health outcomes: CRNA adults were nearly twice as likely to perceive their health as poor (O.R.=1.86); nearly twice as likely to feel their health got worse (O.R.=1.75), and nearly one and a half times as likely to be hospitalized in the last year (O.R.=1.49) (all at $p < .001$). In a similar study, Heisler and colleagues (2004) found in a national sample of 7,991 older adults that participants who self-reported restricting

their medications due to cost, were two years later nearly twice as likely to experience a decrease in their health status (i.e., went from rating their health as good-excellent to fair-poor) (A.O.R.: 1.76 [1.27-2.44]). Those participants with cardiovascular disease also experienced a 50% higher rate of angina and/or episodes of nonfatal myocardial infarction/stroke.

Less is known, however, about ways to promote effective patient self-management in older adults with chronic conditions. Whereas medication nonadherence is recognized as a significant problem among older adults (Murdaugh & Insel, 2009), a recent Cochrane review by Haynes and colleagues (2008) of over three decades of medication adherence research found that even the most effective interventions did not produce “large improvements” in medication adherence. In addition, whereas many older adults rely on their family members and friends when it comes to managing their health and healthcare needs, researchers have found that few medication adherence interventions have targeted family members and/or caregivers (Ruppar, Conn, & Russell, 2008; Haynes et al., 2008). Researchers are now calling for more theory-driven interventions with a systems-based approach (i.e., an approach that recognizes the myriad factors involved in medication adherence) in order to more effectively address the theory of the problem (Ruppar, 2010a; Russell et al., 2011). To answer this gap in the literature, and more importantly to provide new insights in the development of effective interventions, this study examined the contexts and processes of the older person’s medication self-management.

Chapter Summary

Medication nonadherence and its associated morbidity and mortality in the older adult are a significant problem in our country. The unprecedented wave of older adults enrolling in Medicare, along with the rapid increase in our “oldest old” population (those 85 years of age and older), underscore the urgency on the part of clinicians and researchers to better understand medication adherence in order to develop effective interventions that optimize medication self-management and ultimately the health outcomes in community-dwelling older adults. Yet, despite more than thirty years of research on medication adherence in older adults, there is still a lack of agreement on how medication adherence is defined, measured, and operationalized, as well as a lack of understanding about what are the critical components of an effective medication adherence intervention. Nurses spend more time with patients and families than any other healthcare provider, and with their education and training are ideally suited to deliver interventions that optimize community-dwelling older adults’ self-management of their medications. Most of the research to date, however, has been outcomes-focused without attention to the context and processes that impact the older adults’ medication self-management behaviors. This limited understanding of the problem has hindered nursing and behavioral scientists’ ability to develop and implement effective interventions, and has resulted in a plethora of interventions demonstrating minimal to no effect on older adult’s medication adherence.

More research is needed, therefore, that not only recognizes the ecology of an older adult’s medication self-management, but also adopts a theory-driven approach in the development and testing of interventions. This study attempted to fill this gap in the

literature by utilizing medication adherence data from approximately three hundred older adults who participated in the twelve-month nurse care coordination study (Marek et al., 2013). The study included both quantitative and qualitative measures from the original study. This secondary analysis, guided by the IFSMT, examined and described the contexts and processes associated with medication adherence in those frail urban older adults who had participated in the two experimental arms of the nurse-led intervention. The goal of this current study was to further understand the how and why of our phenomenon of interest (i.e., medication nonadherence) in order to inform the development of more effective theory-based interventions.

CHAPTER 2

REVIEW OF THE LITERATURE

This chapter reviews the literature on the patterns and importance of medication adherence, as well as the work that has identified factors that explain variations in adherence. First, the chapter examines the ongoing debate over how medication adherence is defined and measured, and how this shapes our understanding about the significance of the problem. Next, the review identifies the salient contextual factors (i.e. the risk and protective factors) associated with medication adherence, as well as the processes involved in older adults' medication self-management. The chapter then reviews the important intervention studies aimed at improving medication adherence in community-dwelling older adults. Finally, because of the nursing profession's critical role in the delivery of patient health education in the community setting, this review concludes with an evaluation of medication adherence interventions conducted by nurse researchers within the last ten years in order to identify the gaps in the science.

Medication Adherence

The most widely accepted definition of medication adherence comes from the World Health Organization which describes adherence as, “the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” (Sabate, 2003, p. 3). Researchers who investigate the issues involved in medication adherence and its corollary, medication nonadherence, have conceptualized medication adherence as both a multistep “process” (Murdaugh & Insel, 2009; Russell et al., 2011), and as an “outcome” (George, Elliott, & Stewart, 2008; Haynes, Ackloo, Sahota, McDonald, & Yao, 2008)

depending on whether they operationalized medication adherence as a set of mediating variables or a dependent variable. When researchers conceptualize medication adherence as a multistep process, this set of actions can then be grouped into several different behaviors with each component often targeted by a specific intervention. Where the larger problem exists, however, is when researchers operationalize medication adherence as a single outcome.

For example, in the literature, adherence to 80% of a prescribed regimen is often used as the accepted dichotomous cut point for determining adherence versus nonadherence (Berg & Arnsten, 2006; Esposito et al. 2009; Ho et al., 2009). However, Wu, Moser, Chung, & Lennie (2008a) found in a longitudinal sample of heart failure patients that an even higher medication adherence cut-off ($\geq 88\%$) produced a statistically significant improvement in event free survival. Additional studies have also found that medication adherence and its therapeutic effect varies across medications such that 95% adherence level may be necessary in order to effectively manage chronic diseases, such as HIV (Berg & Arnsten, 2006) and CHF (Esposito, 2009); and that the measurement threshold of 80% is “arbitrary” (Ho et al., 2009). Health related outcomes of medication adherence, notwithstanding, there are also economic implications for how we measure medication adherence. For example, Esposito and colleagues (2009) found in their study of adults with CHF that when “adherent” patients were further stratified into groups “ $>95\%$ adherence” vs. “80-95% adherence”, patients in the former group had significantly lower annual healthcare costs than the latter group (\$17,665 vs. \$20,747, $p < .01$).

In addition to the inconsistency related to how medication adherence is operationalized (dichotomous, categorical, or continuous), significant debate exists in the scientific community on the reliability and validity of the divergent measures used to indicate medication adherence. The only agreement appears to be that each method comes with its own set of strengths and limitations. The following briefly describes each of these types of measures, starting with self-report, which is generally regarded as the least reliable indicator of medication adherence (United States Department of Health & Human Services [USDHHS], 2010).

Self-report measures vary in the literature from single question (Kennedy, Tuleu, & Mackay, 2008; Lewis, 2010; Wu et al., 2008a) to multi-item surveys such as the Hill-Bone Compliance questionnaire (King, 2010; Krousel-Wood, 2005). One of the most common self-report measures is the Morisky-Self Report scale (Morisky, Green, & Levine, 1986), a brief 4-question assessment of a person's medication-taking behavior. The survey assesses reasons a person might miss or stop taking medications and includes structured responses such as forgetfulness, carelessness, feeling better and/or feeling worse. The benefits of self-report measures are that data collection is less time-intensive to the patient and staff and the surveys are often brief and easy to administer (Berg & Arnsten, 2006). The use of self-report, especially single-item reports, however, could significantly bias study results. Indeed Wu and colleagues (2008a) examined medication adherence in a group of heart failure patients (N=134) and found that self-report medication adherence (a single question from the MOS-Specific Adherence Scale) did not predict event-free survival, whereas the MEMS adherence data (an objective measure) did. Some researchers speculate that self-reports are more likely to overestimate

the actual level of adherence for numerous reasons, including social desirability and/or recall bias (Berg & Arnsten, 2006; Wu et al., 2008a), and thus caution against its use.

Moving away from self-report, researchers have also used objective measurements of medication adherence that have included pharmacy refills, pill counts, and the Medication Event Monitoring System (MEMS) caps; but as with self-report, each of these specification strategies also introduce measurement bias. For example, pharmacy refill (which is the most often used measure for medication adherence in pharmacy studies) is often calculated as a percentage of medications the patient had obtained over the number of days between refills. This is typically referred to as the medication possession ratio (MPR). Studies that have used the MPR as the dependent variable have usually defined MA as a dichotomous outcome with $\geq 80\%$ MPR as the cut-off (e.g., Choudhry et al., 2011; Doshi, Zhu, Kimmel, & Volpp, 2009; Egede et al., 2011). The use of pharmacy refills, however, only assesses the act of filling prescriptions, and can potentially overestimate the actual pills taken (MacLaughlin et al., 2005).

Pill counts are another common objective measure of adherence because they can be performed on many devices including prescription bottles, mediplanners, and/or pharmacy blister packs. Nevertheless, with pill counts there could also be an overestimation if the participant took the medication out, but then dropped it and/or lost it, and thus never actually took the medication. Conversely, pill bottle counts could underestimate medication adherence when patients obtain refills on their medications before they have finished the last dispensed bottle (Grymonpre et al., 1998). Compounding the problem is the fact that many older adults lack a complete and accurate medication regimen because they have prescriptions from more than one provider (Vik,

Maxwell, & Hogan, 2004). Another reason for pill bottle count overestimation stems from individuals who choose to hide or hoard their missed doses (Urquart, 1994).

Another threat to reliability with pill counts, is the need for more than one client encounter in order to ensure accuracy in the medication regimen. For example, when Vik and colleagues (2005) conducted an in-home cross-sectional study of 319 urban and rural adults aged 65 years or older, the authors found that pill counts to assess medication adherence were either not feasible or were inaccurate in more than one third of the sample (34.7%). Artinian and colleagues (2003) noted similar difficulties with pill counts, noting that they were unable to assess adherence across their study participants because “most patients did not follow our instructions” (p. 231). Therefore, medication reconciliation prior to pill counts is a crucial first step in obtaining accurate pill counts.

More recently, researchers have utilized the MEMS caps (Aardex, 2005) because of the microprocessing chip’s ability to capture and save several pieces of information, such as date and time bottle cap was removed. The MEMS cap has been called the “gold standard” for measuring adherence (Ogedegbe, 2012), although the system has two important limitations. First, in most studies, only one medication had a MEMS cap attached to the bottle, so adherence with the other medications taken could not be monitored. This monitoring limitation might affect the validity of the measure given that nearly 40% of adults aged 60 years and over take at least five medications (Gu, Dillon, & Burt, 2010), and among adults 65 years and older, 18% take ten or more medications (Sloane Survey, 2006). Second, Bova and colleagues (2005) reported that in their study, the MEMS cap did not always record the opening of the bottle, which may have underestimated adherence. Furthermore, MacLaughlin and colleagues’ review (2005)

cited several additional limitations to the MEMS cap for both research and practice: (1) The cap only monitors the opening and closing of the cap, and not whether or not the medication was actually taken; (2) For older adults already using mediplanners, the addition of a MEMS cap could interfere with already established routines; and (3) The cost of the cap at \$80-\$142 each may not be scalable for adoption in clinical practice.

The review of the literature illustrates two important issues that impact our understanding of medication adherence as a health behavior: (1) The inconsistency in the definition of medication adherence; and (2) The questionable reliability and validity of the multiple measures used to assess medication adherence. Working toward the resolution of these issues is a critical step toward identifying the risk and protective factors associated with medication adherence and the development of more effective interventions for community-dwelling older adults.

Causative Factors of Medication Nonadherence

Whereas research has consistently demonstrated that nonadherence to medication regimens is a risk factor for adverse health outcomes and for increased healthcare utilization, there remains inconsistency in identifying protective/risk factors for medication adherence in older adults. Therefore, the findings to date on the individual- and family-level factors are discussed in further detail to identify the gaps in the literature.

Individual-level Characteristics. Whereas some research has found individual demographic variables to be poor predictors of medication adherence (Russell et al., 2011; Vik et al., 2004), several studies have linked individual-level characteristics medication adherence and nonadherence, including: age, gender, financial limitations,

and education. Most researchers examining these factors have conducted multivariate analyses to assess the independent effects of each of these variables.

Choudhry and colleagues (2011) conducted multivariate analyses in a larger sample of older adults (N=3.3 million; mean age 63 years old) to assess the effect of therapeutic drug regimens on longitudinal adherence. The authors measured medication adherence as the “proportion of days covered” (i.e., when patients obtained refills), and then examined individual-level characteristics that predicted the adults’ adherence rate over 12 months. Age was found to be a significant and positive predictor of adherence to statins and ACEI/ARBs (both $p < .001$). The authors also found that female gender was a significant positive predictor of medication adherence.

Contributing to these age and gender findings, Ho and colleagues (2006b) examined medication nonadherence (measured as discontinuation of cardiac medications one month post-discharge) in a sample of 1,521 adults who were hospitalized for acute myocardial infarction and found an interesting gender by age interaction. Specifically, the authors found that for every 10 year increment, women had a 1.77 odds ratio (95% C.I.=1.34-2.34) of discontinuing their medications, whereas for men the odds ratio was only 1.

Several recent studies also found that African American race is an important predictor of medication adherence in older adults (Egede et al., 2011; Gazmararian et al., 2007; Gerber, Cho, Arozullah, & Lee, 2010; Krousel-Wood et al, 2005; Wu et al., 2008b). For example, in a five year longitudinal study, Egede and colleagues (2011) examined the racial differences in medication adherence in a nationwide sample of veterans diagnosed with type 2 DM (N=690,968). The mean age of the veterans was

65.77 (11.28 S.D) years old. The researchers measured medication adherence as a continuous variable by calculating the veteran's annual medication possession ratio (MPR) per drug class per year. Across all races, African Americans had the lowest MPR--6% lower than Non-Hispanic Whites.

Bosworth and colleagues (2006) similarly found in their sample of older military veterans (N=569) that African Americans were nearly twice as likely as their White counterparts to be nonadherent to their blood pressure medicines (O.R. 1.81, C.I. [1.28-2.58]). In that study, the authors had assessed participants' adherence by creating dichotomized scores from the self-report Morisky scale. Krousel-Wood and colleagues (2005) similarly controlled for other demographic variables and found that African Americans had more than twice the risk for nonadherence (O.R.=2.53, C.I.=1.37-4.66). More recently, Bautista and colleagues (2011) also found among a cohort of middle aged adults living with epilepsy that African American race was significantly associated with lower medication adherence (p=.037). Gerber (2010) hypothesized that race would no longer be a significant predictor of nonadherence, once they controlled for other sociodemographic variables, but in a sample of 489 veterans, the authors found that African American patients were still more than twice as likely as Whites to report being nonadherent due to not following their physician instructions on how to take their medications (O.R.=2.49; C.I.=1.07-5.80).

Recent descriptive and qualitative studies may help explain these disparities in medication adherence. Lewis and colleagues (2010) conducted three focus groups with 40 hypertensive low-income African Americans (mean age: 57.2 \pm 12.7 years old). Adherence was ascertained by a single yes/no question about whether the individual had

taken their medication every day as prescribed. In this sample, only 65% of the respondents reported they were adherent. Participants specifically discussed their distrust of healthcare providers along with longstanding issues of racism as reasons for nonadherence. Similarly, Lukoschek (2003) found in a sample of hypertensive African Americans that distrust of the physicians and the pharmaceutical industry along with poor communication with one's physician were important reasons for nonadherence. With the population of African American elderly expected to triple from 2.9 million in 2000 to 8.9 million by 2050 (Yee, 2006), there is an urgent need to further understand these disparities in medication adherence.

Low Health Literacy and Education Level. Estimates are that 90 million Americans have difficulty reading and/or processing health information (NCPIE, 2007), and low health literacy is linked to increased risk for medication nonadherence (Armstrong, 2010; Kripalani et al., 2006). Education was examined as a risk for medication nonadherence but the findings are mixed. For example, Catz, Heckman, Kochman, & Dimarco (2001) reported that their multivariate analysis of middle and older adults (M age 53.8 SD=5.5 years) demonstrated that higher education significantly predicted better self-reported medication adherence (O.R.=1.42, $p<.009$). Similarly, Schoenthaler and colleagues (2009) found that low education significantly predicted self-reported low MA. When Insel and colleagues (2006), however, included education in their hierarchical regression model predicting medication adherence (by MEMS cap), the authors found education made no significant change in the model. Krousel-Wood (2005) also did not find education was a significant predictor of MA as measured by the self-reported HBC subscale.

Financial Limitation. Cost-related nonadherence (CRNA) is another common factor, but particularly among financially vulnerable older adults. For example Piette and colleagues (2004) conducted a nationwide survey of adults ages 50 years and older (N=4,055) to examine the problem of cost-related adherence and found that 18% of adults reported at least one episode of CRNA in the prior year. Of those who reported cutting back on their medications, 78% of them reported doing so at least once a month. In a multivariate analysis, the authors found that income and monthly expenses were significant while race, gender, and educational attainment were not significant predictors of CRNA. The findings from this study may actually underestimate the problem, however, as the respondents to this online survey were significantly more likely to be White, older and have more education. Indeed, the authors suggest that older adults who have access and are comfortable with the internet may not truly represent older adults most at risk. Supporting this assumption, Soumerai and colleagues (2006) found that older adults most likely to report CRNA are from the more vulnerable groups (i.e., having low income; being African American; having more than one comorbidity; and/or having difficulty with one or more ADLs).

In January 2006, CMS implemented the Medicare Prescription Drug Coverage (Part D) to assist older adults with the high cost of prescriptions. In order to participate in this program, older adults were required to pay a monthly premium, drug copayments, and when their drug costs during the year exceeded \$2,830, no coverage would be available until their drug costs reached \$4,550 in year. Once the Medicare participant reached this out-of-pocket drug expense level, they would become eligible for the “catastrophic coverage” and would only pay a copay toward each subsequent prescription

(CMS, 2010). Older adults who qualified for Medicaid were automatically eligible to receive “Extra Help” which included assistance with their monthly premiums and annual deductible, and were exempt from the coverage gap. Interestingly, in a 2004 CMS national panel survey, Kennedy and colleagues (2008) found that dual-eligible Medicare/Medicaid enrollees were significantly less likely to fill their prescriptions than those Medicare enrollees not on Medicaid (6.3% vs. 4.0% $P = 0.001$). The study did not explain why these differences occurred.

Since then, however, several studies have attempted to further describe the relationship between CRNA and copays. For example, in a sample of 3,240 adults, Shah et al. (2009) examined the effect of financial factors on first-fill adherence and found that adults who had copays of more than \$10.00 were less than half as likely to be adherent (i.e., to fill their prescriptions within 30 days ($p < .0001$) when compared to those whose copays were less than \$10.00). Doshi and colleagues (2009) also found in a sample of 5,604 veterans with medication copayments that an increase from \$2 to \$7 per copayment significantly decreased the odds of being at least 80% adherent by nearly a half (O.R.=0.58, $p < .0001$). With the passage of the 2010 Patient Protection Affordable Care Act (PPACA), Medicare recipients are now receiving additional assistance from the federal government to help with the “donut hole”, and by 2020 recipients will be responsible for only 25% of their total prescription drug costs (Medicare Rights Center [MRC], 2014).

Condition-Specific Factors. Research has also found that condition specific factors including: a person’s health status (e.g., depression, cognitive impairment, physical functioning, and/or number of comorbidities); and complexity of medication

regimen (number of medications and doses) can be significant predictors of medication adherence. Each of these will also be briefly reviewed.

Health Status

Cooper and colleagues (2005) conducted a multinational study, (the Aged in Home Care project [AdHOC]), with 3,643 older adults from eleven countries to examine risk factors for self-reported nonadherence (i.e., <80% of doses taken in the last week). Using multivariate logistic regression, the authors found that those with ADL and/or cognitive impairment were significantly more likely to be nonadherent, however, those with vision impairment were no more likely to be nonadherent. Conversely, Schuz and colleagues (2011a and 2011b) examined the relationship of multi-morbidity and medication adherence and found that decreases in functional health were associated with increased medication adherence. The authors hypothesized that worse health led to belief in the medication necessity and in turn to an increase in adherence.

Depression has also been linked to medication taking/health behaviors. For example in a prospective observation study, Kronish and colleagues (2006) examined medication adherence among 492 older adults (mean age 60.6, S.D.=12.2 years) who were three months post acute coronary syndrome and found persistently depressed older adults were only half as likely to taking their medications as prescribed compared to those where persistently non-depressed (O.R.-0.50, [95% C.I.=0.27-0.95]). Similarly, Gonzalez (2007) studied 879 older adults living with Type II DM (mean age 66.22, S.D=12.4 years) and found that those adults with major depression scores (i.e., scoring ≥ 9 on the Harvard Department of Psychiatry/National Depression Screening Day Scale [HANDS]) were more than twice as likely to have reported missing medications in the

last week when compared to those with HANDS scores <9: (O.R.=2.31, [C.I.=1.50-3.56], $p<.001$). More importantly, the authors also found that increases in depressive symptoms significantly increased the risk for missing medication in the previous week ($p<.001$).

Of note, in a study of 167 older African Americans with hypertension, Schoenthaler and colleagues (2009) found that depressive symptoms significantly predicted low medication adherence, however, this relationship was mediated by self-efficacy such that once this individual-level factor was included in the model, the relationship to adherence was no longer significant. This has important implications for Ryan and Sawin's (2009) theory that suggests a person's knowledge and beliefs (i.e., self-efficacy and goal congruence) can improve one's self-management behavior. Maddigan, Farris, Keating, Wiens & Johnson (2003), on the other hand, examined adherence rates after patients had participated in a medication self-management program and found the opposite relationship with the diagnosis of depression predicting increased adherence. The authors acknowledged, however, that because their study was retrospective chart review it is possible that depression might not have been a current health condition for some of the participants. In addition, their study design did not include pre-intervention data that might have helped interpret this unexpected relationship.

Cognitive Impairment. Stilley and colleagues' (2010) pooled-analysis of three recent studies on medication adherence demonstrates the difficulty in measuring the effect of cognitive functioning on medication adherence. In the team's findings, all four of the cognitive processes tested (i.e., attention/psychomotor speed, mental flexibility/working memory, verbal learning and memory, and executive functioning)

significantly predicted medication adherence, in at least one of the three study samples, but the significance of the relationship often varied between each specific aspect of cognitive processing and a particular measurement of medication adherence. For example, in only one of the three studies, did attention/psychomotor speed significantly predict percentage of days with a correct dose. In two of the studies where medication adherence was defined as “percent of prescribed number of doses” and “percent of days with a correct dose”, executive functioning predicted medication adherence, but in only one study was the relationship significant. One possible reason for the differences in findings is that different aspects of cognitive functioning may affect different aspects of the medication-taking process.

The Mini-Mental Status Exam (MMSE) (Folstein, Folstein, & McHugh, 1975) is a common screening test that researchers and clinicians use to assess cognitive functioning in older adults and may be an easy clinical tool for identifying adults at risk for medication nonadherence. Indeed when Insel, Morrow, Brewer, and Figueredo (2006) conducted their medication adherence study with community-dwelling older adults (N=95), their initial analysis, using hierarchical linear regression, found MMSE to be a significant predictor of adherence. However, when the authors simultaneously entered the executive functioning working memory composite score (EWM) before MMSE, the effect of MMSE on medication adherence disappeared. Of note, the bivariate correlation between the MMSE and the EWM was strong ($r=.61, p<.01$), and this overlap may explain why the MMSE effect disappeared in the final model. While the EWM may be a better predictor medication adherence, the complicated calculation of the EWM composite score may also limit its translation to clinical practice.

Similarly, Park, Willis, Morrow, Diehl, and Gaines (1994) have also noted that the process of medication-taking includes both literal and inferential cognitive ability. In their study, the team compared a group of “normal” older adults to a group of adults with early Alzheimer’s Disease (i.e., median group MMSE score of 17) on their ability to answer literal versus inferential questions. Literal questions referred to facts on a label such as the medication’s side effects, whereas, inferential questions required the older adult to calculate how many pills would be needed for a specific time period. The authors found that the early AD adults were much less likely to correctly answer both literal and inferential questions: The “normal” older adults answered the literal questions 97% of the time compared to only 79% of the time for the early AD adults. Even more compelling, when the team posed inferential questions to the older adults, the “normal” older adults gave the correct answer 84% of the time, but the early AD adults were only half as likely (42%).

Ownby, Hertzog, Crocco, and Duara (2006) later used the Park and Jones (1997) model to examine factors associated with medication adherence in a cross-sectional convenience sample of adults referred to their memory clinic (N=63). The sample was predominately Anglo (55.6%), female (71.4%) and included (22.2%) with a primary diagnosis of a psychiatric illness. For this study, the team assessed the medication adherence rates for each participant’s prescriptions by asking the caregiver and participant to rate adherence on a 5-point likert scale between “Almost never” to “Almost always”. Using the MMSE to measure cognitive status, the authors found an indirect relationship between cognitive function and medication adherence. While the multilevel regression model did not show that MMSE scores significantly predicted medication

adherence, it did show that the participant's reliance on self to take medications was significantly and positively associated with medication adherence. Thus, for older adults with even mild cognitive impairment, living alone could be a tipping point if there were no one else available to help them manage their medications.

In a study of community-dwelling older adults (N=771), Jerant, Chapman, Duberstein, Robbins and Franks (2011) found that low cognitive functioning significantly predicted medication nonadherence ($p < .04$). In addition, Fitten, Coleman, Siembieda, Yu, and Ganzell (1995) tested older adults on their ability to self-manage their medications and found that both manual dexterity and the ability to read/comprehend a prescription correlated significantly with MMSE scores. More research is therefore needed to understand the impact of cognitive impairment, and the MMSE in particular, on medication adherence in older adults.

Medication Regimen Complexity. Another condition specific factor that has been identified in the literature is the complexity of a person's medication regimen. A common measurement is the medication complexity index (MCI). Maddigan, Farris, Keating, Wiens, and Johnson (2003) conducted a retrospective chart review on 301 older Canadian adults at a rehabilitation hospital and found that MCI score alone did not predict a person's risk for a medication self-management error. There was an interaction effect, however, with cognitive impairment and MCI on medication errors. Among older adults with moderate to severe cognitive impairment, the risk of medication error was similar regardless of the patient's MCI score. In those adults with mild cognitive problems, however, there was a statistically significant increased risk ($p = .019$) in making a medication error once the MCI score was greater than 26. Similarly, Hinkin and

colleagues' (2002) work with HIV + adults found that cognitive functioning and medication complexity had an interaction effect on medication adherence such that adherence dropped significantly among the cognitively impaired adults once the treatment regimen comprised three or more doses a day. Age, on the other hand, was a positive predictor of adherence in this group such that those aged 50 years and over had significantly better adherence.

Social Environment Factors. Social Support has also been identified as a significant predictor of health promoting behaviors in older adults (Carlson et al., 2012; Hopman-Rock, Vries, Bakker, & Ooijendijk, 2012; Resnick, Orwig, Magaziner, & Wynne, 2002). The findings for social support as a predictor of medication adherence, however, are mixed. For example, Tang and colleagues (2008) found in their cross-sectional study of African American (mean age 60 years) that nonsupportive social support had a negative effect on medication adherence ($r=-.348$, $p<.01$). Conversely, positive social support had no effect on medication adherence. Sayers, Riegel, Pawlowski, Coyne, & Samaha (2008) also tested the effects of different forms and sources of social support on medication nonadherence using the Morisky self-reported measure for medication nonadherence and the Multidimensional Scale of Perceived Social Support (MSPSS) to measure both emotional and instrumental support. The authors found that as emotional support increased, medication adherence increased. Instrumental support, however, had no significant effect on medication adherence. Similarly, Siegel, Turner, and Haselkorn (2008) examined the relationship of medication adherence and the specific aspects of the caregiver relationship (i.e., medication-specific support and relationship qualities of support and/or conflict) in a group of 54 veterans

with multiple sclerosis. Medication adherence was a single self-reported question of how many doses the person missed in the past month. Using multivariate logistic regression, the authors found that among the three types of social support, only supportive qualities (e.g., willing to listen, provide advice, and help with a problem) significantly predicted medication adherence (odds ratio [OR] = 3.58, 95% CI= 1.09-11.80). Of note, these are skills that perhaps a nurse or informal caregiver could provide in the absence of a friend or family member.

The effect of social support may also vary based on other individual-level characteristics such as personal health beliefs. Indeed, Voils, Steffens, Flint, and Bosworth (2005) examined the interaction effect of social support and a patient's internal locus of control (LOC) and found that for those patients with high internal LOC, social support was significantly associated with medication adherence, but for those with low internal locus of control, the relationship was no longer significant.

Living Situation. Similar to social support, family living environment has been found to have both a positive effect (Wen, Parchman, & Shepherd, 2004) and a negative effect on older adults' self-management behaviors (Dunbar-Jacob, Bohachick, Mortimer, Sereika, & Foley, 2003). In studies examining the impact of older adults' living situation on health outcomes, the findings have also been mixed. For example, Naylor and colleagues' (1999) randomized clinical trial of comprehensive discharge planning and home follow-up for older adults found that living with others decreased the risk for first hospital readmission by half (Incidence Density Ratio=0.50, p=.009). Yet, five years later, Naylor's team (2004) found that living alone decreased the risk for first hospital

readmission or death by nearly 40% (Incidence Density Ratio=0.59, p=.043) (Naylor et al., 2004).

Vik and colleagues (2006) similarly found in their study of Canadian community-dwelling older adults (N=319) that living in a communal senior setting versus a private home was protective and reduced the risk for nonadherence by more than half (O.R.=.46; C.I.=.27-.78). To help explain these findings, the authors also found that those adults who reported receiving assistance with their medications were half as likely to be nonadherent (O.R.=.49; C.I.=.29-.82). With regard to adherence to medical treatment, a meta-analysis of 17 studies by Dimatteo (2004) found that adults living with others had a modest, yet statistically significant increase, in treatment adherence (O.R.=1.38, C.I. [1.04-1.83]). The author cautioned, however, that living with others was more likely to positively affect behavioral regimens than to affect medication regimens.

Qualitative Studies on Medication Self-Management

The context of risk and protective factors (i.e., individual characteristics, social environment, and condition-specific factors), however, does not alone explain older adults' medication self-management behavior. Indeed, medication nonadherence can also be an intentional act to not take one's medications, and stem from the patient's knowledge, attitudes, and beliefs about their medications. These factors, however, are often more difficult to measure because of the nuanced reasons people have for not taking their medications exactly as prescribed. Several qualitative research findings thus aid in our understanding of why older adults either intentionally or unintentionally miss and/or are late taking their medications. For example, August (2005) conducted a qualitative study using focus groups with 49 community-dwelling older adults (aged 65 years or

older) and identified several individual-level factors that were barriers to medication adherence. Analysis of the older adults' responses identified the following risk factors in rank order of frequency (1) cognitive factors (e.g, forgetting); (2) physical factors (e.g., dexterity/seeing); (3) cost factors; and (4) other factors (e.g., side effects or disliking taking the medication).

Similarly, Vik and colleagues (2005) examined older adults' reasons for not taking their medications and found the participants had both intentional and unintentional reasons for not taking their medications. The most common intentional reasons were: nonadherence due to side effects; altering dose as they saw fit; and/or did not think the medication was effective. Unintentional reasons offered included: forgot, confused, and ran out of medication. When viewed as processes some adults are actively self-managing their medications by intentionally choosing to be nonadherent, while others perhaps are attempting to self-manage, but not effectively enough to be adherent.

Research examining healthcare provider relationships also found a significant effect on medication adherence in older adults. In a qualitative study with 98 community-dwelling cardiac patients, Gordon, Smith, and Dhillon (2007) found that most individuals are indeed self-managing their medications, but often without seeking the advice and/or informing their healthcare provider of their dosage adjustments. Moreover, those individuals who did report speaking with their clinician also expressed dissatisfaction with their encounters (i.e., not feeling their particular medication questions or concerns were adequately addressed by their provider). Many of the adults also expressed the desire to be active participants in their medication self-management, but reported several barriers to effective communication with their provider: being confused

by the medical jargon; feeling inferior to their physician; and receiving inconsistent advice from different providers. From these individuals' experiences, the authors observed that medication-taking is a dynamic process for an individual, and thus requires regular ongoing consultation with clinicians in order to meet their unique healthcare needs.

Rifkin and colleagues (2010) similarly provide insight into the interaction between the context and processes of self-management. In a set of semi-structured interviews with older patients diagnosed with chronic kidney disease (N=20), the authors specifically describe how the interactions between social environment (i.e., access to provider and provider relationship) and patient processes (knowledge/beliefs and self-regulation skills) can lead to medication nonadherence. The patients were on multiple medications, and shared that they even though they intended to take all their medications, they would also prioritize medications, and sometimes skip the ones they felt were less important. In addition, the patients reported that medication side effects were common and provoked feelings of anxiety. Unfortunately, the patients also reported that conversations with their providers were often delayed and/or unfulfilling.

Wilson and colleagues' (2007) nationwide study of 17,569 community-dwelling older adults from high-poverty neighborhoods also illustrates the benefits of patient-provider communication about medication management issues. The researchers examined patient self-reported rates of medication nonadherence as well as the effect of patient-physician dialogue on the provider switching to a lower cost medication. The authors found that 40% of the older adults reported being nonadherent at least once in the last year, and among those with three or more chronic conditions, more than half (52%)

admitted to being nonadherent. There were also differences in the rates of patient-initiated dialogue depending on the type of reported nonadherence. For example, older adults with cost-related nonadherence were less likely to have had a discussion with their physician (61%) than those who had experienced side-effects from the medication (73%). Nevertheless, as the number of reasons increased for why an older adult engaged in CRNA, the more likely they were to report having a dialogue with the physician about the medication management issue. The authors demonstrated that older adults with CRNA could ultimately benefit from these dialogues: Their multivariate analysis found that having a patient-physician dialogue resulted in a five-fold increase in a patient being switched to a lower-cost medication (O.R. 5.04 [C.I. 4.28-5.93, $p < .001$]). What is not known from this study, however, is what impact these dialogues ultimately had on the older adult's subsequent medication adherence.

Medication Adherence Interventions Targeting Older Adults

As previously noted, medication adherence (i.e., the process of taking the correct medication at the correct time and dosage) requires the older adult to perform a complex combination of cognitive and behavioral activities (Alspach, 2011; Marek & Antle, 2008), and when the older adult lacks the requisite skills and/or resources, the risk for nonadherence increases. Several recent reviews of the literature have attempted to identify what works and what is still unknown, and these are briefly summarized below.

In 2008, Marek and Antle conducted an evidence-based review of interventions targeting medication management in the community-dwelling older adult, and identified 52 studies published between 1990 and 2005. The inclusion criteria limited the analysis to those studies published in English and included participants ages 65 years and older.

The majority of the interventions were randomized controlled trials delivered by nurses and pharmacists. The authors' in-depth analysis of the interventions identified several strategies for promoting medication adherence (e.g., assistance with medication reconciliation and procurement; assessment of knowledge, physical and cognitive deficits; and ongoing monitoring). The authors also noted that while the most effective interventions included multiple components, they could not assess the effectiveness of individual components due to the lack of studies that separately tested each individual component.

Haynes and colleagues (2008) also conducted a systematic review of the literature, but found that the interventions varied too much to conduct a quantitative analysis of the findings. Nevertheless, similar to Marek and Antle (2008), their qualitative analysis found that numerous medication adherence strategies had been employed including: patient education and counseling; telephone and packing reminders; simplified dosing; and patient self-monitoring of health. The authors also found that long-term therapy interventions are often complex and labor intensive, yet the evidence of what constitutes an effective intervention "remains surprisingly weak" (p. 17): Less than half the studies demonstrated a significant improvement in medication adherence, and less than a third showed significant improvement in the targeted health outcome. The authors concluded that the following methodological issues need to be resolved including: agreement on a reliable and valid measurement of medication adherence; ensuring adequate power in the sample sizes to detect clinically significant differences; and designs that actually test the effects of the individual components of an intervention.

Coleman and colleagues' (2009) review of the literature raised another important criticism about current adherence interventions. Most programs still target the patient without focusing attention on the development of practice designs that could better meet the patients' needs. This is in spite of the fact that several studies have found that the quality of the patient-provider relationship significantly impacts a patient's adherence behaviors (Drennan et al. 2011; Gordon, et al., 2007; Lewis et al., 2010), and that the Chronic Care Model (Bodenheimer, Wagner, & Grumbach, 2002), a model recommended by both the IOM and RWJF, emphasizes the importance of the healthcare system in providing self-management support.

In addition, a review by Schlenk, Bernardo, Organist, Klem, and Engberg (2008) suggests that more research is needed regarding the effect of ongoing self-management support. The concern is that most studies have not produced sustainable patient behavior change (i.e., once the intervention ends, so does its effects). For example, Lee, Grace, and Taylor (2006) conducted an elegant design where all patients received the pharmacy care intervention for six months, and then the patients were randomized into two groups where one group went back to usual care and the other group continued with the intervention. At the end of the first phase the average adherence rate was 96.9%, but once the usual care group lost the support, their adherence rates dropped down near baseline, whereas the intervention group maintained adherence: 69.1% (16.4) vs. 95.5%(7.7%). Murray and colleagues (2007) and Schulz, Porter, Lane, Cornman, and Branham (2011) similarly found that once their interventions ended, the intervention effects were no longer significant.

Finally, Ruppap, Conn, and Russell (2008) reviewed 63 intervention studies and found that medication adherence strategies fell into three categories: patient focused factors, medication factors and medication administration factors. The authors also concluded that more studies are needed that acknowledge informal caregivers and the social context surrounding medication adherence. They further observed that nurses in the hospital setting are the primary health professional working with patients as clinical educators, discharge planners, case managers, inpatient medication management, and in the outpatient setting as home health nurses, community health nurses and parish nurses. Thus nurses are ideally suited to provide ongoing medication management support. Interestingly this observation stands in contrast to a review by Hughes (2004) that did not acknowledge the role of the nurse on the healthcare team, and only discussed the relationship between the pharmacist and physician.

Nursing Interventions on Medication Adherence in Older Adults

In addition to the several meta-analyses reviewed here, this author conducted a search of recent (within the last ten years) nursing interventions and found only five nurse-led interventions designed to increase medication adherence in community-dwelling older adults. Specific inclusion criteria for this search were:

1. Participants were community-dwelling older adults (mean age 60 years or older) living in the United States;
2. Nursing care (including patient education) was an active ingredient of the intervention;
3. Medication adherence was a targeted outcome.

Originally, a total of five studies met inclusion criteria, but upon closer examination, Artinian and colleagues' study (2003) did not meet inclusion criteria because the control group in the study had failed to accurately complete their pill counts. The study characteristics of the remaining four interventions are summarized below:

Study Design and Theoretical Framework. Three of the studies used a randomized controlled trial design (Barnason, Zimmerman, Hertzog, & Schulz, 2010; Ruppap, 2010b; Wu, Corley, Lennie, & Moser, 2012), and one study was quasi-experimental with a pre-post test design (Kim, Han, Park, Lee & Kim, 2006). All four studies focused on patients with heart disease (either heart failure or hypertension). In addition, all four studies used individual-level theories/models for their conceptual framework including: Social Cognitive Theory (Barnason et al., 2010); Theory of Planned Behavior (Wu et al., 2012); Leventhal's Self-Regulation Model (Ruppap, 2010b); and Braden's Self-Care Model of Learned Response to Chronic Illness (Kim et al. 2006). Wu and colleagues (2012) did note, however, the importance of social norms in health behavior change, and thus had invited significant others to participate in the education and counseling sessions.

Setting and Study Population. Two of the interventions were delivered in the participants' private homes (Barnason et al., 2010; Ruppap, 2010b; Wu et al., 2012), one by telephone (Barnason et al., 2010), and one was delivered in a group community setting (Kim et al., 2006). Only two of the researchers specifically targeted patients with adherence issues. Barnason and colleagues (2010) included only those heart failure patients who were recently discharged (within 48 hours), had at least five medications, and at least one of the medications with twice or more daily dosing. Ruppap (2010b)

conducted a one-month run-in with the MEMS caps, and only included those participants who were less than 85% adherent with their hypertension medication. Wu and colleagues (2012), on the other hand, included both adherent and nonadherent (defined as having less than 88% adherence during the MEMS cap one-month run-in) patients, but stratified the two groups prior to their randomization.

In three out of the four studies older adults with cognitive impairment were excluded: Barnason and colleagues (2010) and Ruppap (2010b) both screened participants with the Short Portable Mental Status Questionnaire (SPMSQ); and Wu and colleagues (2012) used the Mini-Cog Exam. Three of the studies were pilot studies so their sample sizes were small (<50 participants). The exception being Wu and colleagues' (2012), whose sample included 82 older adults. Racial diversity was also uneven among the studies. For example, Kim and colleagues (2006) study sample comprised solely of Korean Americans (N=31), whereas Barnason and colleagues (2010) did not report the racial composition of their 40 participants. Ruppap's (2010b) study sample of 15, however, included 5 African Americans and 1 Pacific/Islander, and Wu and colleagues' study (2012) included 17 African Americans.

Medication Adherence Measurement. Similar to the studies' settings and samples, measurement of adherence also varied. Barnason and colleagues (2010) used a self-report assessment tool, the Brief Medication Questionnaire (BMQ), to measure medication adherence as the percentage of medications taken in the last week. The authors measured both medication adherence at baseline, one month and three months. Kim and colleagues (2006) also used a self-report measure, the medication-taking subscale of the Hill-Bone Compliance to High Blood Pressure Therapy scale (Kim et al.,

2000). The researchers collected medication adherence scores at baseline (pre-test) and at six month follow up (post-test). Ruppap (2010b) and Wu and colleagues (2012), on the other hand, used the MEMS cap in order to calculate the percentage of medications taken correctly. Both studies, however, only tracked one prescription per participant regardless of the number of medications prescribed. Ruppap (2010b) assessed medication adherence over several data points (i.e., baseline, 4 weeks, 8 weeks, 12 weeks, and 20 weeks), whereas, Wu and colleagues (2012) collected medication adherence data at baseline, 2 months and 9 months. The former study, however, analyzed medication adherence as a continuous variable while the latter dichotomized the variable.

Intervention Components. All four studies used theory to inform the intervention components, but differed in the dosage and/or active ingredients. For example, Barnason and colleagues (2010) developed an algorithm for the nurse intervener in order to individually tailor the medication self-care modules to the participants' self-care needs. The authors did not describe the details of the algorithm, but explained that the educational program was based on recommendations by the Heart Failure Society of America, and focused on promoting participant self-efficacy and problem-solving regarding barriers to adherence. In total, the intervention consisted of three self-care modules that the nurse delivered over the course of two telephone calls lasting 20-30 minutes each. The authors also did not describe the interval between the two calls.

Ruppap (2010b) delivered a five-component biobehavioral feedback intervention through a series of four biweekly home visits. Based on the intervention's guiding theory that a person's health behavior is influenced by perceived symptom feedback, the author

chose to use MEMS Smart Caps with LCD display, which not only allows the participants to see when they had last taken their medications, but also the nurse to download biweekly data on the participant's medication taking habits and discuss the results with the participant. In addition to the medication adherence assessment, the nurse conducted biweekly blood pressure readings to share the results with the participant. Additional intervention components included assessment of medication-taking skills, habit adjustments, and education on hypertension and the participant's specific medications.

Kim and colleagues (2006) similarly designed an intervention to promote the participants' self-help skills in medication adherence in managing their hypertension. The intervention nurse conducted group seminars designed to educate the participants on a variety of medication self-management strategies including increased knowledge about hypertension, skills needed to self-monitor their blood pressure at home, and general problem-solving skills. Social support from a bilingual nurse was also thought to promote adoption of the participant's self-help skills. The nurse delivered the two-hour education and skills sessions once a week over the course of six weeks, and then offered monthly one-hour support group sessions. The only home visit the nurse conducted was after the first education session in order to assess the participant's ability to properly use the home-based blood pressure medication adherence machine.

Wu and colleagues (2012) conducted a three-arm intervention in order to assess whether the education plus MEMS feedback group (PLUS) would achieve higher adherence rates than those in either the education alone group (LITE) or the usual care group (UC). Based on the Theory of Planned Behavior (TPB), the authors hypothesized

that education and counseling would foster the participant's positive personal beliefs as well as subjective norms regarding medication adherence, and that this would in turn lead to positive intention and ultimately behavior change. In order to promote positive subjective norms, the participants were encouraged to identify those supportive persons who could help them with optimizing their medication-taking behavior. Supportive others were also invited to attend the education sessions. In total there were four biweekly sessions: Two one-hour home visits (1st and 3rd sessions) and two telephone calls (2nd and 4th sessions) that lasted approximately 15-20 minutes each. The PLUS group participants also received MEMS cap data feedback from the nurse at the two home visits in order to discuss the reasons why doses were missed, and thus provide additional insight into ways to reduce barriers to adherence.

Intervention Effects on Medication Adherence. Barnason and colleagues' (2010) initial multivariate analyses using ANOVA found no significant intervention effect on medication adherence. The team then measured medication adherence as a dichotomous variable using Wu and colleagues' (2008) $\geq 88\%$ cut-off for heart failure adherence, and found significant group differences at one month ($p=.003$) and three months and ($p=.03$). Because of the small sample size ($N=15$), Ruppert (2010b) used nonparametric testing (i.e., Mann-Whitney) in order to assess intervention effects over time (i.e., from baseline to Week 20), but only found significant median group differences at Week 8 ($p=.013$). Wu and colleagues (2012) used repeated measures ANOVA and found that participants in the PLUS group had a significantly higher mean adherence rate than the control group at both 2 months ($p=.05$) and 9 months ($p=.021$), but the LITE group only had a significantly higher rate at 9 months ($p=.04$). Kim and

colleagues (2006), however, found no significant intervention effect when they compared the pre-test post-test scores on the HBC medication-taking scale.

Synthesis of the Intervention Findings. Unlike the majority of pharmacy-based interventions that target pharmacist behaviors in order to increase patient medication adherence, nursing science, has moved beyond treating the patient as a passive recipient and toward recognizing the patient as an active participant in the management of their medications. These four interventions thus focused on developing patient self-capacity through knowledge and skills training as a way to optimize adherence. This emphasis by the nursing profession is further reflected in recent qualitative studies (Lewis et al., 2010; Gordon et al., 2007) where nursing researchers specifically elicited the patient's perspectives on medication management in order to develop more effective patient-centered interventions.

There are several limitations, however, to these intervention findings. In general, the studies had small sample sizes, and this may have limited their power to detect significant intervention effects. In addition, for most of the studies the participants' baseline adherence rates were already high and this may have caused a ceiling effect. For example, Barnason and colleagues (2010) reported that the mean baseline adherence rates for the intervention and usual care group were 98.3 (SD=.1) and 93.7 (SD=.1) respectively. Despite the importance of social environment-especially social support, only one study encouraged the participation of a supportive other. In addition, none of the studies reported whether or not there were qualitative findings to help explain what worked and what did not work in the intervention.

Chapter Summary

This review of the literature identified several gaps in the science: (1) There remains inconsistency in how medication adherence is measured; (2) There is questionable reliability and validity of the existing measures of medication adherence; (3) There is conflicting evidence and/or lack of evidence on what are the significant protective/risk factors as they relate to medication adherence; (4) There continues to be a lack of evidence on effective interventions for older adults who have difficulty self-managing their own medications; and (5) Few nursing interventions have been developed and tested in the United States, and of those identified in the literature, the sample sizes were either too small and/or homogenous to evaluate their effectiveness.

This review underscores the need for a mixed-methods study that has the power not only to identify which older adults are at risk for medication nonadherence, but also the data to explain why these older adults are at risk. The current study, with its larger sample size and qualitative component, has the potential to make a significant contribution to nursing science and to the development of more effective interventions for older adults in the self-management of their medications. The study contributes to the state of the science by attempting to:

1. Increase our understanding of the contextual factors associated with medication adherence in frail urban older adults.
2. Describe the processes involved in older adult's medication self-management.
3. Utilize the qualitative data to better understand why older adults missed their medications.

CHAPTER 3

METHODOLOGY

This chapter describes the study design, population, data collection, protection of human subjects, and data analysis. The study took an alternative approach from that of the standard postpositivist (i.e., quantitative) stance by integrating a qualitative component for the purposes of developing a more complete understanding of medication adherence in older adults. The “mixed methods” approach is often referred to as “pragmatic” because the design of the study is guided by a “what works” paradigm in order to inform real-world practice (Creswell & Plano Clark, 2011, p. 41). The philosophical assumptions of a pragmatic approach are that multiple realities exist for any given phenomenon, and that in order to capture these varied perspectives, mixed methods are needed to more fully explore the phenomenon (Creswell & Plano Clark, 2011). Similarly, Tashakkori and Teddlie (1998) argue, “The best method is the one that answers the research question(s) most efficiently, and with foremost inference quality (trustworthiness, internal validity)” (p.167). Thus, taking a pragmatic stance, informed by Ryan and Sawin’s (2009) Individual and Family Self-Management Theory, the study used a mixed methods design in order to better understand the complex phenomenon of medication adherence in older adults. As previously noted, the specific purposes of the study were to:

- (1) Identify significant risk and protective factors for medication adherence/nonadherence in frail urban older adults;
 - (2) Describe the processes involved in older adults’ medication self-management;
- and

(3) Utilize qualitative findings to enrich our understanding of the quantitative findings of the study.

Design

A common criticism of randomized-controlled trials is the standard “black box” approach in which the researchers generate statistically significant findings through the use of quantitative methods, but then lack the ability to explain how or why the intervention worked (Sidani & Braden, 1998). Qualitative studies, on the other hand, provide researchers with a better understanding of the “nature” of the problem by examining the perspectives of the person(s) experiencing the problem (Strauss & Corbin, 1998, p.11). In response to this challenge, social science researchers are increasingly using a mixed methods approach in order to provide “a more comprehensive account” of the phenomenon of interest (Creswell & Plano Clark, 2011, p. 62).

Ascribing to this argument, this study utilized an explanatory sequential mixed methods design in order to describe as well as explain the context and processes involved in the participants’ medication self-management. As previously noted, the Individual and Family Self-Management Theory (IFSMT) (Ryan & Sawin, 2009) was specifically chosen to inform this study because the theoretical propositions for medication self-management go beyond the individual-focused approach that has dominated most of the adherence research to date. If the ultimate goal of research in chronic health conditions is to increase self-management, we must first recognize that the majority of older adults are indeed “members of a social unit” (Ryan & Sawin, 2009). Based on this understanding, we must then acknowledge that older adults’ health behaviors are influenced by the contexts of their social environment. The constructs and propositions of the IFSMT thus

served as a conceptual lens in the analysis of both the quantitative and qualitative components of the study.

With its sequential design, the study first used the quantitative data from this sample of frail older adults to identify “who” was at risk for medication nonadherence (based on measured factors), at Month 1 as well as over time. The quantitative component alone, however, could not explain the underlying processes driving the relationships. To address this methodological limitation, the qualitative component attempted to explain the “why” by analyzing and describing the reasons the participants gave for missing their medications.

Study Population. The population of interest for the original study were frail older adults living in a Midwestern metropolitan area who had been recently discharged from one of the area’s three home health care agencies, and who at discharge were identified as having an impaired ability to manage their medications. Specific inclusion criteria were:

1. Age 60 years or older;
2. Medicare as the primary payer;
3. Impaired medication management (i.e., a score of 1 or higher on the OASIS-B1 (USDHHS, 2001) assessment item [M0780]) indicating an inability to correctly take oral medications at the prescribed dosages and times); and/or
4. Mild cognitive impairment (i.e., a score of 1 or 2 on the OASIS-B1 item [M0560] indicating need for prompting and/or assistance with focusing attention on an intended task); and
5. A working telephone.

Exclusion criteria were:

1. Not English speaking;
2. Having a terminal diagnosis (a risk for attrition);
3. Already using another device for medication management;
4. Enrollment in a Medicare Advantage plan.

Participants were randomized to either one of two intervention groups (mediplanner or MD.2 machine) or to a usual care control group. For the present study, only the data from the two intervention groups were included as the data for the dependent variable, medication adherence, were not collected in the usual care group.

Setting and Sample Size. The time period for the initial study began in May 2006, and concluded with the last data collection in May 2010. Participants enrolled in the study were followed by the research team for a total of 12 months or until they withdrew from the study (either voluntarily, were hospitalized, moved, or expired). The setting of the initial randomized controlled trial was a nurse care coordination program. As a result, all study staff conducted home visits in order to collect the data and to deliver the intervention. Once participants enrolled in the study, the intervention nurses made home visits at least biweekly, and then anytime there was a medication change and/or the participant's clinical condition warranted additional visits. Data collectors made quarterly home visits in order to complete the various study instruments.

To give the original study an 85% probability of detecting a 2-point difference among the three group's mean SF-36 PC and MC subscale scores and a <5% probability of a Type I error, a final analytic sample size of 300 was required. Based on experience from a previous study of chronically ill older adults, the team anticipated a 25% attrition

rate over a one-year period (Marek, Popejoy, Petroski, & Rantz, 2006; Marek et al., 2005), and thus enrolled an additional 100 participants to account for the expected attrition. Whereas the targeted sample size was originally 113 participants for each of the three study groups (N=339), the actual final sample size for those who completed the study was 414. For the current study, the estimated sample size needed for multivariate analyses was based on Mertler & Vannatta's (2010) recommendation of at least 15 cases per independent variable tested. The inclusion of up to fourteen variables in the predictive models required a minimum of 240 participants. The total number of intervention participants included in this study (N=268) met the threshold.

Procedures for Data Collection

The data for this current study were collected as part of a larger repeated-measures randomized controlled trial (i.e., the Home Care Medication Management for the Frail Elderly Study) that tested the effects of a nurse care coordination intervention on health outcomes, and cost outcomes of frail older adults. Approval to conduct a secondary data analysis was obtained from the Institutional Review Board (IRB) at Arizona State University under an expedited review process.

For the quantitative component, the data collectors obtained the baseline independent variable data during a home visit with the study participants. Data related to the dependent variable, medication nonadherence, were collected every two weeks for the mediplanner group at the home visit as the nurse interventionist filled the mediplanner. For the MD.2 group, the MD.2 machine notified the nurse by phone when the participant missed a dose.

For the qualitative component of the study, the intervention nurses collected the data at the biweekly home visit. The setting of the participants' home was especially important for collecting this data as it provided a safe, nonthreatening environment that would be more likely to promote an honest disclosure by the participants about their medication nonadherence (Hammersley & Atkinson, 1995). Every two weeks, the intervention nurse documented the number of medication doses missed, and then asked the participant if there was a reason for missing the medication dose(s). The nurse then entered the number of missed doses and the responses into the participant's electronic health record (Carefacts®). Participant responses were later extracted/transcribed into a secured file that included: the participant's ID, the month they missed the medication dose(s) and the participants' reason(s) for why they missed the medication doses.

Protection of Human Subjects

This study posed minimal risk to human subjects. The quantitative data were in a SPSS dataset with only the participant study ID as a link to the variables of interest. Similarly, the qualitative data were de-identified prior to analysis: The study file, and spreadsheets only had the participant's study ID linked to his/her monthly response(s). There is always the small possibility that participants might recognize themselves in the qualitative analysis, but it is unlikely.

Data Analysis

The data for the quantitative and qualitative components of this study were collected concurrently as part of the original study. For the purposes of the present study, the quantitative and qualitative data were incorporated into an explanatory sequential design with the qualitative analyses primarily used to deepen our understanding of the

quantitative results. Thus, the quantitative data were examined first in an effort to answer the initial two research questions. Once the quantitative findings were generated, the qualitative data were then analyzed with the dual purposes of: (1) Exploring and describing the diverse processes the participants used to self-manage their medications; and (2) Explaining the significant risk and/or protective factors identified by the statistical modeling. For example, for each independent variable that significantly predicted medication adherence, the participant responses were compared/contrasted along the variable in order to identify any underlying processes that might account for quantitative differences. With this sequential mixed-methods design, the findings from the quantitative component largely guided the analysis of the qualitative data. The two design elements were then further integrated in the final discussion of the study findings.

Quantitative Component. The two Research Questions were:

1. What are the contextual and/or process dimensions that emerge as significant risk and protective factors for medication adherence at Month 1 of the study?
2. What are the contextual and/or process dimensions that emerge as significant risk and protective factors for medication adherence over the course of the study?

Dependent Variables for Research Questions 1 and 2. Medication adherence was measured as a monthly percentage. During the biweekly visit, the nurse would count how many pill doses were missed, and then enter this count into the participant's electronic health record. The monthly medication adherence rate was then calculated by taking the monthly count of missed prescribed pill doses and dividing this by the total number of

monthly prescribed pill doses. These monthly percentages were then entered into the study's SAS file. For Research Question 1, the dependent variable was the participant's Month 1 medication adherence percentage. For Research Question 2, the dependent variable was the average of the participant's monthly medication adherence percentages.

Measurement Tools for the Independent Variables. This study used data from a combined set of data collection forms and measurement tools included in the original study. The primary data collection form was the discharge version of the Outcome and Assessment Information Set (OASIS-B1), (USDHHS, 2001). The specific variables of interest and the instruments are further described below.

Individual Characteristics. Individual characteristics included participant age, race, and gender. All three of these variables were taken from the OASIS-B1. In 2004, Hittle and colleagues reported excellent interrater reliability (1.00) for both race and gender. Because the dependent variable for Question 2 was medication adherence over time, a continuous variable "number of months in study" was also created to account for the participants' differential opportunities over time.

Condition-Specific Variables. Condition-specific variables included cognitive functioning, physical functioning, psychosocial well-being, medication regimen complexity, and vision problems and hearing problems. The data for each of these variables were taken from the participant's baseline measurements. Vision and hearing were taken from the OASIS-B1. Hittle and colleagues (2004) reported an interrater reliability of .85 for vision and .69 for hearing. For the remaining variables, their corresponding measures are further described below.

Cognitive Functioning was measured using the Mini Mental Status Examination (MMSE) as it has been found to be "useful in quantitatively estimating the severity of cognitive impairment" (Folstein et al., 1975, p. 196). The instrument is a widely used 11-item measure of a person's cognitive ability across five domains (orientation, registration, attention and calculation, recall, and language). The MMSE has a maximum score of 30, but can be scored as a dichotomous, categorical, or continuous. A comprehensive review of the MMSE by Tombaugh & McIntyre (1992) found test-retest reliability between .80 and .95 among studies where the retest interval was two months or less, and when the authors examined the evidence for construct validity, they found correlations with other cognitive screening tests in the range of .70 to .90. The authors also found that criterion validity (i.e., sensitivity and specificity to detect dementia) was at least 79% for 70% of the studies when the cut-off criterion for the MMSE was set at 23 or less.

Psychosocial well-being was measured by the Geriatric Depression Scale (GDS). The GDS is a 15-item yes/no dichotomous questionnaire that is a widely used as a screening tool for late life depression. Friedman and colleagues (2005) tested the psychometric properties of the GDS on a sample of N=960 cognitively intact, community-dwelling patients ages 65 and older. The authors found good internal consistency reliability ($\alpha=.75$) as well as good construct validity for measures of major depression, depressed mood, low life satisfaction, and suicide ideation. The authors also found the GDS to have an acceptable criterion validity (sensitivity=.814 and specificity=.754) at a cutoff value of 6.

Physical functioning was measured by the 7-item Physical Performance Test (PPT) (Reuben & Siu, 1990) which allows for direct assessment of an older adult's

ability to complete various tasks such as writing a sentence, putting on a coat, and simulating eating. Reuben and Siu (1990) tested the PPT in 183 older adults across a variety of settings, and reported acceptable levels of reliability and validity for the instrument including: Interrater reliability of 0.93; Cronbach's alpha of .79; and .80 construct validity with the Tinetti gait score.

Medication Regimen Complexity was measured by the Medication Complexity Index (MCI) (Kelley, 1988) which is based on a composite score of the patient's number of medications, doses, and instructions. For example, if a medication is prescribed three times daily, the medication receives a score of 3 versus a score of 1 if only a once daily dose. Conn, Taylor, & Kelley (1991) reported excellent validity and reliability with this scale: An expert's ranking of medication regimens and their corresponding MCI scores correlated at .89, and the test-retest reliability after one week ranged from .80-1.00.

Social Environment. Social Environment was measured by four dichotomous variables that are part of discharge version of the Outcome and Assessment Information Set (OASIS-B1) (USDHHS, 2001) including: living situation; caregiver residence; receiving ADL assistance; and receiving IADL assistance.

Process Dimension. The process of medication self-management can include the use of cognitive prostheses (i.e., calendars, alarms, pill organizers) to optimize medication adherence. In this study, process was measured by the participant's intervention group assignment: MD.2 or mediplanner.

Table 1 describes the variables and measures to be used in the quantitative component of the study.

Table 1
Variables and Measures

Framework Construct	Variable	Instrument/Source	Reliability & Validity
Individual-Level Characteristics			
	Age	OASIS-B1 (M0066)	-
	Race	OASIS-B1 (M0140)	Test-Retest Reliability=1.00
	Gender	OASIS-B1 (M0069)	Test-Retest Reliability=1.00
Condition-Specific Characteristics			
Cognitive Functioning			
	MMSE	Baseline MMSE	Test-Retest Reliability =0.80-0.95 Construct Validity=0.70-0.90
Psychosocial Well-being			
	GDS	Baseline GDS	Cronbach's alpha=0.75 Criterion Validity (sensitivity =.814; specificity=.754)
Complexity of Treatment			
	MCI	Baseline MCI	Test-Retest Reliability=0.80-1.00
Physical Functioning			
	PPT	Baseline PPT	Cronbach's alpha = 0.75 Interrater reliability = 0.93 Construct Validity = 0.80
Visual Acuity			
	Vision	OASIS-BI (M0390_1)	Interrater Reliability=.85
Hearing Acuity			
	Hearing	OASIS-B1 (M0400_1)	Interrater Reliability=.69

(table continues)

Table 1 (*continued*)

Framework Construct	Variable	Instrument/Source	Reliability & Validity
Physical & Social Environment			
Living Situation			
	Lives Alone	OASIS-B1 (M0340_1)	-
Caregiver Residence			
	In-Home CG	OASIS-B1 (M0350_2)	-
Supportive Assistance			
	ADL Support	OASIS-B1 (M0380_1)	-
	IADL Support	OASIS-B1 (M0380_2)	-
Process			
Cognitive Prosthesis			
	Pill Organizer	Group Assignment	-
Proximal Outcome			
Month 1 Adherence			
	MNA	Month 1 Percentage	-
Adherence Over Time			
	MAOT	Average Adherence Percentage	-

Pre-Analysis Data Screening

The quantitative component of this study included descriptive statistics and multiple regression equations in order to identify those participant and family characteristics that significantly predicted risk for medication nonadherence at Month 1 as well as over time in this sample of frail urban older adults. In order to answer Research Questions 1 and 2, the data were first examined for any missing values among

the independent and dependent variables. Even though all participants in the original study were required to complete baseline questionnaires, there were five cases where the participant either did not complete a baseline MMSE (N=4) or PPT (N=1) as they were aphasic and/or unable to complete. These five participants were not included in the study, because it was not possible to estimate or impute their scores without introducing bias into the models. An examination of the data also found that eight participants had missing adherence for Month One. The adherence percentage from the next measured month was then used as the Month One adherence rate. For seven of the participants, the Month 2 adherence percentages were used, and for one case the Month 3 adherence percentage was used.

Next, ordinary least squares regression models were run for Research Questions 1 and 2 to identify any outliers that might put undue influence on the two full models as well as any potential multicollinearity among the predictor variables (Field, 2005; Mertler & Vannatta, 2010). Residuals statistics (i.e., Cook's Distance and its standardized version DFBeta) were first examined for cases that might be exerting undue influence on the model. Field (2005) recommends that cases with a Cook's Distance and/or DFBeta > 1 should be further examined, however, all cases fell below that threshold (data not shown). A second recommended check for outliers, the calculation of Mahalanobis' distance, (Mertler & Vannatta, 2010) also found no outliers (i.e., none of the cases exceeded the $X^2(14)=36.123$ threshold at $p<.001$). Diagnostics on both models also found no collinearity problems with VIF scores all less than ten and tolerance scores all greater than 0.1 (Field, 2005).

Qualitative Component

Qualitative data analysis is a multilevel process that begins with data management and/or organization of the data, follows with reading and reflecting on the text, classifying and interpreting the data, representing the data in the form of a table or figure, and then discussing the findings (Creswell, 2007). Because the primary purpose of the study's qualitative component was to enrich our understanding of the quantitative findings, the qualitative analysis focused on why the participants experienced an episode(s) of medication nonadherence. Content analysis is a systematic approach that identifies, organizes, and clusters units of meaning within a text in order to describe a phenomenon (Hsieh & Shannon, 2005; Lincoln & Guba, 1985). A specific type of content analysis, directed content analysis, is often used when the goal is to validate or extend existing theory and/or the state of the science (Hsieh & Shannon, 2005). Directed content analysis follows a more deductive approach to content analysis with the use of initial codes (generated from a theory and/or existing research) to begin moving the data inferentially from themes, to categories, to overarching themes that support or extend a theory or conceptual framework (Zhang & Wildemuth, 2010). The use of existing theory and research in this study's coding process allowed for not only a discussion of how the findings enhanced our understanding of medication nonadherence in this group of frail older adults, but also how the findings compare with and/or extend the existing science on medication adherence.

The two research questions guiding this inquiry were:

Question 3: What are the themes that describe the participants' medication self-management processes?

Question 4: How do the qualitative data help explain the quantitative findings and contribute to a more complete understanding of the participants' medication adherence?

Definition of terms for qualitative analysis.

Below is a list of terms to describe the major components of my qualitative analysis. I present the terms in the order in which I organized, categorized, and interpreted the data.

Participant Response: An extracted nurse's note from the participant's electronic health record, under the Care Plan note: "Number of Missed doses and Why". In some instances, the note contained only the nurse's description of the participant's answer. In other instances, the nurse included direct quotes of the participant's response to the question.

Domain Analysis: An analytic procedure that "makes use of the semantic relationships" between the words used by a group of individuals for the purposes of gaining a deeper understanding of the cultural scene (Spradley, 1979, p. 107). For example, in the case of "nurse" and "healthcare provider", the domain is "healthcare provider", the semantic relationship is "a kind of", and "nurse" is a type of healthcare provider.

Meaning unit: A word an/or phrase within the participant response that describes the reason why the participant missed his/her medication dose(s) (Miles & Huberman, 1994).

Theme: A recurring idea in the data (Ryan & Bernard, 2003).

Code: A label assigned to a meaning unit, representing a theme (Miles & Huberman, 1994).

Category/Domain: A cluster of at least two or more themes that share conceptual similarities, and are linked by a single semantic relationship (Spradley, 1979).

Start List of Codes: A “provisional” list of categories and themes used to describe and label the participant reasons (Miles & Huberman, 1994).

Overarching Theme: A clustering of the categories (domains) that captures the meaning of the processes involved in medication nonadherence (Fereday & Muir-Cochrane, 2006). Overarching themes represent an overlap between two or more domains, and convey a higher “degree of generality” (Spradley, 1979, p. 186).

Procedures. An important assumption of this study’s conceptual framework is that, “Persons engage in behaviors for personally meaningful reasons that may or may not be directly related to optimizing their health status” (Ryan & Sawin, 2009, p. 21). This assumption follows a similar tenet of the theory of Symbolic Interactionism that “human beings act toward things on the basis of the meanings that things have for them” (Blumer, 1969, p. 2). Based on these two propositions about human behavior, I took an ethnographic approach to this qualitative inquiry in order to understand from the participants’ point of view why this highly managed group of frail older adults still experienced episodes of medication nonadherence. An “efficient” ethnographic strategy for understanding meaning within a culture is the use of a domain analysis because it provides a systematic procedure for examining the symbolic nature of words, and the identification of folk domains (Spradley, 1979, p. 107). In this case, I used a domain analysis worksheet to systematically examine the participant responses in order to

increase our understanding of why the older adults were nonadherent. To further strengthen my systematic approach to the data, I also followed steps outlined by Hseih & Shannon (2005) and Zhang and Wildemuth (2010) for qualitative content analysis. Figure 3 provides a diagram of the analytic process.

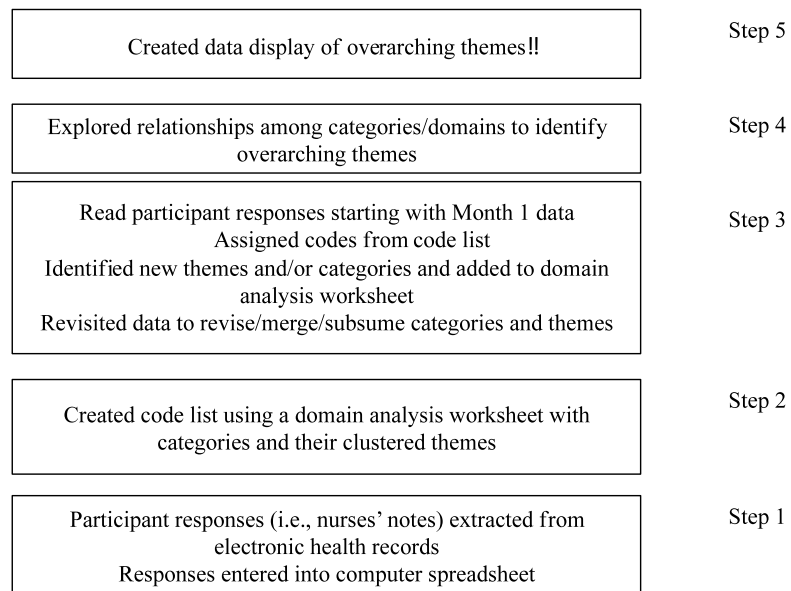


Figure 3. Diagram of Analytic Process.

In Step 1, Participant responses were extracted from their electronic health records and then entered into an Excel spreadsheet. The spreadsheet was organized with Participant ID in the first column, and then subsequent columns of the participant responses followed a temporal order: Month 1-13. For each visit the nurse provided a note, I entered that participant response under the corresponding month. Participants had

anywhere from zero to 4 responses per month. Next to each participant response was a blank cell for its assigned code.

Once I entered all the data, I proceeded to Step 2, which was to create a start list of codes derived from my review of the literature and the relevant constructs identified in the IFSMT. The inclusion of the theoretical constructs provided an organizing structure to the data analysis process, and allowed me to test how well the IFSMT fit or did not fit the data (i.e., explained the behavior of medication self-management) (Evans, Coon, & Ume, 2011). I used a domain analysis worksheet as the organizing template for my start list of codes (Crabtree & Miller, 1999). The domain analysis worksheet included each category (domain), its operational definition, and the themes belonging to that category based on a specific semantic relationship. For example, “rationale” is a type of semantic relationship whereby “X is a reason for doing Y” (Spradley, 1979, p. 111). Each theme on the domain analysis sheet had a coding number for notation purposes, its operational definition, and then an exemplar of the theme.

I next proceeded to Step 3. Using the start list of codes, I began reading through the first month of the participant responses, and then attempted to assign a code to each response. For each response that fit a theme’s operational definition, I entered the assigned code on the right hand column of the Excel spreadsheet. When a participant’s response did not fit one of existing themes, I then made a marginal remark, and continued reading through the participant responses. Once I had read the first month’s reasons, I went back and reviewed the marginal remarks to develop additional themes for the participant responses. I then added these themes to the domain analysis worksheet. In

concert with this process, I also maintained a reflective log with notes to myself documenting my reactions, reflections, and decision-making processes.

In order to maximize the dependability of this coding process, I followed Miles and Huberman's (1994) recommendations for testing both the intra- and intercoder reliability. To test intracoder agreement (internal consistency), I returned to this initial set of participants, a few days after the initial coding, and using a clean, unmarked Excel file, recoded the participant responses. Once I had achieved 90% intracoder agreement, I then checked for intercoder reliability by asking a trained second-reader to code this same set of participant responses. This process of check-coding with another researcher contributed to the dependability of the study findings by showing where disagreement occurred and allowed for refinement of codes and definitions. Once 90% intercoder reliability had been achieved, I proceeded with coding the remaining monthly participant responses. Again, any participant response that did not fit one of the initial start codes was assigned a new code that best reflected the statement, and this new code was then added to the working list of codes (Hsieh & Shannon, 2005). After all coding was done, I conducted another round of check-coding with Month 8 of the data set to increase the dependability of the analysis, and again achieved 90% agreement.

The list of themes and categories expanded as part of the iterative process inherent to qualitative inquiry (Bradley, Curry, & Devers, 2007). Table 2 illustrates the final Coding List for this study.

Table 2

Domain Analysis: Themes and Categories

1 Experiencing Problems with Planning and/or Action (unintentionally missing a prescribed medication dose due to forgetting and/or a disruption) ^is a reason for^		
Code Number	Definition of the Theme	Exemplar
1B	Having no daily routine - Missing a medication because there is no routine associated with the medication-taking process	“I don’t take them at the same time each day”
1C	Experiencing disruption in daily routine – Missing a dose because of a healthcare related event or being distracted by other event	“I had a doctor’s appointment”; “Participant was at dialysis”; “got busy with granddaughter”
1D	Leaving home without medication – Missing a prescribed dose because they were out for the day or on a trip and did not take their medication with them	“I went on a trip and forgot to pack them”; “pt was not home & forgot to early dose”
1G	Falling asleep – Missing a dose because they were asleep at the time it was due	“Fell asleep before the machine went off”; sleeping and didn’t hear machine”; slept late.
1H	Forgetting – Not remembering to take a dose, but either the participant did not offer a reason why they forgot, or the nurse did not document one	“forgot”

(table continues)

Table 2 *continued*

Code Number	Definition of the Theme	Exemplar
II	Dispensing dose from MD.2 then forgetting – Participant acknowledged dispensing the medication but then forgot to actually take the dose	“pt took from machine then forgot to take”
IJ	Forgetting Other Reason – Participant offered reason for why they forgot that does not correspond to other theme related to forgetting	“Put in his pocket and forgot”; “one nexium (accident)”; “forgot to take additional doses out of bottle”
2	Not Possessing the Medication (unintentionally not having enough medication to take scheduled dose) ^is a reason for^	
2A	Lacking transportation to pick up new prescription – Note indicated that transportation was the reason participant ran out of medication	“My daughter works and couldn’t take me to the pharmacy”
2B	Lacking a refill or prescription from provider – Note indicated that pharmacy could not dispense due to provider issue	“The pharmacy said there were no refills on file”; “waiting for MD office to call it in”
2D	Not possessing the medication but no reason given – Note documented medication was out, but no other reason given	“did not have furosemide, Klor con or 10 additional mg lisinopril with AM meds”
3	Being Physically Unable to Take the Medication (having a barrier [i.e., decreased physical strength, decreased visual acuity, hearing problem or organizer issue] that leads to unintentionally missing a dose) ^is an example of^	
Code Number	Definition of the Theme	Exemplar
3A	Experiencing visual problems – Note indicating they had trouble seeing the pill or missed seeing it there	“I didn’t see the pill in the container”; “didn’t white pill on white placemat”

(table continues)

Table 2 (continued)

Code Number	Definition of the Theme	Exemplar
3B	Experiencing dexterity problems – Having trouble with retrieving pills or with coordination to take pills	“family found 3 pills on floor since last visit, R/t clt transferring pills from cup to hand”
3C	Experiencing physical weakness – Lacking the physical strength or feeling too fatigued to take dose	“fell as was in pain and did not get out of bed on Monday”
3D	Organizer malfunctioning – unable to take because of machine malfunction or mediplanner issues	“pill stuck to planner; pt unplugged machine; ”
3E	Experiencing hearing problems – lacking ability to hear MD.2	“client didn’t hear machine, family gave when they arrived”
4	Relying on Social Facilitation (being dependent upon the influence, support, and/or collaboration of someone in order to take medication) ^is an outcome of^	
4A	Missing medication because CG did not give – Relying on family member who fails to follow through	“my spouse forgot to give to me”; “My daughter was called into work and wasn’t there to give me my pills”
4B	Taking medication incorrectly due to CG process error – CG behavior leading to an error in dosing or missed dose	“Took meds but incorrectly set up by grandson”; “caregiver states he gives to her, but sometimes she forgets to take”
4C	Experiencing nonadherence due to hospitalization – Missing a dose because of a transition in care	“Has not had any meds since hospital D/C 5 days ago”; “? Unable to tell, clt not clear on exactly how many days he was hospitalized”
5	Experiencing Problems with Knowledge & Beliefs (lacking the self-efficacy, outcome expectancy, and goal congruence needed to stay adherent with their medication) ^is an example of^	

(table continues)

Table 2 (continued)

Code Number	Definition of the Theme	Exemplar
5C	Lacking knowledge about the medication – Missing doses because they did not know the purpose and/or process for taking the medication	“I didn’t take it because I didn’t know what it was for; “My doctor gave me this medication but I didn’t know how to take it”
6	Using Self-Regulation Skills & Abilities (using goal setting, self-monitoring, reflective thinking, decision-making, planning & action, self-evaluation to intentionally miss medication dose) ^is an example of^	
6A	Choosing to skip a dose – Missing a dose because it conflicted with their life circumstance	“I know the medications are important, but I was going out, and didn’t want to deal with the side effects”;
6B	Recognizing they should hold dose – Not taking medication because either they or prescriber decided it was not warranted	“Did not take warfarin past 2 days b/c gums were bleeding...”
6C	Feeling burden outweighing benefit – Not taking meds related to fatigue or side effects	“Client reports she gets tired of taking all these pills”; “clt picks and chooses which meds she might want to take on any given am per her CG”; “meds give her HA”
7	Needing Additional Information from Participant (Lack of clarity in participant responses in relation to nonadherence) ^is an example of^	
Code Number	Definition of the Theme	Exemplar
7A	Denying they missed medications – RN noted missed med, but client denied	“saw one pill cup in bedroom; pt denies missing any doses”
7B	Having no reason – Either participant did not give a reason or the RN did not document a reason	“I don’t have a reason”; no reason noted

(table continues)

Table 2 (continued)

Code Number	Definition of the Theme	Exemplar
7C	RN being confused due to participant behavior – RN noted that she is unsure of what happened or is confused by what she saw with regards to missed doses	“unsure of insulin” taken; “client wouldn’t let me see the planner”; “No missed doses from MD.2; RN found 7 full cups of pills scattered around the apt.”
7D	Taking dose during RN visit – Missing a dose that day, but willing to take once RN alerted them	“did not take AM meds today; took at 2pm while RN in home; “missed this AM metoprolol, brought to clt attention & she took it”
7E	Being unsure of what happened- Participant unsure or unable to determine what happened	“Pt unsure why”; “doesn’t remember why”; “couldn't remember if took meds this morning or not”
<p>Experiencing Cognitive Difficulties (Specifically exhibiting trouble with memory and/or executive functioning that affects their ability to take their medications as prescribed) ^is a reason ^</p>		
8A	Being confused about organizer – Missing a dose because of confusion about how to use organizer	“got confused thought he was to start on Friday”; “missed with box change”; “confused about use of mediplanner”
8C	Unintentionally taking more than was prescribed – Nurse or participant noted that more medication was taken than prescribed	“Pt took meds after RN left instead of next day; no meds until RN arrived”
8E	Having trouble remembering - Missing a medication because they have trouble remembering	“I have trouble with my memory”; “I cannot seem to remember to take”

The next step was to count both the frequencies of the themes and categories within the overarching themes. Counting assisted me in “seeing” where the older adults

struggled the most with their medication self-management, and in maximizing my analytic honesty by not ignoring responses I did not anticipate (Crabtree & Miller, 1999; Miles & Huberman, 1994). Sandelowski (2000b) similarly notes that counting/frequencies can provide an additional source for confirming/validating the findings of a study, but this process should only be “a means to an end, not the end itself” (p. 338). Indeed the primary purpose of the directed content analysis was to describe the group’s medication self-management processes in order to deepen our understanding of why they were nonadherent. However, because the science still lacks an adequate theoretical understanding of the problem, a secondary purpose was to evaluate to what extent the concepts within Ryan & Sawin’s (2009) Individual and Family Self-Management Theory explained the health behavior of medication adherence among these older adults.

I then proceeded to Step 4, which was to examine how the domains/categories related to each other (i.e., the identification of overarching themes) in order to move the data inferentially to a higher level of abstraction (Miles & Huberman, 1994), and thus allow me to summarize/explain the processes the older adults used to self-manage their medications (Creswell, 2007). In the final Step 5, overarching themes were generated and a data display created.

I utilized several strategies to increase the “trustworthiness” of the analysis (i.e., the confirmability, dependability, credibility, and transferability of the findings) (Lincoln and Guba, 1985) while still allowing for the responsiveness (i.e., the creativity, flexibility, and insight) that is integral to the qualitative analysis (Morse et al., 2002). I addressed the issue of confirmability (i.e., maximizing objectivity and minimizing

researcher bias) by using several tactics suggested by Miles and Huberman (1994): (1) explicating the study's methods and procedures; (2) attending to my own assumptions, values, and biases, and making them explicit in my reflective journal; (3) checking and rechecking the data when codes were added and/or revised; and finally (4) retaining the study data and making it available for future reanalysis.

Demonstrating the dependability of the findings (i.e., the findings are consistent and could be repeated) included strategies such as: (1) demonstrating that the research questions are clearly written and connected to a theory (Miles & Huberman, 1994); (2) creating a preliminary code list to standardize the analysis of meaning units (i.e., participant reasons) into themes and categories (Creswell, 2007); (3) having a peer review process in place (i.e., someone outside the team reviewing the interpretations and findings) (Miles & Huberman, 1994); and (4) maintaining a reflexive journal to document issues related to both self and method so there is an audit trail and rationale for the methodological decisions made (Teddlie & Tashakkori, 1998). For example, The Individual and Family Self-Management Theory posits that multi-level factors (i.e., personal, familial, and cultural norms), as well as “dynamic iterative processes” are central to self-management health behaviors (Ryan & Sawin, 2009). The questions for this study were thus written to specifically describe and explain the contextual factors and processes involved in medication self-management of older adults. The coding list also served as a guide to both the analysts involved in the study and the auditor. I maintained a reflexive journal of the analysis process and had a copy of this “audit trail” available to my outside reviewer.

With regard to credibility, study participants ideally serve as the experts for judging the credibility of the findings (Trochim, 2006). Because this was a secondary data analysis, however, the participants in the intervention were no longer available to serve in this capacity. Nevertheless, because the primary study was a 12-month home-based intervention, there was prolonged engagement between the primary nurse interventionist and the participants in the previous study. The primary nurse interventionist, Linda D. Bub, MSN, RN, GCNS-BC therefore serve as a consultant to this author as a surrogate for the participant “experts” in the original study. The credibility of the study was further enhanced by the following strategies: (1) keeping the data in context; (2) considering rival explanations; and (3) discussing negative cases (i.e., those that did not fit the “main pattern”) (Patton, 1999, p.1192). Keeping the data in context meant recognizing that medication adherence processes in this population were influenced by the intervention, and therefore limited the generalizability of these findings to older adults who are not so highly managed. Considering rival explanations meant providing alternative interpretations for what was going on, and discussing negative cases meant describing those participant responses that did not fit in the final model.

I also used several strategies as suggested by Miles & Huberman (1994) to optimize the study’s transferability (i.e., the ability to draw inferences from the study results to real world/clinical practice). First, I fully described the study’s sample, setting, and processes so that the audience could make comparisons with other older adult populations. Second, I discuss in Chapter 6 how my findings support the existing literature, and how well they support to the study’s conceptual framework of medication

self-management. Finally, I disclose in Chapter 6 the limitations of the study, and address their impact on the generalizability of its findings to other populations.

Summary

This mixed methods study utilized both quantitative and qualitative data for the purposes of gaining a more complete understanding of medication adherence in an urban sample of community-dwelling older adults. The study was sequential in design with an emphasis placed on the quantitative component and with the qualitative component used to provide a more nuanced understanding of the quantitative findings (Creswell, 2009). A conceptual framework based on Ryan & Sawin's IFSMT (2009) guided the analysis and interpretation of both the quantitative and qualitative components of the study. The quantitative component utilized multivariate statistics to identify significant individual- and family-level characteristics that predicted increased risk for medication nonadherence at Month 1 as well as over time. The qualitative component followed a pragmatic approach of "abductive reasoning" (Morgan, 2007) that included both the tenets of naturalistic inquiry (i.e., inductive reasoning) as well as those of deductive reasoning to describe the older adults' processes of medication self-management. The two components are integrated in the interpretation phase of the study (i.e., Chapter 6) with a discussion on how the qualitative findings explain the quantitative component's results.

Chapter 4

QUANTITATIVE RESULTS

The purpose of this descriptive explanatory study was to better understand the self-management behavior of medication adherence in a sample of frail urban older adults. The first research question hoped to identify protective and risk factors for medication adherence at Month 1. Because medication adherence has been know to drop over time (Benner et al., 2002; Ho et al., 2006b) the second research question attempted to identify risk and protective factors for medication adherence over time. This chapter reports the results for each of these research questions.

Descriptive Summary

The descriptive findings for this sample population are presented in Table 3. Continuous data are reported with frequency, percentage, mean and standard deviation, and categorical data are reported by frequency and percentage.

Table 3
Sample Population Characteristics (N=268)

Variable	N	Percentage	Mean	SD
Age				
60-69 years	27	10.1%	79.69	7.68
70-79 years	101	37.7%		
80-89 years	114	42.5%		
90-98 years	26	9.7%		
Gender				
Male	85	31.7%		
Female	183	68.3%		
Race				
White	218	81.3%		
Black	50	18.7%		

(table continues)

Table 3 (continued)

Variable	N	Percentage	Mean	SD
Months in Study	268		10.80	3.81
MMSE			25.21	3.53
Normal (30-27)	120	45.8%		
Mild (26-21)	112	41.8%		
Moderate (20-16)	36	13.4%		
PPT			14.45	4.97
Independent (21-28)	23	8.6%		
Intermediate (20-16)	108	39.2%		
Dependent (1-15)	137	52.2%		
GDS			4.16	3.19
Normal (0-4)	162	60.4%		
Mild Depression (5-8)	74	27.7%		
Moderate (9-11)	29	10.8%		
Severe (12-15)	3	1.1%		
MCI			39.94	23.57
(7-23)	68	1 st quartile		
(24-34)	66	2 nd quartile		
(35-50)	67	3 rd quartile		
(51-141)	67	4 th quartile		
Vision				
Normal	214	79.9%		
Partial Impairment (can't see labels)	49	18.2%		
Significantly Impaired	5	1.9%		
Hearing & Understanding				
None	187	69.8%		
Minimal	76	28.3%		
Moderate	5	1.9%		
Home Setting				
Alone	132	49.3%		
Significant Other	83	31.0%		
Family Member	52	19.4%		
Friend	4	1.5%		
Paid Help/Other	2	.8%		

(table continues)

Table 3 (*continued*)

Variable	N	Percentage	Mean	SD
Caregivers				
Reside outside home	139	51.9%		
Lives in home	96	35.8%		
Paid help	56	20.9%		
None of the above	30	11.2%		
Relationship Caregiving				
No one person	37	13.8%		
SO/Spouse	57	21.3%		
Adult Child	121	45.1%		
Other Family	26	9.7%		
Friend/Neighbor	14	5.2%		
Paid	28	10.4%		
Unknown	3	1.1%		
Frequency of Care				
Several Day & Night	20	7.5%		
Several times Daily	69	25.7%		
Once a Day	25	9.3%		
≥ 3 times/week	31	11.6%		
1-2 times/week	52	19.4%		
$< \text{once/week}$	22	8.2%		
Unknown	4	1.5%		
Type of Care				
ADLs	41	15.3%		
IADLs	154	57.5%		
Environmental	160	59.5%		
Psychosocial	160	59.5%		
Med Appt Advocate	129	48.1%		
POA, Financial	62	23.1%		
HCPOA	117	62%		
Unknown	3	1.1%		
Intervention Group				
MD.2	137	51.1%		
Mediplanner	131	48.9%		
Medication Adherence				
Adherence Month 1	268		98.5	4.9
Month 1 ($<95\%$)	25	9.3%		
Adherence Over Time	268		98.1	4.6
($<98\%$)	44	16.4%		

Individual-level factors

Individual-level factors included: age, gender, race, and length of time in the study. The average age of participants in this study was 79.69 years (SD=7.68). More than three-quarters of the participants (80.2%) were between the ages of 70 and 89 years with 10.1% between the ages of 60-69 years and the remaining 9.7% between the ages of 90-98 years. Women made up more than two-thirds of the sample (68%) and African Americans comprised 19% of the total sample. The intervention group assignment was almost equal: 51% used the MD.2 machine and 49% used the mediplanners. The average length of participation in study was 10.80 months (SD=3.81) with 73.9% of the participants completing 12-13 months of the intervention. Only two participants dropped out after 1 month.

Condition-specific factors

Health condition-specific factors included: cognitive functioning (MMSE), physical functioning (PPT), psychosocial well-being (GDS), treatment complexity (MCI), vision, and hearing. The average MMSE score for this sample was 25.21 (SD=3.53). Based on current recommendations from both research (O'Bryant et al., 2008; Ravaglia et al., 2005; Grundman et al. 2004) and clinical practice (National Institute for Health and Clinical Excellence [NICE], 2009), this study used the following cut-off scores to describe the cognitive functioning of the sample: 45.8% were within the normal range of cognitive function (27-30); 41.8% had mild cognitive impairment (26-21); and 13.4% had severe cognitive impairment (16-20). Given that there has been mixed evidence, however, on the reliable thresholds for cognitive impairment (Crum,

Anthony, Bassett, & Folstein, 1993; Tombaugh & McIntyre, 1992) this study will treat MMSE as a continuous variable for the analysis.

The average score on the PPT was 14.45 (SD=4.97) with a range of 1-23. According to Lewis and Shaw (2005), clients with scores between 21-28 are able to function independently and those with scores between 3-15 are considered dependent. The majority of the participants (52.2%) scored as functionally dependent, whereas only 8.6% scored as functionally independent. The average score on the GDS was 4.16 (SD=3.19) with a range of 0-15. The majority of the population scored within the normal range of the GDS (60.4%), but more than a quarter (27.7%) had mild depression and another 10.8% had moderate depression. The mean MCI score for this sample was 39.94 (SD=23.59) with a range of 7-141. This average is twice as high as the scores reported by Conn et al. (1991)'s two studies where the means were 18.42 (SD=10.08) and 16.35 (SD=9.62). While the authors did not find a statistically significant correlation between MCI and medication adherence, there was a trend ($p=.08$) toward a negatively inverse relationship with medication adherence going down as MCI scores went up. Vision impairment affected over 20% of the participants with 18.2% having difficulty seeing labels and 1.9% having significant impairment. Hearing impairment was similarly affected with 28.3% having minimal impairment and 1.9% having moderate impairment.

Physical and social environment

Physical and social environmental factors included: financial factors, living arrangement, caregiver relationship, types and quantity of care received. Because the social environment variables were collected from a data form that allowed for more than one answer, the frequencies and percentages of these variables could total more than

100%. A significant majority of the participants reported no financial problems (89.6%) with only 7.5% reporting problems with medications or copays and 6.6% reporting problems with food/rent or other. Nearly half lived alone (49.3%) and nearly half lived with either a significant other (31.0%) or a family member (19.4%). Less than three percent (2.3%) lived with a friend or other.

A majority of the caregivers for these participants lived outside the home (51.9%), while just over a third lived in the home (35.8%). Around 20% of the participants had paid help and another 11% reported none of the above. The reported relationships to caregivers ranged from no one person (13.8%) to unknown (1.1%). Adult children were the largest group (45.1%) followed by significant other/spouse (21.3%), other family (9.7%), and friend/neighbor (5.2%). The quantity of care ranged from several times day and night (7.5%) to less than once/week (8.2%). More than a third received daily care either several times daily (25.7%), or once a day (9.3%), while another third received care either three or more times/week (11.6%) or 1-2 times/week. The participants received myriad forms of assistance including: help with ADLs (15.3%); help with IADLs (57.5%); psychosocial support (59.5%); medical appointment advocacy (48.1%); financial power of attorney (23.1%); healthcare power of attorney (62%); and environmental support (59.5%).

Medication adherence

In this study, the participants' mean medication adherence at Month 1 was 98.5% (S.D.=4.9%). Minimum adherence was 60% and maximum was 100%. Only 4.9% of the sample had less than 90% adherence and 9.3% had less than 95% adherence. The study participants' mean medication adherence over time was similar to the Month 1: Mean

adherence was 98.1% (S.D.=4.6%) with a range of 61-100%. Because the data on medication adherence at Month 1 and overtime did not meet the assumptions of ordinary least squares regression (i.e., normal distribution or homogeneity of variance) (Cohen et al., 2003), the decision was made to measure medication nonadherence as a categorical dichotomy (adherence versus nonadherence) in order to build in adequate variance into the dependent variable. Logistic regression was then used to answer Research Question 1 and Generalized Linear Modeling to answer Research Question 2.

Measurement of the Dependent Variable. To identify which context and process dimensions might predict risk for medication nonadherence at Month 1, a dichotomous dependent variable was created with 0=medication adherence rate between 100-95% and 1=medication adherence rate <95%. Although it may have been preferable to lower the adherence threshold to 88% (Wu et al., 2008a), the dependent variable had constrained variance in this highly managed population. In this sample, N=25 (9.3%) of the participants missed more than 5% of their prescribed doses, with the remaining participants (N=243) having a Month 1 adherence rate of 95-100%

An examination of the data also found important variation over time within certain participants such that even in this highly managed population, there were participants who still missed their medications. To identify which individual and family characteristics might predict risk for nonadherence over time, a dichotomous dependent variable was created with 0=mean monthly medication adherence between 98 and 100% and 1=mean monthly medication adherence <98%. In this sample, N=44 (16.4%) had a mean medication adherence that was less than the study's mean of 98%.

Research Question 1 Results

Research Question 1: What are the context and/or process dimensions that emerge as significant risk and protective factors for medication adherence at Month 1 of the study?

In Block 0 just the constant was in the model. The initial -2 Log likelihood of the model was 166.197 and the overall correct classification was 90.7%. In Blocks 1, 2, 3, & 4 the independent variables were added with individual-level variables first, the condition-specific variables second, the social environment variables in the third block, and then the process variable in the final block. In Block 1, the individual-level characteristics included age, gender and race. Table 4 summarizes the regression findings for individual factors only.

Table 4
Month 1 Logistic Regression Model: Block 1

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
Male Gender	0.219	0.445	0.241	0.623	1.245	0.520	2.980
Age	0.038	0.032	1.432	0.232	1.039	0.976	1.106
Race (Black)	1.069	0.521	4.207	0.040	2.911	1.049	8.082
Constant	-5.661	2.662	4.522	0.033	0.003		

N=268 cases; Dependent Variable = Adherence Month 1; Initial -2LL =166.197; Final LL = 161.700 (Chi-Square = 4.498; p = .212); Overall correct classification = 90.7%

The -2 log likelihood of the model decreased to 161.700 indicating an increase in the model's strength and predictability (Field, 2005). The Hosmer-Lemeshow test was not significant (Chi-square 14.532, p=.069) indicating that the observed data did not

differ significantly from the predicted model values (Field, 2005). The Omnibus Test of Model Coefficients, however, indicated that neither the block nor the model was significantly better at predicting Month 1 nonadherence than Block 0 ($X^2=4.498$, $p=.212$). The Nagelkerke R^2 value which indicates the proportion of the variance explained by the predictors (Mertler & Vannatta, 2010) was .036. The overall percentage correct for this block also remained the same at 90.7%. Among the individual factors, only race was a significant predictor with African Americans having nearly three times the risk of being nonadherent than whites (O.R.=2.911, [C.I=1.049-8.082], $p=.040$).

In Block 2, the condition-specific variables of MCI, MMSE, PPT, GDS, vision, and hearing were entered into the model. See Table 5 for a summary of the findings.

Table 5
Month 1 Logistic Regression Model: Block 2

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
Male Gender	0.173	0.483	0.128	0.720	1.189	0.461	3.063
Age	0.041	0.037	1.224	0.269	1.042	0.969	1.120
Race (Black)	0.617	0.585	1.113	0.291	1.854	0.589	5.839
MCI	-0.005	0.012	0.211	0.646	0.995	0.972	1.018
MMSE	-0.241	0.067	13.077	0.000	0.786	0.690	0.896
PPT	0.134	0.057	5.632	0.018	1.144	1.024	1.278
GDS	0.062	0.067	0.848	0.357	1.064	0.933	1.213
Vision	0.992	0.592	2.806	0.094	2.698	0.845	8.617
Hearing	0.061	0.537	0.013	0.910	1.063	0.371	3.047
Constant	-2.310	3.723	0.385	0.535	0.099		

N=268 cases; Dependent Variable = Adherence Month 1; Initial -2LL = 166.197;
Final LL = 143.398 (Block Chi-Square = 18.302, $p = .006$; Model Chi-Square = 22.800, $p = .007$);
Overall correct classification = 90.7%

The -2 log likelihood of Block 2 decreased significantly compared to Block 1 (143.398, $X^2=18.302$, $p=.006$), and the overall model also predicted significantly better than the original model ($X^2=22.800$, $p=.007$). The model continued to fit the data well (Hosmer-Lemeshow Chi-square 6.696, $p=.570$), and the Nagelkerke R^2 quadrupled from .036 to .176 indicating a much larger percentage of the variance was explained. The overall correct classification of cases, however, remained the same at 90.7%. With the addition of the condition-specific variables, race was no longer a significant predictor of nonadherence suggesting that race in the first model might have reflected underlying health status differences between the two groups.

Among the new condition-specific predictor variables, both MMSE and PPT scores significantly predicted a participant's risk for nonadherence, but in opposite directions: Those with higher MMSE scores or higher cognitive functioning were less likely to be nonadherent (Wald 13.077), while those with higher PPT scores were more likely to be nonadherent (Wald 5.632). As expected, for example, for every unit increase in MMSE score, a participant was 21% less likely to be nonadherent (O.R.=.786, [C.I.=.690-.896], $p=.000$) suggesting that higher cognitive functioning was a protective factor against nonadherence. Conversely, higher physical functioning was a risk factor for nonadherence, such that for every unit increase in PPT score, the participant was 14% more likely to be nonadherent (O.R.=1.144, [C.I.=1.024-1.278], $p=.018$). The remaining health condition variables in Block 2 (i.e., MCI, GDS, vision and hearing), were not significant predictors of nonadherence at Month 1.

Block 3 added the social environment variables (i.e., participant living alone versus with others, caregiver residing in the home, and participant receiving ADL and IADL assistance) into the model. Table 6 summarizes the regression findings for Block 3.

Table 6
Month 1 Logistic Regression Model: Block 3

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
Male Gender	0.152	0.510	0.089	0.765	1.165	0.429	3.164
Age	0.054	0.039	1.905	0.168	1.055	0.978	1.139
Race (Black)	0.631	0.615	1.053	0.305	1.879	0.563	6.270
MCI	-0.001	0.012	0.003	0.955	0.999	0.976	1.023
MMSE	-0.262	0.072	13.295	0.000	0.770	0.669	0.886
PPT	0.159	0.062	6.528	0.011	1.172	1.038	1.323
GDS	0.085	0.070	1.494	0.222	1.089	0.950	1.249
Vision	0.961	0.615	2.443	0.118	2.615	0.783	8.732
Hearing	0.044	0.550	0.006	0.937	1.045	0.355	3.071
Lives Alone	0.885	0.591	2.240	0.134	2.423	0.760	7.719
In-Home CG	0.904	0.664	1.855	0.173	2.469	0.672	9.070
ADL Support	1.175	0.725	2.625	0.105	3.238	0.782	13.415
IADL Support	-1.088	0.528	4.241	0.039	0.337	0.120	0.949
Constant	-4.195	4.129	1.032	0.310	0.015		

N=268 cases; Dependent Variable = Adherence Month 1; Initial -2LL=166.197; Final -2LL=134.998 (Block Chi-Square=8.40, p=.078; Model Chi-Square=31.200, p=.003); Overall correct classification=91.0%.

Block 3 did not significantly improve over the preceding block ($X^2=8.40$, $p=.078$), but the model did significantly improve in strength and predictability over the original model: The -2 log likelihood decreased to 134.998 [$X^2=31.200$, $p=.003$] and Nagelkerke R^2 increased to .238. The Hosmer and Lemeshow test continued to be

nonsignificant ($p=.297$). The overall model's classification increased negligibly from 90.7% to 91.0%, as the number of cases correctly identified as being “nonadherent” increased. Among the condition-specific factors, PPT and MMSE scores continued to be significant predictors of nonadherence. Those with higher PPT scores were again more likely to be nonadherent (O.R.=1.172 [C.I.=1.038-1.323], $p=.011$), and those with higher MMSE scores were less likely to nonadherent (O.R.= .770, [C.I.=.669-.886], $p=.000$). Among the three social environment factors, only receiving assistance with IADLs was a significant predictor of Month 1 nonadherence. Those who received IADL assistance were nearly two-thirds less likely to be nonadherent (O.R.=.337 [C.I.=.0120-0.949], $p=.039$). A possible explanation is that those receiving help with IADLs were indeed receiving assistance with taking their medications.

The final Block 4 tested the additional direct effects of the process dimension as measured by the use of a cognitive prosthesis (i.e., MD.2 versus mediplanner) on medication nonadherence. Table 7 summarizes the regression findings for the full model.

Table 7
Month 1 Logistic Regression Model: Full Model

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
Male Gender	0.156	0.521	0.090	0.764	1.169	0.421	3.243
Age	0.051	0.039	1.694	0.193	1.052	0.975	1.136
Race (Black)	0.547	0.635	0.743	0.389	1.728	0.498	5.993
MCI	0.003	0.012	0.053	0.818	1.003	0.980	1.026
MMSE	-0.275	0.075	13.404	0.000	0.760	0.656	0.880
PPT	0.178	0.065	7.490	0.006	1.194	1.052	1.356

(table continues)

Table 7 (continued)

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
GDS	0.089	0.071	1.592	0.207	1.093	0.952	1.256
Vision	1.066	0.631	2.857	0.092	2.903	0.844	9.993
Hearing	0.010	0.563	0.000	0.985	1.011	0.335	3.044
Lives Alone	0.798	0.612	1.700	0.192	2.221	0.669	7.372
In-Home CG	1.115	0.713	2.449	0.118	3.051	0.755	12.332
ADL Support	1.352	0.765	3.124	0.077	3.866	0.863	17.315
IADL Support	-1.123	0.544	4.261	0.039	0.325	0.112	0.945
Mediplanner	1.207	0.519	5.420	0.020	3.345	1.210	9.242
Constant	-4.90	4.189	1.366	0.242	0.007		

N=268 cases; Dependent Variable = Adherence Month 1; Initial -2LL=166.197; Final -2LL=129.028 (Block Chi-Square=5.970, p=.015; Model Chi-Square=37.170, p=.001); Overall correct classification=92.2%.

The final block significantly improved over the preceding block ($X^2=5.970$, $p=.015$), and the final model significantly improved in strength and predictability over the original model: The -2 log likelihood decreased to 129.028 [$X^2=37.170$, $p=.001$] and Nagelkerke R^2 increased to .280. The Hosmer and Lemeshow test continued to be nonsignificant ($p=.647$). The overall model's classification increased from 91% to 92.2%, as the number of cases correctly identified as being "nonadherent" increased. Among the condition-specific factors, both PPT and MMSE scores continued to be significant predictors of nonadherence. Those with higher PPT scores were again more likely to be nonadherent (O.R.=1.194 [C.I.=1.052-1.356], $p=.006$), and those with higher MMSE scores were less likely to nonadherent (O.R.=.760, [C.I.=.656-.880], $p=.000$). Among the three social environment factors, only receiving assistance with IADLs was a significant predictor of Month 1 nonadherence. Those who received IADL assistance were nearly

70% less likely to be nonadherent (O.R.=.325 [C.I.=.112-.945], p=.039). The process dimension was also a significant predictor: Mediplanner group participants were three times more likely to miss a medication dose than those in the MD.2 group (O.R.=3.345 [C.I.=1.210-9.242], p=.020).

This first model was cross-sectional, and based only on the first month of the study. Medication adherence, however, is an “ongoing and dynamic” process (Gordon et al., 2007; Schulman-Green et al., 2012) so it was of equal interest, to test how these factors might predict a person’s risk for nonadherence over time even in this highly managed population.

Research Question 2 Results

Research Question 2: What are the context and/or process dimensions that emerge as significant risk and protective factors for medication adherence over the course of the study?

The second model tested the effects of individual-level, condition-specific, and social environment factors on the risk for nonadherence over time. Given the temporal nature of the dependent variable (i.e., average medication adherence percentage over the study period), I used the Logit form of the General Linear Model as opposed to standard the Logistic Regression model to test this hypothesis. While the latter was suitable for testing the baseline cross-sectional hypothesis, the former (GLM) offers a more reliable estimate of the effects of the participant’s time in the study by allowing the analyst to specify an exposure variable. The reason being that a participant’s opportunity to deviate from her/his average medication adherence is, in part, a function of how long the participant lasted in the study. Some participants stayed, for example, three months in the

study, while other participants lasted 13 months. These differential exposures to time in the study means that the participants would have had varying opportunities to deviate from their averages, independent of the other measured factors.

A form of the Generalized Linear Model that specifies a binomial distribution (i.e., logistic function) allows the analyst to include an “exposure” variable in the background, which helps standardize the potential differential effects of time on the outcome. In the present case, I took the log of the “number of months in study” (which included a range of 1-13) and specified it as an exposure variable, which then creates the rate of the average medication non-adherence per month (without having to include months in study as an independent variable). As Greene (2000) has noted, using the exposure method with an independent variable that does not have much variation produces more reliable estimates than controlling for the linear effects of time as an independent variable. The following reports on the results of the GLM with exposure analysis.

Based on the log likelihood omnibus Chi-square goodness of fit test, the model was highly significant ($X^2=38.28$; $p<.001$), indicating that the model reliably fits the data. There is, however, no reliable analog to the coefficient of determination (i.e., R^2) used in OLS, which makes it difficult to determine how much variance the model explains (Cohen et al., 2003).¹ Table 8 summarizes the findings of the regression model.

¹ In a separate analysis (not shown) using logistic regression to test Research Question 2, the standard logit model produced a Nagelkerke $R^2=.221$.

Table 8
Over Time Logistic Regression Model

Variables	B	S.E.	Wald	Sig	Exp (B)	95% CI for Exp (B)	
						Lower	Upper
Mediplanner Group	1.057	0.392	7.250	0.007	2.877	1.333	6.207
Race (Black)	0.475	0.514	0.856	0.355	1.608	0.588	4.401
Gender	-0.162	0.405	0.160	0.689	0.850	0.385	1.880
Age	0.156	0.217	0.516	0.473	1.169	0.764	1.789
MCI	-0.030	0.224	0.081	0.892	0.970	0.626	1.504
MMSE	-0.571	0.203	7.900	0.005	0.565	0.379	0.841
PPT	0.547	0.241	5.127	0.023	1.728	1.078	2.769
GDS	0.420	0.184	5.238	0.022	1.522	1.062	2.181
Vision	0.046	0.505	0.008	0.928	1.047	0.389	2.818
Lives Alone	0.169	0.476	0.988	0.320	0.582	0.200	1.692
In Home CG	-1.135	0.586	3.748	0.053	0.322	0.102	1.014
ADL Support	1.355	0.614	4.871	0.027	3.878	1.164	12.921
IADL Support	-0.946	0.419	5.108	0.024	0.388	0.171	0.882
Constant	-4.094	0.898	20.789	0.000	0.017		

N=268 cases; Dependent Variable = Nonadherence Over Time

The risk and protective factors for nonadherence over time were similar to those found at baseline with some additional new predictors. Again, none of the individual-level factors was significant. Among the health condition variables, three of the five factors (MMSE, PPT, and GDS) significantly predicted a participant's risk for nonadherence over time. As with the Month 1 logistic regression model, the present

model found that higher MMSE scores significantly reduced the risk for nonadherence: (O.R.=0.565, [0.379-0.841], $p=.005$) and that higher PPT scores significantly predicted a participant's increased risk for nonadherence (O.R.=1.728, [1.078-2.769], $p=.023$). Unlike the Month 1 logistic regression findings, however, GDS now significantly predicted an increased risk for nonadherence over time (O.R.=1.522, [1.062-2.181], $p=.022$).

In the cross-sectional model, only assistance with IADLs was a significant social environment variable. Over time, however, three of the four family-level/social support variables were significant predictors of nonadherence. Having a caregiver residing in the home was a protective factor such that participants with a caregiver in the home were two-thirds less likely to be nonadherent (O.R.=0.322, [C.I.=0.102-1.014], $p=.053$). Similar to the Month 1 findings, assistance with IADLs was a protective factor with those receiving assistance being significantly less likely to be nonadherent (O.R.=0.388, [0.171-0.882], $p=.024$). Receiving help with ADLs, on the other hand, was a significant risk factor with those needing ADL assistance nearly four times more likely to be nonadherent (O.R.=3.878, [1.164-12.921], $p=.027$). One possible explanation is that these older adults could not self-manage their medications alone, and were thus at risk for nonadherence when a caregiver was not there to assist them. Once again the process dimension (intervention group assignment) was a significant predictor: Mediplanner participants were nearly three times more likely to be nonadherent over time (O.R.=2.877, [C.I.=1.333-6.207], $p=.007$).

Summary

Research Questions 1 and 2 sought to identify the protective as well as risk factors associated with medication nonadherence in a sample of frail older adults who received the nurse care coordination intervention. A comparison of the two models, finds that even in this highly managed population, there were several significant factors that either protected against or increased the risk for nonadherence. Among the condition-specific variables, cognitive and physical functioning were significant predictors in both models, but in the opposite direction: Higher MMSE scores were protective, but higher PPT scores were a risk. Having a higher depressive symptoms score (GDS) was also a risk factor, but only over time. At the social environment level, only “Receiving IADL Assistance” was protective both at Month 1 and over time. Two additional social environment level factors were significant predictors for nonadherence over time, but in the opposite direction: Having a caregiver in the home was protective, whereas receiving assistance for ADLs was a risk factor. Finally, at the process level, using a mediplanner was a significant risk factor for nonadherence both at Month 1 and over time.

These findings taken together demonstrate that even with the intensive nurse care coordination intervention, some older adults still had difficulty self-managing their medications. The significant predictors may alert us to who might be at increased risk for nonadherence either cross-sectionally and/or over time, however, they do not tell us why. Findings from Chapter 5, which includes an examination of the reasons that participants gave for missing their medication doses each month, may help us better understand why.

Chapter 5

QUALITATIVE FINDINGS

Research Question 3 sought to identify themes that describe the frail older adults' medication self-management processes. This chapter reports the results of this qualitative inquiry. First is a presentation of the descriptive findings of the participant responses. Next is a presentation and discussion of the overarching themes and domains that describe the self-management processes associated with medication nonadherence.

Descriptive Findings

Over the course of 13 months, the nurses documented a total of 1,459 statements from the participants explaining why they missed their medication dose(s). Monthly fluctuations occurred in both the number of participants who had a documented response (Range = 36-115 participants), as well as the total number of participant responses (Range = 56-190). Coding of the participant responses resulted in eight categories/domains and thirty-two associated themes. Appendix A is a frequency display of the themes over the course of the 13-month study. Further exploration of the relationships among the eight domains led to the three overarching themes and one remaining domain.

Overarching Themes

As previously noted, medication adherence is a multistep process that begins with a prescriber ordering a medication and ends with a client actually taking the medication as directed. In working with the data, I realized that one way to better understand the theory of the problem of medication nonadherence would be to examine the participants' responses along the continuum of this multistep process and see where the breakdowns

occurred. Using the IFSMT as a theoretical guide, I also began examining the domain analysis worksheet to see how the domains might cluster (relate to each other) along this multistep process (Spradley, 1979). For example, I noticed that the domain “Problems with planning and/or action” shared similar attributes as the domain “Experiencing cognitive difficulty”. In both domains, participants were “not ready” to take their medications because they either forgot and/or had experienced disruptions that led to them missing a medication. With further analysis, I then subsumed the particulars (i.e., seven categories and 29 themes) into the general by clustering the categories into three overarching themes to describe the self-management processes associated with the older adults’ episodes of nonadherence (Miles & Huberman, 1994). One domain “Needing Additional Information from Participant” did not fit in this model, but is discussed separately because it provides insight into the challenges to assessing a client’s medication adherence. Figure 4 is a thematic representation of the older adults’ medication self-management processes. Table 9 is a list of the overarching themes.

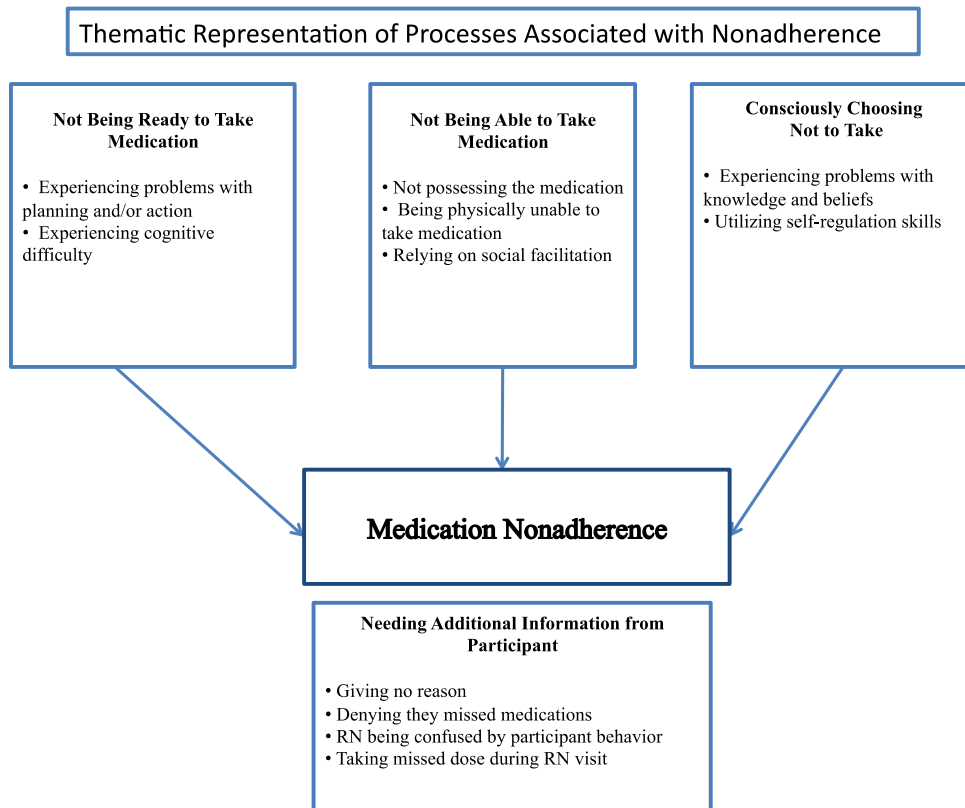


Figure 4. Thematic Representation of Processes Associated with Nonadherence

Table 9

Overarching Themes of the Medication Self-Management Processes

1. Not Being Ready to Take Medication
 2. Not Being Able to Take Medication
 3. Consciously Choosing Not to Take One's Medication
-

Overarching Theme 1: Not Being Ready to Take the Medication. A significant proportion of the participants had difficulty in this step of the medication-taking process with half the older adults' responses (N=732) having this attribute of "not being ready to take their medication dose" when it was due. The two Categories/Domains in this overarching theme included: "Experiencing Problems with Planning and/or Action" and "Experiencing Cognitive Difficulty". Similar to findings in the literature (August, 2005; Hindi-Alexander & Throm, 1987; Vik et al., 2005), several of the themes within the two domains centered around the process of forgetting. The two domains were distinct, however, in that some responses suggested the participant had a specific problem related to memory and/or cognitive functioning (i.e., "Experiencing Cognitive Difficulty") while others suggested episodic issues of forgetting (i.e., "Experiencing Problems with Planning and/or Action"). Because a large proportion of participant responses fell under the theme "forgetting, but no reason noted", these responses were coded globally under "Experiencing Problems with Planning and/or Action". It is possible that further description might have revealed some underlying issues with

memory and/or cognitive functioning. More importantly, further description might have indicated what interventions were needed to improve adherence.

Indeed, when a reason for why the participant forgot was documented, there was an opportunity for the nurses to document suggested strategies for improving adherence. For example, when a participant in Month 7 was having trouble remembering on her own, the nurse documented, “Reports she is going to have daughter call to remind her about morning pills”. The words “going to” illustrate a *plan* (i.e., self-management strategy) for how the participant could improve her medication adherence. Unfortunately when the participant later missed medications due to forgetting, no additional reasoning was noted. We, therefore, cannot conclude that this intervention was implemented and/or continued. In another example, a husband and wife in Month 2 were both having trouble so the nurse documented “a plan” that the participants would leave their mediplanners on the table “to remind each other”. Despite these efforts, the couple still continued to have trouble remembering that month. By Month 3, however, the participant did not miss any medications. Additional social facilitation appeared to solve the problem with the nurse noting that, “family members are ensuring the patient is taking her meds”. The participants subsequently withdrew from the study so it is unknown whether or not this intervention became a long-term strategy for them.

Another problem associated with “Not Being Ready” was specific to the MD.2 group: Participants who were ready at first, but then were not. These participants when asked why they missed their dose(s) admitted they had dispensed their medications, but then had forgotten to take them. Even though only half the participants used the MD.2, this problem still ranked as the 7th overall response that study participants gave for

missing a dose. Knowing how frequently this problem occurred, not only draws our attention to this common barrier, but also allows us to develop future strategies to reduce this risk. For example, one nurse noted, “[the participant] took PM meds out of machine, set them down on table, and then forgot”. Another participant dispensed the medication as “an early dose, went to an event and then forgot to take it”. In another example, a nurse noted a pattern with the participant’s use of the MD.2, “missed one yesterday; pt not good about remembering to retrieve from the machine”. This problem highlights how the MD.2 often served as an effective audio and visual prompt, but did not guarantee that the participant would eventually take the dose once dispensed. Indeed one nurse wondered if the participant ever took the dose, “? Family put back in bottle, took all med cups from MD.2 but did not necessarily swallow meds”.

Another common theme was “Not being home” with N=133 or 24% of the participant responses within this domain. Often participants were out with friends or family, and then did not take their medications once they returned home. For example, one participant would go out, not take her medications, but then planned on taking them when she got home. Yet, often she forgot once she returned home. This reason persisted for four months, and then stopped. The nurse did not document what changed, so it is difficult to tell what strategies she might have used to overcome this problem.

Conversely, in another case, a participant attended an adult day care (ADC) and missed medications because the MD.2 was at home. The nurse noted, “Now have a pill box with noon doses in case this happens again”. After this nursing intervention, the participant no longer reported this problem. Participants who used the MD.2 often forgot to early dose, even when the nurse pointed that out as an option. Sometimes, the nurses were able to

adjust the dosing times to better accommodate the participants' social schedule and this solved the problem. For example a nurse noted,

“[Participant] out...and forgot to take when got home. Eliminated 6pm dispense and changed 8pm to 9:30pm so she can go out w/o worrying about the 6pm.”

Participants with mediplanners, on the other hand, could take their medications with them, but still cited being out of the house as a reason. In most cases, they were out for the day and just forgot, but in other situations, they went out of town and were nonadherent for several days. Some of the responses suggested a lack of self-regulation processes (i.e., reflective thinking, planning or action): Some of the nurses noted:

“[Participant] left town last week & ‘grabbed a few bottles & went’ completely unsure of what he took”.

“7 full days missed, participant not concerned, she has often missed throughout life, was out of town which threw her off”.

“Participant admits to missing several doses while on vacation, participant very nonchalant about this.”

It is unclear from the notes, whether or not the nurses further explored these responses during the visit to encourage the participant to develop strategies for future planning and action.

Another missed opportunity noted in the participant responses was the potential role of family members in helping the participants self-manage. In several instances, participants shared that they forgot because they were out of the house spending time with family:

“Was at daughter's late and was tired, forgot to take his meds”;

“Went to son's house and forgot to take meds with her”;

“Forgot was at daughters”;

“Was out at her son's”;

“Client was staying overnight with her brother”.

Given the number of examples in this study where family members took an active role in helping the participant self-manage, it is possible that had these other family members been more involved/aware of participant's medication self-management issues, they could have provided the necessary social facilitation by reminding the participants to bring their medications with them. It is also possible that some participants might not have wanted their family members involved in their medication management.

Another common theme for the participants was experiencing disruptions to their daily schedule (N=48). Of note, 73% of these cases (35 out of 48) were due to participants having to go to healthcare related appointments (e.g., dialysis, dental care, therapy, primary care providers) and/or the emergency department. Sometimes, the participants responded that they were told not to take the medication, and were thus following prescriber advice: “had dialysis appt in AM-instructed by MD not to take on those mornings”. Eight of the cases had disruptions due to getting busy doing something else (e.g., housecleaning or making coffee) and/or distracted by holidays. Interestingly, eight of the participants were not ready to take their medications because of family visiting or they themselves being in a caretaker role (e.g., “getting granddaughter ready for school”, “spouse being in the ED” or, “wife came home from the hospital”).

A final theme in the first domain was “Falling Asleep”. Nurses noted for example, “slept through dispense”, “too tired and went to bed”, “forgot, fell asleep”. Sometimes solutions that worked might include: the “family dispensed the med cup when client was sleeping” or “dispense times changed today and client moving MD.2 to his bedroom”. In other instances, the problem was more complicated, such as a case where the spouse noted that participant was “sleeping at different interval[s]” (Month 4) and “sleeping erratically” (Month 12). In this case, perhaps decreasing the medications to once or twice daily might have given a greater window of time for dosing, or perhaps the sleep patterns were too difficult to work around.

The second domain, “Experiencing Cognitive Difficulties”, reflected specific problems that participants had with memory and/or executive functioning (N=48). For example, the nurse might think that once the mediplanner (i.e., cognitive prosthesis) was set up the participant could manage the rest of the process, but in some cases, confusion with the planner still led to nonadherence. The theme, “Being confused about organizer” illustrated in particular the additional cognitive functioning needed to manage a mediplanner versus the MD.2 (a machine that controlled the delivery of the medication doses):

“Did not take any pills from 2nd MP!!!! Said she thought I was just here last week, but I haven't been here for 2 wks”;

“Had some med changes & took meds out of her box, meds were missed & not in correct locations”;

“Missed 1 warfarin, thought it was a mistake”.

Some participants, however, recognized their confusion with their medications and shared with the nurses where the problems occurred:

“Confused over if they were the right pills for him to take so put AM dose back in med bottles”;

“Missed Sat, is having difficult time in the middle of the week”;

“Skipped 6 doses of prednisone thinking she eliminated her Lasix”;

“Thought MD told her to D/C one HS med but didn't know which one so stopped all HS”.

Confusion could also lead to overdosing, although this was less common (N=11). Some responses nurses noted were:

“Pt took meds after RN left instead of next day; no meds until RN arrived”;

“Pt does think she took 2 AM doses in one day; cannot remember which day she did this”;

“Extra insulin dose for supper missing-clt thinks she may have taken extra dose”;

“Took too many pills since last visit”.

Some participants, however, specifically admitted they had trouble with their memory and/or with remembering (N=8). In one case, the participant admitted to being forgetful, but no intervention was noted, and she continued to forget doses over the course of the study. In another case, however, there was an attempt to overcome this barrier by enlisting the help of a family member,

“forgetting noon metoclopramide in the planner, son will give more verbal reminders”.

Overarching Theme 2: Not Being Able to Take the Medication.

The overarching theme, “Not Being Able to Take the Medication” was less of a problem for the participants in this study than not being ready: Over the course of the study, it accounted for approximately 8% of the responses (110 out of 1,459). Nevertheless, the categories and themes help us to understand where the participants had trouble in this stage of the medication taking process and provide insight on ways to improve medication adherence.

For example, a small minority of participants had trouble with this step in the medication-taking process because they did not possess the medication. Indeed, there were only 24 out of the total 1,459 responses given. Of note, half of the instances (12 out of 24) occurred in the 2nd and 3rd months of the study, and then only happened sporadically for the remainder of the study. This finding is not surprising given that an important component of this nurse care coordination intervention was to assist the participants in obtaining their medications (e.g., call the prescriber, call the pharmacy, and/or inform participant or caregiver when refills were needed). Themes in this domain included: lacking transportation; experiencing MD or pharmacy issues; and lacking the finances to buy refills. In many cases, however, the nurses documented that medications were out, yet did not document why (e.g., “has not had ASA x 1 week”, “medication not available to fill in mediplanner”, or “did not have all medications last week”). As a result, it is difficult to understand whether they ran out of medication related to transportation, refill issues, or cost-related issues. Also of note, during the initial round of coding some

participant responses had two possible codes. For example, the documented response might begin with the fact that the participant did not possess the medication, but then the nurse would finish the note with, “denies need for med r/t not episode of reflux”. In this instance, the response was coded as a belief issue primarily, and then the “not possessing” issue as secondary. Over the course of the study, there were nine instances where the code “not possessing the medication” had been dropped. Some of the nurses’ observations of the participant responses suggested that cost may have been an issue and that the participant perhaps chose not to disclose it as a problem. For example, one nurse charted that the participant reason was “not being home”, but then noted, “doesn't give explanation as to why she doesn't take when gets home, I get feeling related to cost savings on meds.” Without more information, however, we cannot know why the participant did not take the dose once she got home, and/or whether or not additional planning would have helped.

On the other hand, the nurses’ notes also illustrated how the care coordination intervention prevented the participants from running out of medication. In one case, a participant (with high medication adherence) wanted to coordinate/call in her own refills, but then forgot to have her daughter pick up the medication before the visit. The nurse then went to the pharmacy and picked up the medication so the mediplanner could be filled. In another case, on admission, the nurse noted that there were no medications in the home. To facilitate medication adherence, the nurse called the pharmacy for refills, and then called the PCP in the morning to get the prescriber’s order for another refill. The nurses’ notes also described situations where caregivers facilitated the process. One participant’s son was highly involved in filling the mediplanner and assisting with refills

and physician samples. The participant did not miss any medications. Five months into the study, however, the nurse no longer mentions the son's involvement, and now documents that medications in mediplanner are "jumbled" and "client confused over use". It is unclear what happened to the son's involvement, but the nurse assumed the role of social facilitator and asked the participant to wait for nurse's visit and they would refill the planner together.

The most common category/domain in this overarching theme was where the participant did possess the medication, but then was physically unable to take the dose (N=85). Responses centered around: (1) Lacking the physical ability and/or visual acuity to take the pills (N=37); (2) Lacking the ability to retrieve the pills from the organizer (N=22); and (3) Relying on social facilitation in order to take the prescribed dose (N=26). For those patients who lacked a physical ability, there were myriad causes such as, a participant who "missed 6 days [because] states she felt too tired and weak to get OOB and take meds", while another, "missed 3 full days of meds...could not reach med cassette in cabinet so did not take". In a third case, the participant fell...was in pain and did not get out of bed on Monday".

Visual acuity issues were more common and centered around the difficulty in seeing a white pill in a white mediplanner or not seeing the pills at all:

"Missed 4 out of last 7 days PM caduet r/t it being small white pill in white container";

"1 HS metoprolol missing, white box & white pill so client could not see she missed it";

"Very small white pill and he did not see it was left in white box";

“2 missed doses of carvidolol, small pill, pt not seeing it, encouraged to dump out pills”.

Here again, we can see the importance of having a caregiver or friend who might have been able to assist those participants who lacked the physical capacity to take them.

Although a rare occurrence, twenty-two participants did experience episodes of nonadherence due to problems with the MD.2 machine or mediplanner. Again the participant responses provide insight into the difficulties encountered even after the participant remembered to take their medication. Most of the issues were with the MD.2 such as:

“MD.2 not dispensing and d/c from phone line so missed doses not alerted”;

“[Participant said], ‘two cups came out when I pushed the button’, but I think she dispensed the AM pills and the HS were there”;

“Missed 2 doses, clt reports they came out of the MD.2 in the wrong order so he did not take them”;

On occasion, participants also had trouble with their mediplanners, which then led to missed dose(s):

“Said I did not fill it complete”;

“Dropped planner on the floor didn't tell dtr b/c she is busy with baby, dtr will check on him more often”;

“Missed 1 lasix dose, sticks to bottom of mediplanner. New planner given to clt”.

The vast majority of these responses (15 out of 22), however, occurred during the first half of the study possibly indicating that the ongoing support from the nurses and/or caregivers helped the participants in overcoming this barrier to adherence.

Yet another category/domain, “Relying on Social Facilitation” (N=26) further highlighted the importance of effective social facilitation to optimize participant adherence. For example, participants were instructed to call the nurse if there were medication changes and/or went into the hospital so not surprisingly, confusion due to hospitalization was very uncommon (9 out of 1,459). Nevertheless, the nurses’ notes highlight the problems that participants still experienced with the transitions in care as well as the difficulty for the nurse in assessing medication adherence,

“Has not been taking meds as prescribed since D/C from [hospital]”;

“? Unable to tell, client not clear on exactly how many days he was hospitalized”;

“All AM slots in box 2 full, was in the hospital a few days but that means client at least 4 days [missed]? Hard to tell since he was hospitalized”;

“Has not had any meds since hospital D/C 5 days ago”.

Still other examples where the older adult relied on caregivers for assistance with the management of their medications illustrated how some well-intentioned caregivers might need, at times, additional support and/or suggested strategies from the nurses in order to optimize adherence:

“4 missed: son reminds and will put back in MP if she forgets to take”;

“Caregiver states he gives patient meds & sometimes she forgets to take”;

“Took meds but incorrectly set up by grandson”;

“Pt relies on spouse to remind her & if he forgets, she doesn't take Pt & spouse both forgot”.

One solution that a nurse tried was to change the dosing schedule to reduce the risk for nonadherence, “[Significant Other] dispensed noon dose for her two times this week. Now will have only one dispense daily.” This instance happened at the end of the study, so we cannot tell whether or not the intervention solved the problem.

Overarching Theme 3: Consciously Choosing Not to Take One’s Medication.

In nearly one out of ten responses, (140 out of 1,459) participants acknowledged that they had consciously chosen not to take their medications. Their responses were captured by two categories/domains: “Experiencing Problems with Knowledge and Beliefs” (N=15) and “Utilizing Self-Regulation Skills” (N=125). Knowledge and belief issues occurred less frequently, which is not surprising given that a primary component of this intervention was to educate the participants on their medication regimen. Nevertheless, participants still struggled at times with not believing the medications were important. For example, the nurses noted:

“Pt said doesn't want to take daily as he feels same if he takes them or not”;

“Client is taking plavix from some cups and only taking that; feels she doesn't need other meds”;

“Denies need for med r/t not episode of reflux”;

“Did not take meds after MD.2 empty; does not feel important to miss a few days”

“Continues to occasionally skip PM cellcept when not experiencing symptoms”.

The Individual and Family Self-Management Theory (Ryan & Sawin, 2009) helps us to understand how knowledge and beliefs impact goal congruence for our participants. For example, if the goal was medication adherence, but the participants did not believe the medications were important, then they experienced goal incongruence. In some cases, further discussion with the nurse might have resolved this problem and promoted goal congruence.

Less frequently, the participants lacked knowledge about their medication regimen, and this in turn led to a lack of self-efficacy to take their doses as ordered. Indeed, the nurses’ notes support this explanation as it appears that once the participants received the necessary education they were willing to take the medication. The following examples thus highlight the importance of access to health care providers, including pharmacists, to facilitate older adults’ self-management of their medications:

“She thought 2 of the meds would upset her stomach or interact with other meds; patient education re: this, patient will resume taking”;

“RN was not able to get RN over the weekend. Client did not take new medications”;

“Did not get a hold of RN with new meds after visit last week. Did not take until visit today”;

“Does not know how to take warfarin & am unsure”.

In nearly 90% percent of the instances (125 out of 140), however, participants utilized self-regulation skills and abilities to consciously choose not to take their

medications. Sometimes participants chose to skip a dose because it conflicted with their life circumstance. In these cases, the nurses' notes suggest that the participants wanted to go about living and enjoying their life, and if they didn't have time to take them, or if the medication side effects interfered with their plans, then they didn't take their dose(s). Nurses noted for example: "Reports pills make her feel dizzy and tired and she was going out" or "Missed one dose while on vacation, was very busy and wasn't able to get to his meds". The vast majority of the time, the competing demands were because the participants wanted to leave the house and didn't want to deal with the need for finding a bathroom. As a result, they would choose not to take their diuretic as prescribed.

"[Participant] did not take furosemide because had to go out to pick up meds";

"One am dose of diuretics b/c was going to see lawyer";

"Does not take furosemide when he has to leave house";

"Missed 1 dose each of Lasix & Metolazone r/t being out of the house without access to a BR";

"Thought she was skipping lasix as she was going out frequently";

"Missed water pills Sunday AM b/c she went out to breakfast going out and didn't want to be urinating".

While "Choosing to skip a dose" wasn't a significant problem during most of the study (N=24), it is interesting to note that the majority of the instances occurred in the last three months of the study. Perhaps as participants became more comfortable with their nurse, they were more willing to make their own decisions about which dose to take or not take. More importantly, this highlights the importance of patients discussing the

lifestyle effects of taking diuretics, and then negotiating with the prescribers on a dosing schedule that is more congruent with their activities of their daily life.

In contrast, other participants utilized self-regulation skills to recognize that because of health reasons, they should hold their next dose. In nearly one-third of the time (N=47), participants held off taking their medication dose(s) because they or their provided decided it wasn't warranted:

“[Participant] told to hold Aggrenox in urgent care”;

“Missed 7 HS doses; MD said she can skip QOD b/c meds give her HA in the am”;

“Reports she was ‘took sick’ to take them. MD aware that client doesn't always take her pills as Rx'd”;

“Missed whole wk. pt had flu was vomiting. Ready to resume regimen”;

“Did not take warfarin past 2 days b/c gums were bleeding profusely on Wednesday when she had INR drawn”.

One case in particular, highlights the importance of health care providers regularly checking in with clients about their medication self-management. A nurse noted:

“[Participant] has not taken coumadin in 11 days b/c she had HA and said she was told to hold it when that happens and get INR drawn but she never got the INR drawn.”

Here we see that a participant had the correct knowledge about her medication, but perhaps social facilitation would have helped her get her INR drawn sooner. Conversely, without the nurse's visit, it is possible the participant would have gone longer without this critical medication.

The final theme, “Feeling burden outweighing benefit” was much more common. Indeed, more than a third of the time, (54 out of 140 instances) the participants consciously decided for themselves that the burden of taking the medication outweighed the benefit. Through the nurses’ notes, we learned that participants were tired of taking all these medications or believed they were taking enough of what they needed:

“Client reports she gets tired of taking all these pills”;

“[Client] didn't feel like taking them”;

“Client never really gives a reason for missed doses. ‘well I was taking cough syrup...and some [antibiotics] and that was enough medicine for me.’ I don't think she forgets”;

“Missed several potassium & iron pills by choice as he does not like to swallow them”;

“[The participant] Gave me a tumbler full of pills she took out of MD.2 but never took!!! Just doesn't feel like taking her meds sometimes”.

These participant responses can help us reflect on the benefit versus burden of taking multiple medications, as well as recognize the importance of ongoing dialogue between healthcare providers and patients if we are to move toward a model of shared decision making and optimal adherence.

One case, in particular, demonstrates the challenging aspects of optimizing a person’s medication self-management. This case also serves as an excellent illustration of the Individual and Family Self-Management Theory’s proposition that there exists an inter-relationship between the theoretical constructs of self-regulation and social facilitation (Ryan & Sawin, 2009). The case involved a participant in his late 60s with

kidney disease and severe vision impairment who was taking over 350 doses a month. He lived alone without a caregiver. During the first four months of the study, his monthly adherence rates were 95% or higher, but beginning in month 5, his adherence rates dropped to an average of 38%. Through the nurse's notes, we hear the participant's frustration, the healthcare team's concerns, and the resulting nonadherence. The nurse's notes also illustrate some strategies the participant's healthcare team tried to improve adherence:

“Did not take 10 of the 14 doses. He stated that he didn't do much the last few weeks and that he was not in a good way. RN to see next week though he doesn't need to be filled”;

“Pt confronted by his nephrologist about his labs and pt admit he has not been taking his pills. RN to start calling to check on pt”;

“Only missed 2 am and 2 pm. Friend over that spends time with pt, she is encouraging him to take and will check on pt”;

“Just does not take them. Enc pt to be more compliant and he said he would try”;

“Pt aware of need to take but is frustrated with the amount he needs to take and often dispenses and just piles up”.

Even with all the healthcare team's social facilitation efforts, the participant continued to have high monthly rates of nonadherence. It is unclear if a full team meeting with the participant and caregivers might have led to fewer pills and greater medication adherence.

Domain 7: Needing Additional Information from Participant.

The three overarching themes help us to understand when and/or why participants encountered problems with their medication self-management process. However, despite the ongoing and consistent monitoring by the intervention nurses, approximately 40% of the participant responses (595 of 1,459) belonged to the category/domain of, “Needing Additional Information from Participant”. This category had five themes to describe why more information was needed. Of the five themes, “Having No Reason (N=293) was the most numerous and accounted for nearly half the participant responses in this category. As previously noted, the nurses would simply document, “no reason” and/or “1 missed dose” and not include a reason. Further dialogue with either the participant and/or family member might have led to a better understanding of why the medications were missed, and perhaps the identification of effective strategies to improve medication adherence.

The next most common theme, “Being unsure of what happened” (N=115), was also one of the most common themes for this group of frail older adults: It was consistently one of the top five themes for 12 out of the 13 months of the study. “Being unsure of what happened” is distinct from “forgetting” because it reflects the participant’s inability to explain what happened. Most of the responses were documented as, “unsure what happened”, “cannot say why”, or “unsure as to why”. An examination of those participants who were at times “unsure”, found that their other responses often varied. For example some of them would later say they missed a dose because they were out, while others simply said they forgot. In these types of client situations, the clinician might have to continue to assess for a pattern in order to identify the underlying reason for nonadherence before suggesting specific self-management strategies.

Another common theme among both intervention groups was the participant, “Denying Missing Medications” (N=80). With the MD.2 group, some participants would deny missing a medication dose. Instead, they would acknowledge they were late, but then assure the nurse they took the medication:

“[Missed] one yesterday, out shopping took when she got home”;

“Niece gave from holding area”;

“Took medication when she got up per her report”;

“Watching TV and lost track of time; took from holding area”;

“Participant did take AM cup out of dispenser & then lost it, reports took meds from bottle that day”.

These responses nonetheless help us to see one problem with the controlled dosing of the MD.2: The machine might record nonadherence, but according to the participants they eventually took their doses so they were late, but still adherent. Sometimes, however, the nurses would see pills in MD.2 cups in the home, wonder if these were missed doses, but still the participant would deny it: “Saw one pill cup in bedroom; pt denies missing any doses” or “found a Cozaar & warfarin in separate used cups, client doesn't recall missing these doses”.

Similarly, with the mediplanner group, the nurses might note that pills were still in the planner, but the participants would deny they missed any doses:

“Client states she takes meds out of bottles b/c easier for her”;

“pt states she took meds from bottle not planner, 2 full days”;

“Participant forgets, but then insists she takes”;

“Said I put 2 tabs in some of the days (synthroid)”.

Equally as common (N=79) was the theme, “RN being confused due to participant behavior”. In these instances, the nurses would document what they encountered in the home as well as their confusion about the participant’s adherence:

“Pt had meds sitting out for RN in cups. Missed most of her meds if these are her current pills. Will update MD today at appt”;

“Son alerted RN to cups in medicine cabinet in cups and bottles. RN removed, unsure how long in there”;

“Vague about what she did for pills (last filled MP for 2wks was 3wks ago)”;

“?!?! Reports she filled her box last week, however, date on bottle...she should have run out, [but] has 10 days worth”;

“not able to accurately determine which meds are missing due to pt not taking them from correct boxes”.

In many cases, the lack of agreement between what the nurse believed were missed doses, and the participant’s denial of any missed medications led to some overlap between the two themes: “Denying they missed medications” and “Nurse being confused due to participant behavior”. The following examples illustrate the need more information to better understand the participant’s medication self-management:

“Pt seemed to take additional doses but denied this”;

“? missed 7? Says she put the pills in the box when she saw it was getting low”;

“Unsure what happened, appears she missed 3 days of meds in a row, but pt denies this”;

?!! Clt has not had enough meds for awhile but reports she is taking them.

? Says she has been taking them but unless she had some bottles hidden...meds ran out over a week ago”;

“?Doing her own thing!!!! Says she used BP on vacation but I cannot really tell what she took and didn't take”;

These examples also illustrate the difficult challenge that the nurses faced when attempting to optimize medication adherence with a client who denies that a problem exists. It is unclear in most cases whether or not the nurses had reached out to family and/or caregivers to clarify the situation, but in some cases, even the family members were confused:

“Completely unsure, pt son? Set up a week's worth of meds in cups on the table. Not set up correctly”;

“Missed some HS and pm meds. Son put in cup for RN but couldn't remember if fell out or pt missed”.

The last theme in this domain was, “Taking dose during RN visit” (N=28). Responses were coded under this theme if it was unclear why the older adult missed their medication dose, but the nursing note documents that the participant took the dose during the visit. On the one hand, this theme could demonstrate the importance of social facilitation for two reasons: (1) The responses suggest the participants did not realize they missed a dose until the nurse brought it to their attention, (e.g., “thought he had taken his meds last night but did not”); (2) The

responses suggest that the participants appeared willing to take the medication once the nurse offered the dose(s) to them:

“Did not take meds yet today. Took during visit”;

“2:42pm RN had pt take meds during visit; dispensed but had not taken yet”;

“Had pt take meds during visit”;

“Pt not taken AM pills before today's visit (son instructed pt to take them & she complied)”;

“Did not take AM meds today; took at 2pm while RN in home”;

“Had not taken morning meds as of 3 pm; did not take his insulin”.

These instances suggest that if social support from someone such as a caregiver or nurse had been available (i.e., social facilitation) the participant might have been more adherent. On the other hand, there is also the possibility that the participant did not want to take the medication, but took the dose(s) with the nurse because he/she did not want to disappoint and/or contradict the nurse. Interestingly, participants in both the MD.2 and mediplanner groups had instances where the nurse had to instruct the participant to take their missed dose.

Summary

A template approach using a domain analysis to code and classify the participant responses led to the identification of thirty-two themes clustered within eight distinct domains. Further analysis of the domains and their relationships to each other led to the identification of three overarching themes that described when and/or why the participants' experienced trouble with the multistep process of medication adherence. Seven of the eight domains were categorized into one of three overarching themes. The

remaining domain, “Needing Additional Information from Participant” was nonetheless important because it highlighted the challenges of assessing medication adherence in the community setting. Chapter 6 integrates the qualitative findings with those in the quantitative component in order to: (1) Enhance our understanding of medication nonadherence in this group of frail older adults; and (2) Evaluate how well the theory explains this health behavior. The final chapter then offers direction for clinical practice and future research.

Chapter 6

DISCUSSION

This descriptive explanatory study attempted to advance the science with a better understanding of medication adherence in a group of frail urban older adults. The study used a combination of quantitative and qualitative methods to analyze data from a larger twelve-month study of a nurse care coordination intervention. This chapter first summarizes the results of the quantitative and qualitative analyses, and then integrates the findings in order to enrich our understanding of the context and processes involved in medication self-management. The chapter concludes with a discussion on the study's strengths and limitations as well as recommendations for clinicians and researchers.

Protective and Risk Factors for Medication Nonadherence

Research Question 1: What are the context and/or process dimensions that emerge as significant risk and protective factors for medication nonadherence at Month 1 of the study?

Using logistic regression to test the effects of the participants' context and process dimensions on medication nonadherence at Month 1, the study results provided mixed support for previous research findings. For example, similar to other researchers' findings (Russell et al., 2011; Vik et al., 2004; Wu et al., 2008b), the individual-level characteristics, age and gender, were not significant predictors of nonadherence. Conversely, unlike prior research (Bosworth et al., 2006; Egede et al., 2011; Krousel-Wood et al., 2005; Wu et al., 2008b), African American race was not a significant predictor: Whereas the initial model for Month 1 found African American race to be a risk for nonadherence, this relationship disappeared once controlling for condition-

specific factors (e.g., physical functioning, cognitive functioning, psychosocial well-being, vision, and hearing). While none of the individual-level characteristics in the overall model were significant predictors, it is possible that other individual-level characteristics, (i.e., ones that might more accurately measured one's ability to self-manage medications), could have been significant predictors. Indeed, previous research has found that low health literacy (Armstrong, 2010; Kripalani et al., 2006) and lower education levels (Catz et al., 2001; Schoenthaler et al., 2009) increase an individual's risk for nonadherence.

Among the five condition-specific variables included in the model, only two were significant predictors at Month 1: cognitive and physical functioning. The strongest risk factor for medication nonadherence in this group of frail older adults was the participant's baseline MMSE score. Similar to findings in the literature (Cooper et al., 2005; Insel et al., 2006; Jerant et al., 2011; Park et al., 1994; Stillely et al., 2010), decreased cognitive functioning was significantly and positively associated with nonadherence. This is an important finding particularly for community-dwelling older adults because more recent nursing interventions have excluded older adults with cognitive impairment (Barnason et al., 2010; Ruppert, 2010; Wu et al., 2012). This study, on the other hand, included participants with mild cognitive impairment. As a result, the mean MMSE of this frail group older adults was only 25.21 (S.D.=3.53), and more than half the participants scored in the mild to moderate range of cognitive impairment. Despite this significant risk factor, however, the mean adherence at Month 1 was very high 98.5% (S.D.=4.9) demonstrating that even those with mild cognitive impairment can maintain high levels of adherence if given the proper support.

Higher physical functioning (i.e., higher PPT score) was also a significant risk factor, and supported the findings by (Schuz and colleagues, [2011a & 2011b]) that higher functioning adults are more likely to be nonadherent with their medications. Schuz and colleagues (2011a & 2011b) identified that necessity beliefs about medications mediated the relationship between health and adherence: Higher functioning older adults were less likely to believe in the necessity of taking some or all of their medications. Given the ongoing interaction between the nurses and participants in this study, it is possible that the older adults believed that their medications were necessary, but that those with higher physical functioning were more likely to leave the house and/or engage in activities during the day, and these disruptions interfered with their medication-taking regimens.

Among the four social environment factors included in the model, only one (receiving IADL assistance) was a significant and protective factor against nonadherence at Month 1: Participants receiving IADL assistance were only one-third as likely (O.R.=0.33) as those not receiving this assistance to be nonadherent. This finding is consistent with the extensive body of research demonstrating that social support is a critical factor in an older adults' maintaining healthy lifestyle behaviors (Carlson et al., 2012; Hopman-Rock, et al., 2012; Resnick et al., 2002). Wu and colleagues (2008b) similarly found that perceived social support was a significant protective factor against nonadherence among older adults living with heart failure. This study contributes to this literature by directly testing IADL assistance, which includes assistance with medications, and supports findings by Scheurer, Choudry, Swanton, Matlin, & Shrank (2012) that practical support increases medication adherence.

A final important finding at Month 1 was the significant protective effect of the MD.2 machine (a process dimension) against medication nonadherence. In this study, the Medi planner participants were three times more likely to be nonadherent (O.R.=3.3) than those who used the MD.2. This finding is similar to Buckwalter, Wakefield, Hanna, & Lehmann's report (2004) where MD.2 users (over the course of six months) had missed, on average, less than half as many doses as those using the medi planner (2.9 vs. 7.3 doses). For the participants in this study, it is possible that the MD.2 was a more effective cognitive prosthesis because of its audio/visual alerts. These alerts may have cued the older adults' memory throughout the day, and thus reduced their risk for forgetting to take their medication. While the medi planner also served as a memory prompt, it still required the older adult to remember to go to the planner and take their scheduled dose. The effect of the MD.2 as a cognitive prosthesis was significant even after controlling for participants' cognitive functioning. It should be noted, however, that the medi planner worked well for the majority of participants, and that those in which the machine helped were only a small percentage of the older adults in the study.

Research Question 2: What are the context and/or process dimensions that emerge as significant risk and protective factors for medication adherence over time?

A GLM with exposure analysis of medication adherence over time made similar findings as the cross-sectional model, but also expanded on them with three additional factors to explain nonadherence. First, a participant's baseline psychosocial well-being score (GDS) was now a significant predictor, and similar to the findings in the literature (Gonzalez et al., 2007; Kronish et al., 2006; Wu et al., 2008b) a higher depressive symptom score was a risk factor for nonadherence. A second identified risk factor was

the participant receiving ADL assistance. This level of assistance is needed when a person can no longer compensate for cognitive and/or functional disability. It is not surprising then that those frail older adults needing ADL assistance would be more likely to experience difficulty at some point along the multistep process of taking a medication. For example, without a caregiver to assist at the time that a medication is due, the older adult would be at risk for either not remembering to take their medication, and/or having physical difficulty with self-administering the medication. As a result, over time those participants who received ADL support were nearly four times more likely to be nonadherent (O.R.=3.8) than those not receiving such assistance. To further support this explanation, having a caregiver living in the home was a significant protective factor and decreased a participant's risk for nonadherence by two-thirds (O.R.=0.32).

These social environmental findings are particularly important because most medication adherence interventions target the individual. Yet, a survey of caregivers for adults over the age of 50 found that 48% of recipients needed assistance with taking their medications (National Alliance for Caregiving [NAC], 2009). A review by Maidment, Fox, Boustani, & Katona, (2012) found that even though caregivers play an important role in medication management for adults diagnosed with dementia, evidence on effective interventions is still lacking. To add to the significance of this issue, While, Duane, Beanland, and Koch (2013) found in their qualitative study that many dementia caregivers expressed both a need and desire for more formal education about medication management skills in order to assist their care recipients.

In summary, both models were consistent with the progressive proposals by researchers that human health behavior must be considered within the context of a

person's ecology of health (Schneider & Stokols, 2009) and/or personal systems (Russell et al., 2011), and that interventions targeting only individuals are incomplete (Ruppar, 2010a). The models also add support to Ryan and Sawin's (2009) theoretical proposition that a person's self-management behavior is influenced by both the contextual (i.e., condition-specific factors, and social environments), and process (i.e., cognitive prosthesis) dimensions of one's life.

Research Question 3: What are the themes that describe the participants' medication self-management processes?

A directed content analysis identified three overarching themes to describe the participants' struggles along the multistep process of medication adherence. The overarching theme, "Not Being Ready to Take Medication", was the most common issue for participants in this study. While it was primarily the most vulnerable participants who struggled with this stage of the medication-taking process, many of the participants still had problems at some point with forgetting, and/or being out and about, and then missing their medication doses. A less common overarching theme, although still important, was "Not Being Able to Take" one's medication. Review of the nurses' notes found that family member support spanned across all steps of the medication-taking process. In some cases, family members would divide up the tasks and each would take responsibility for a step in the process. For example in one case, one son would pick up the prescriptions, another son would fill the mediplanner, and both would help the participant with obtaining samples and looking into prescription plans. In another case, the participant had three children providing ADL and IADL care. Both these overarching themes illustrated how physical and/or cognitive disabilities can increase an older adult's

risk for unintentional nonadherence, especially in the absence of caregiver assistance. Of note, despite a large body of research on the problem of cost-related nonadherence, only a small number of participants in this study had trouble with “not possessing” their medication. This finding is not surprising, however, given the study’s intensive nurse care coordination, which included assisting the participants with ordering and refilling prescriptions.

The final overarching theme, “Consciously Choosing Not To Take One’s Medication” is similar to themes described by Voils and colleagues (2006) of “intentional nonadherence” and by Weintraub (1981) of “intelligent noncompliance”. The participants’ intentionality in this study also highlights an important assumption of the Individual and Family Self-Management Theory that, “Persons engage in behaviors for personally meaningful responses that may or may not be directly related to optimizing their health status” (Ryan & Sawin, 2009, p. 21). Community-dwelling older adults, living with chronic conditions, are charged with the day-to-day responsibility of monitoring their own health and well-being. They are responsible not only for taking their medications, but also monitoring for any development of worsening symptoms and/or medication side effects.

The participant responses in this study provided insight into the processes older adults used to self-manage their medications including self-monitoring, reflective thinking, and decision making. This overarching theme also reminds us that the medication self-management process requires ongoing clinical assessment and support if clients are to remain adherent. A final domain in the qualitative analysis, “Needing Additional Information from Participant” illustrated the challenge for both client and

clinician in identifying the barriers to achieving optimal self-management. Without the additional information, it appeared difficult for the nurse and/or client to then develop targeted strategies for improving the participant's medication self-management.

Integration of the Findings

Research Question 4: How do the qualitative data help explain the quantitative findings and contribute to a more complete understanding regarding the participants' medication adherence?

The findings from the quantitative component of this study help both clinicians and scientists by identifying several context and process dimensions that can put frail older adults at greater risk for medication nonadherence. The study's conceptual framework aided in the interpretation of these quantitative relationships, however, it is the qualitative data that helps us to understand why certain context and process dimensions were significant protective or risk factors for medication nonadherence.

In practice, prescribers often work under the assumption that once their clients have the knowledge and skills to take their medications, they are then ready and capable of being 100% adherent. This study demonstrated that for a majority of the older adults the assistance of the nurse care coordination and cognitive prostheses made such a goal achievable: 52% of the participants had perfect adherence and another 23% achieved 99% adherence over the course of the study. In fact, whereas the participants might have missed some doses over the course of the study, only twenty-one participants (7.8%) had an average monthly adherence rate of less than 95%. Further examination of the study's vulnerable adherers (i.e., having <95% adherence either at Month 1 and/or over time)

alongside their responses for missing medications can help us to better understand the challenges of medication self-management among frail urban older adults.

For example, a review of the literature found that African American race was a significant predictor of nonadherence. An examination of the study data found that African American participants were indeed more likely to be nonadherent at Month 1: They comprised 18.7% of the population, but were 32% of the nonadherent participants. This significant relationship, however, disappeared once condition-specific variables were added into the model. A closer examination found that the African American participants' MMSE scores only ranged from 18-23, whereas the nonadherent White participants had MMSE scores that ranged from 29-16, suggesting that a higher rate of cognitive impairment might explain this disparity. Another possibility is that a lower educational attainment and/or quality of education among the African American participants might have led to lower MMSE scores (Crum et al., 1993; Pedraza et al., 2012). Examination of participant responses further explained this risk: Both African American and White participants with low MMSE scores were more likely to have missed medications because they forgot, were confused, and/or had no reason.

The quantitative models also found that those with impaired cognitive functioning (i.e., lower MMSE scores) had lower adherence rates. In general, among those participants with normal to high cognitive capacity, their responses clustered around being disrupted, being out of the house, choosing not to take, or having no reason. Participants with mild cognitive impairment, on the other hand, were more likely to report that they forgot, were unsure why, or dispensed but then forgot to take. One participant with a MMSE score of 24 had a daughter who frequently needed to remind

her. This same participant often needed the nurse's prompting as well in order to take her prescribed dose.

In the quantitative models, we also saw that participants with higher physical functioning scores (PPT) were more likely to be nonadherent. It is possible that higher functioning participants had a greater ability to engage in activities outside the home that disrupted their medication-taking routine. Examination of the vulnerable participants' self-management processes, helped explain why physical functioning was a significant contextual predictor. First, those who were classified as physically dependent (i.e., PPT scores between 3-15) were more likely to cite responses that reflected their frail health (both physically and cognitively) such as: had difficulty seeing the pill in the mediplanner; saw dose too late; denied they missed any; or was unsure as to why. Most of the time, however, they had no reason or had forgotten. As physical functioning increased, we begin to see its effect on routine. Among those with intermediate range PPT scores, (i.e., scores between 16-20) the participants were more likely to report being out of the house and/or choosing not to take their medication. There were only five vulnerable participants who scored in the independent range, (i.e., 21-28) and again their responses were similar to the intermediate functioning: They were busy with activities, forgot, or no reason.

These results support findings by Park and colleagues (1999) where middle-aged older adults are more likely to miss their medications. For these healthier adults they may also be more likely to be out of the house or experiencing competing demands, and thus miss their medications. There is also the hypothesis that healthier patients may not be symptomatic and/or have conditions with symptoms that would prompt them to stay

adherent to their medications (Schuz et al., 2011a; Schuz et al., 2011b). More research is needed to support these hypotheses, and then tailor an intervention that targets the medication self-management of more active older adults.

In the literature, depression has been found to be a risk factor for nonadherence (Gonzalez, 2007; Kronish et al., 2006; Wu et al., 2008b), and in this study decreased emotional well-being was similarly a risk factor. Among the participants who scored within the normal range of the GDS, most of their responses were either forgetting or unsure as to why. Just over a third of participants, however, scored as mild or moderately depressed. In general these participants either forgot or gave no reason. Looking closer at the three participants in the overall study who scored as “severely depressed” on the GDS, all three had similar levels of cognitive and physical function. Only one of these participants maintained 98% adherence over time, and was the only one among them with a caregiver living in the home. The other two either denied they missed, had no reason, or consciously chose not to take. Given what is known in the literature, it is possible that older adults with severe depression may need additional nursing intervention such as exploring the reasons why they miss their medications, and/or identifying a support person to encourage them to take their medications.

Surprisingly, MCI was not a significant predictor. One possibility is that the nurses corrected for the treatment complexity challenge when they filled the machines and mediplanners. What was seen in some of the nursing notes were patients who learned to do it themselves, and when the nurses checked there were no errors or very few. These nursing notes, however, were mostly recorded later in the study. The qualitative data again help to explain why MCI was not as strong a predictor as the other risk factors:

Participants with lower MCI scores (10-19) and who missed doses were more likely to report that they had forgotten or had no reason. They were also more likely to be unsure as to why they missed suggesting they'd had trouble remembering what had actually happened. Indeed, among those participants with low MCI scores who experienced nonadherence at Month 1, most of them also had MMSE scores of 23 or less. As MCI scores increased (e.g., scores ranging from 20-39), the participant responses began to vary across all stages of the medication taking process from being confused, to being out and about, to consciously choosing not to take. As the MCI scores continued to increase (e.g., ranging from 44-68), however, the participant responses clustered around not being ready (i.e., being out and about, forgetting) and/or having no reason. This trend continued among those with the highest MCI counts (ranging from 82-112): The participants either reported they forgot or had no reason suggesting that the complexity of the regimen itself might have made it difficult to maintain 100% compliance on an ongoing basis.

Vision and hearing issues were also not significant predictors of nonadherence, and among the responses given, sensory/motor issues accounted for only 2 out of the 82 responses (2.4%) at Month 1 and only 37 out of the 1,459 responses (2.5%) over time. Nevertheless, examination of the participant responses highlighted the importance of assessing a client's ability to see the pills in the mediplanner or cup as well as the physical dexterity to take pills. In particular, participants in this study noted trouble with seeing white pills in a white mediplanner. Those with decreased visual acuity might benefit from additional caregiver support with their medication self-management.

The process dimension tested in this study (i.e., the use of a cognitive prosthetic) was also a significant predictor: Participants using a mediplanner were three times more

likely to be nonadherent than those using the MD.2. An examination of the responses showed that the most common reason why the mediplanner users missed their medications was “Forgetting” to take their dose. Other responses included: being unsure; relying on social facilitation or choosing not to take. Whereas both types of users had a high frequency of “No Reason” responses, it was rare for the MD.2 users to miss because they forgot. They were more likely to report being out of the house, being disrupted, or consciously choosing not to take. It is possible that the MD.2’s use of audio/visual prompts functioned similarly to a caregiver reminder, and thus these participants were less likely to forget. Nonetheless, the machine could not confirm that the participant physically took the medication. As a result, when the MD.2 users did forget; they said it was because they “dispensed” the medication and then forgot to take it. In these cases, nonadherence still occurred. For the two vulnerable MD.2 users who said they had dispensed and then forgotten, both had mild cognitive impairment, lived alone, and received little support.

The qualitative data also helped to explain the difficulty in quantitatively predicting which participants were at risk for being nonadherent. Many of the participants in this study had myriad responses for why they did not take their medications, suggesting that barriers to medication adherence can vary from day to day depending on what other life circumstances have come up. In addition, the quantitative models did not include assessments of the participants’ knowledge, attitudes or beliefs about their medications, which are often important reasons for medication nonadherence (Ruppar, Dobbels, & De Geest, 2012; Wheeler et al., 2014).

Support for the individual & family self-management theory. The findings from this study also validated the proposed concepts and conceptual relationships in Ryan and Sawin's (2009) Individual and Family Self-Management Theory. The theory posits that contextual factors (i.e., individual-level, condition-specific, and social environmental factors) impact on a person's ability to self-manage their health behavior (i.e., the proximal outcome dimension). For this group of frail urban older adults, cognitive and physical functioning, psychosocial well-being, and caregiver assistance each had a significant impact on the participants' risk for medication nonadherence. In addition, to the contextual risk and protective factors, Ryan and Sawin's theory (2009) posits that there are three process dimensions (knowledge and beliefs, self-regulation skills and abilities, and social facilitation) that can positively affect a person's ability to self-manage their health. Results from the quantitative analysis do support the theoretical proposition that increases in self-regulation and skills, (i.e., the process of using of a cognitive prosthesis) can significantly improve one's self-management. In this case, the use of the MD.2 machine was both significantly and positively associated with the health behavior of medication adherence.

The qualitative component of this study also supported Ryan & Sawin's (2009) theory by demonstrating the theory's ability to explain the medication self-management processes within this group of frail urban older adults. Among the eight domains in this study, five reflected aspects of the theory's three process components of self-management: "social facilitation", "knowledge and beliefs", and "self-regulation skills".

For example responses from the participants suggested that they sometimes had difficulty with the self-regulation skills such as “planning ahead” (i.e. early dosing and/or taking their medications with them before going out) and/or “reflective thinking” (i.e., unsure what happened, unable to say why). Given the number of participants in this study with mild to moderate cognitive impairment, this is not surprising, but does illustrate the need for social facilitation and/or cognitive prostheses in order to compensate for an individual’s own decreased ability to self-manage.

Strengths of the Study

This is the largest (in terms of sample size), as well as longest, nursing study to date to examine both the contexts and processes of medication-self management in frail urban older adults. Each of these factors (i.e., size and duration of study) contributes new findings to the science. First, the size of the study provided the power to test several individual and family-level factors associated with medication adherence. Second, the study measured participant monthly adherence rates up to thirteen months, which then increased our ability to assess this dynamic health behavior over time. Indeed, the quantitative examination of nonadherence over time, found three additional predictors and provides further insight how this health behavior can change over time. The ability to examine participant responses over time also helped us to better understand why adherence went up or down for some participants in the study despite the nurses’ support.

Another strength of this study was its use of several standardized and validated data collection instruments that are commonly used in clinical practice (e.g., MMSE, GDS, PPT, and OASIS-B1 Discharge Version). The use of these clinical tools meant that the present findings can be readily translated to, and adopted for clinical practice. The use

of these instruments also made it easier to compare the effects of this study with findings in the literature.

This study is also the first nursing intervention to both test and explain the role of caregivers in helping older adults' manage their medications. These findings support Ryan and Sawin's (2009) theoretical proposition that older adults are part of a social unit, and that self-management interventions should address both individual and family-level contexts and processes. The important role of caregivers in helping frail older adults manage their medications further strengthens Russell and colleagues' (2011) argument for behavioral scientists to move toward a personal systems approach when designing medication adherence interventions. Current self-management programs for persons living with chronic disease, however, still have not capitalized on the family as a resource (Jonsdottir, 2013).

The study is also the first to link participants' nonadherence rates with responses for why they missed. Several descriptive studies have reported the reasons that participants gave for missing their medications (Kennedy et al., 2008; Rifkin, 2010; Vik et al., 2005), but they did not link them to specific individual and/or family-level factors. As a result, we could only know part of the story. As Wolcott (1994) notes, however,

“The effective story should be ‘specific and circumstantial’, but its relevance to a broader context should be apparent. The story should make a point that transcends its modest origins.” (p. 98).

This study's mixed-methods design allowed us to better understand the health behavior of medication self-management by examining why certain participant characteristics were significantly associated with medication nonadherence. The story that emerged is that

while a significant majority of these frail older adults maintained near perfect adherence over the course of the intervention, there were some who still struggled to maintain their adherence. The ability to link the contextual dimensions of these participants to their medication self-management processes provided the opportunity to better understand medication nonadherence in frail older adults, identify the risk and protective factors, and begin to develop interventions that target individuals and their family members/caregivers.

Limitations of the Study

Because this study utilized data previously collected for a larger study, it was subject to several limitations that impacted interpretation of its findings. For example, in the quantitative component of the study, the dependent variable (i.e., medication adherence) was not collected on participants in the usual care group even though the original study was a randomized-controlled trial design. During the design of the original study, the decision was made not to collect data on the usual care group's medication adherence because the process of assessing monthly adherence was an active ingredient of the nursing care coordination. Therefore, all the participants in this study received the intervention, and as a result the group as a whole had near perfect adherence rates both at Month 1 and over time. There was also no run-in period to measure medication adherence prior to the intervention. It is possible that had there been medication adherence data from a run-in period, there might have been greater variance in the dependent variable than that seen in Month 1 of this study.

Another limitation stems from the complexity of trying to test models involving a human health behavior like medication adherence because it is comprised of both

intentional and unintentional behaviors (Lehane & McCarthy, 2007). Intentional behaviors are conceptualized as a person's purposeful actions and often include not taking medication(s) based on one's knowledge, attitudes and/or beliefs about the medication (Ho et al., 2009). Conversely, unintentional behaviors are conceptualized as a person's inability to be adherent because of physical or mental limitations. Because the larger study's focus was on unintentional behaviors, data on the participants' knowledge, attitudes, or beliefs about medications were not explicitly collected. The inability to test this important factor in the quantitative analysis might be a reason for the large amount of variance not explained by the study's two models. Indeed, even though the amount of variance explained in the Month 1 model was similar to, or better than, those seen in other nonadherence models (Schechtman, Bovbjerg, & Voss, 2002; Wu et al., 2008b), models that have had stronger explanatory power (Schuz et al., 2011a; Horne & Weinman, 1999) have also found client beliefs and attitudes toward medications to be the strongest predictors. Our understanding of intentional nonadherence was also limited to only those participants who willingly reported that they chose to not take their medications. There is always the possibility that clients will give alternative reasons (i.e., forgot, unsure, deny) rather than disclose their intentionality to a provider, regardless of the quality of the relationship (Cushing & Metcalfe, 2007; Unni & Farris, 2011).

Another issue was that the Supportive Assistance construct was measured by two OASIS-B1 variables: "ADL assistance" and "IADL assistance". On the OASIS-B1 form, however, examples of IADL assistance included: (medications, meals, housekeeping, laundry, telephone, shopping, and finances). It is possible the primary caregiver gave some type of IADL assistance other than medication assistance. A more specific measure

of medication management assistance such as the type and quantity of the medication management assistance provided might have produced a stronger effect.

The qualitative portion of the study also had limitations, which stem from how the data were collected for the primary study. For example, while nurses documented the reasons older adults gave for not taking their medications, they did not audiotape the older adults' responses. As a result, it is unknown if the "reasons" recorded by the nurses included the exact wording used by the older adult, making it impossible to determine the authenticity of the older adults' "voice" or "perspective" on medication nonadherence. In addition, the participant reasons correspond to a single question with no follow up questions by the nurses, which then limited the ability to make contextual interpretations (i.e., a fuller understanding of why the participant was nonadherent).

Another limitation was that the only participant responses documented were those to explain why medications were missed. Further insights might have been gleaned by having the intervention nurses also document the self-management processes that the participants used to achieve their high rates of adherence. Finally, additional documentation on the participants' medication beliefs and/or the skills that they or their caregivers possessed might have helped us better understand the interaction between the context and processes of the older adults' medication self-management.

Implications for Nursing Practice

The findings from this study help nurses as well as other healthcare professionals better understand the complex issues facing older adults in the self-management of their medications. Nurses in this care coordination intervention worked with the participants to develop strategies to successfully manage this multistep process (i.e., having the

medication, being ready, and being able to take their medications). The strategies mainly targeted the participants' unintentional reasons for missing their medications such as running out of medication, taking the wrong medication/dosage, and/or forgetting. Results from this mixed-methods study showed that the clients who were most at risk for unintentional medication nonadherence were those with decreased cognitive functioning, decreased psychosocial well-being, and/or physical impairments. At the same time, there was a subset of participants, i.e. a group with higher physical functioning scores, who missed medications because of being away from home and not having the medications available to take. Nurses working with healthier, more active, older adults could try self-regulation strategies such as scheduling medication doses around the time of day when the client is most likely to be home, choosing to early dose, and/or carrying a portable medication organizer when away from home.

The results from this study also demonstrated that ongoing clinical case management/support can lead to near perfect adherence rates, even in a group of frail urban older adults (i.e., a group traditionally at risk for medication nonadherence). Thus, screening for these myriad risk factors might alert a healthcare team for the need to conduct a more in-depth assessment of a client's ability to self-manage the medication regimen. The results from this study also showed that family and/or caregivers can be an important source of support for older adults with their medication self-management, especially for those with cognitive and/or physical impairment. Clinicians in both the acute care and community settings should therefore assess both the client's and the caregiver's ability to effectively manage the prescribed medication regimen.

The qualitative findings also showed, however, that some participants who had the capacity to take their medications, consciously chose not to take them. In some cases, the participants needed additional education on how to take the medication and/or understand why they would benefit from taking it. Still others, despite the nurses' best efforts did not want to take the medication. Indeed, some participants shared that they were sick and tired of taking their medications. As a result, even with the nurse's, caregiver's, and/or family's assistance, these participants remained nonadherent. Thus in order to optimize medication adherence, prescribers might consider a more patient-centered approach when working with their clients.

As a first step, the healthcare providers would assess the client's personal values/beliefs about health and well-being in order to gain insights into their decision making (Zoffmann, Harder, & Kirkevold, 2008). With this understanding, providers could then try to engage the client in shared decision making about their prescribed medication regimen. Prescribers and clients could try discussing the benefit versus burden of each medication, and then based on the client's preferences develop a mutually agreed upon regimen. The concept of medication adherence/compliance might then develop into a more democratic concept that reflects this mutual decision making. In the United Kingdom there is already a movement toward "medication concordance": A term that connotes a mutual decision about the client's medication regimen versus the client adhering to a prescriber's decision (Cushing & Metcalfe, 2007; Horne et al., 2005). Once the client and prescriber have developed a mutually agreed upon regimen, the team might then suggest self-management behaviors that best reflect the client's personal values/beliefs as well as capacities. For those clients who still continue to have trouble

and/or lack the capacity to self-manage their medications, the team could then try enlisting the help of family to optimize the individual's medication self-management.

Nurses also need to know that assessment of a client's medication adherence continues to be a challenge, and that currently there is no "gold standard". In the community setting, older adults use a variety of medication organizers including bottles, mediplanners, and bubble packs. In this study, the older adults used either the mediplanner or the MD.2 to organize and administer their medications. For a large percentage of the participants, the mediplanner was an effective, cost-efficient system for managing their medication regimens. Indeed, over the course of the study, only 16 of the 131 mediplanner users had an adherence rate that averaged less than 95% over the course of the study. An examination of the participant responses, helps us to understand why these mediplanner users might have been more vulnerable. The most common reason was they had forgotten. Other common reasons were being unsure of why they missed their dose, being confused about the organizer, and/or not taking the dose until the RN visit. These reasons highlight the extra cognitive challenge that the mediplanner users faced in order to remember which medications to take and when. These users each possessed one or more significant risk factors including: lower cognitive capacity, higher physical functioning, decreased psychosocial well-being, no IADL assistance, and/or no caregiver in the home. Only five of the most vulnerable participants were in the MD.2 group. Most of their responses were "no reason noted". Of those that said that they had forgotten, they also had mild cognitive impairment.

Thus, from the study findings it appears that for the vulnerable older adult, the MD.2 offers several advantages over the mediplanner including: serving as an

audio/visual prompt; controlling client access to only the scheduled dose, and alerting a caregiver if a dose is missed. Another benefit to optimizing medication self-management is the MD.2's ability to record when and/if a medication is dispensed. Indeed the MD.2 data could help clients see patterns in their medication-taking processes. From this information, clients could then increase their self-regulation skills (e.g., reflective thinking, planning and action) by identifying strategies to increase medication adherence. Similar to the adherence strategies used by some of the more successful MD.2 participants in this study, those clients who are still very active could either choose to early dose, and/or bring their medications in a pill case when they go out. For clients who cannot master this additional cognitive effort, it is important for the nurse to help the client plan ahead, and have systems in place to administer medications if the MD.2 is not available. In the study, the nurses also enlisted the support of family members and/or caregivers in identifying family-centered strategies to optimize the medication self-management process.

Finally, the study findings suggest that even with the intensive nurse care coordination, there was still a small number of participants and their caregivers who experienced problems and/or needed assistance at some point along the multistep medication self-management process. These findings support Schulman-Green and colleagues (2012) proposition that self-management is an "ongoing and dynamic" process that varies over time. Indeed, participants in this study utilized myriad self-management processes in order to take their medications, and these processes varied over time. The study results thus further highlight the need for ongoing assessment by the client's

healthcare team as life events change in order to optimize a person's medication self-management.

Implications for Future Research

C. Everett Koop wisely observed, "Drugs don't work in patients who do not take them."² We know that effective management of most chronic conditions includes pharmacotherapy, and that nonadherence to one's medication regimen leads to greater morbidity and mortality. Yet after decades of research directed at the problem of medication nonadherence, few interventions have proven effective, especially among older adults with cognitive impairment (Campbell et al., 2012). The near-perfect adherence rates achieved by this group of frail urban older adults, however, demonstrate that the nurse care coordination study is an effective intervention even among those adults living with cognitive impairment. Based on the combined quantitative and qualitative findings, there are several suggestions for future research.

First, the lack of theory to explain the process of medication adherence has limited the development of effective interventions (Banning, 2009; Haynes, 2008). To effectively target changes in health behaviors, (e.g., medication adherence) we need to develop theory-based interventions that move beyond an individual-level approach and toward a multi-level approach (i.e., person, family, provider, healthcare system) (Ruppar, 2010a, Schneider & Stokols, 2009). Researchers in the field of medication self-management recognize the need for this paradigm shift and are calling for the development of interventions involving a personal system's approach (Jonsdottir 2013;

² This research was unable to locate a source that directly attributes this quote to C. Everett Koop. Many researchers, however, consistently attribute this quote to the late Surgeon General (e.g., Kocurek, 2009; Schneider, Hess, & Gosselin, 2011; Silverman, Schousboe, & Gold, (2011).

Russell et al., 2011). Theory-based interventions, however, require the inclusion of critical inputs (i.e., those factors necessary for the intervention to produce the predicted changes) (Sidani & Braden, 1998). Whereas the findings of the primary study provided preliminary support for the self-management concepts and conceptual relationships in Ryan & Sawin's IFSMT (2009), the quantitative models in this study could only test one of the intervention's components, i.e. the use of a cognitive prosthesis (MD.2 or mediplanner), aimed at supporting the concept of "self-regulation skills and abilities". Nevertheless, in the primary study, the nurse care coordination intervention did include all three IFSMT process constructs of "knowledge and beliefs", "self-regulation skills and abilities", and "social facilitation". Interventions to enhance medication adherence, however, are often multidimensional, and thus the testing of each component may not be practical.

In this study, participants often cited family reasons for why they missed their medications (e.g., visiting family, staying with family, being out with family, or being distracted by family). Therefore, a second recommendation would be to include the family whenever possible in the client's medication self-management process. Helping the family to plan medication management, especially when the client leaves the home is an important task. Continual reinforcement of planning and action is also needed to ensure medication adherence when routines are disrupted. Indeed, without proper training themselves, some family members could unintentionally contribute to an older adult's nonadherence. Whenever possible the nurses in the study assisted clients and their families in this planning and action, and evidence beyond this study shows that practical

support from family members significantly increases medication adherence (Scheurer et al., 2012).

As such, in order to maximize the caregiving value of family members, future testing of this nurse care coordination intervention could include enrolling family members along with the clients. The nurses would then work with client-caregiver dyads to increase medication adherence through enhanced knowledge and skills development. The person's self-management capacity would then increase at both the individual- and family-levels. This should be feasible as the nurses' notes suggested that some families were already doing this informally, and that the nurses found this very helpful. In a recent feasibility study of caregiver/HF patient dyads, Sebern & Woda (2012) found that patient self-care scores increased after the dyad's participation in the intervention, but the number was too small to test for causality. Research also suggests that interventions using frequent human reminder systems rather than nonhuman reminders may be more effective in improving medication management (Campbell et al., 2012).

The review of the literature found that most intervention studies experienced a ceiling effect by including participants who already had high rates of adherence. Similarly, in this study's highly managed population the mean medication adherence rate at both Month 1 and over time was greater than 98%. Because there was no run-in period prior to the nurse care coordination intervention, it was difficult to determine the participants' baseline level of nonadherence. One of the inclusion criterion for the original study was based on the OASIS-1 item M0780 which assesses an individual's ability to take their oral medications, but not their compliance (Shaughnessy, Crisler, Hittle, & Shlenker, 2002). In addition, the intervention was designed to target problems

related to unintentional nonadherence. One suggestion then would be to replicate the nurse care coordination study with frail older adults whose providers have identified as “super-utilizers” (i.e., those who “cycle in and out of the hospital”) (Gawande, 2011) because of *intentional* nonadherence issues. Targeting those clients who are most in need because of knowledge and belief issues could then expand the intervention’s application to other populations. Similar to the first study, the outcomes of interest would be medication adherence, client health and well-being, and healthcare costs.

A final suggestion specific to the nurse care coordination intervention would be to expand upon the nurses’ exploration with participants for the reasons why they missed their medication(s). In this study, the domain, “Needing Additional Information from Participant” was very common with approximately 40% of all participant responses being categorized as either: “Having no reason”, “Denying they missed medication(s)”, “RN being confused”, “Taking dose during RN visit” or “Being unsure of what happened”. The lack of clarity in the participant responses (i.e., an explanation of what had happened) resulted in a lost opportunity to better understand the participant’s medication self-management process. Refining this part of the intervention protocol would not only develop the client’s self-regulation skills of self-monitoring and reflective thinking, but could also help the client with the planning and action skill. A next step then could be to develop a more formative set of probing questions that might assist the participants in discovering reasons they didn’t even realize they had for missing their medications. These reasons could then help the nurse, client, and family better understand why doses were missed and develop strategies to overcome this problem.

Conclusion

Frail older adults depend upon medications to manage their chronic conditions, yet often lack the cognitive and/or physical ability to independently self-manage their prescribed regimens. Findings from this study suggest that caregiver assistance with IADLs reduces the risk for medication nonadherence. Clinicians, researchers, and policymakers need to recognize the significant challenges associated with medication self-management among frail older adults: Nearly 1/3 of caregivers for adults (over the age of 50) report that their recipient suffers from dementia and/or mental confusion, and this subset of caregivers is also more likely to report having a high burden of care (13%) than those providing care to adults with cancer (10%) or simply old age (6%) (NAC, 2009). Still, few researchers have included caregivers in their intervention designs. Future interventions therefore need to not only capitalize on the caregivers' expertise, but just as importantly, also work to reduce their high burden of care. Behavioral health researchers working with frail community-dwelling older adults would do well to partner with programs that serve this vulnerable population (e.g., home healthcare agencies, Program for All-Inclusive Care for the Elderly (PACE), caregiver support groups, adult day care centers, and Area Agencies on Aging) to develop and test more multi-level interventions. A community-based participatory research approach might also prove more effective than the provider-focused models that have been tested to date. With the largest cohort of adults entering into Medicare, and its program expenditures already accounting for 21% of national health expenditures (CMS, 2014), we need to find more cost efficient models of care. The time is now.

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APPENDIX A
FREQUENCY TABLE OF CODED THEMES

Theme/Code	Frequencies by Month in the Study													Total	Rank
	1	2	3	4	5	6	7	8	9	10	11	12	13		
1B		2	2	1	1	2	1	1	1			1		12	19
1C	1	9	7	4	1	5	5	3	5	2	3	1	2	48	9
1D	5	26	10	8	22	15	13	6	12	7	4	2	2	132	3
1G	2	1	2	6		2	1	4	1	2	2	2	3	28	14
1H	20	17	21	21	16	23	26	29	24	24	22	19	15	277	2
1I	1	5	8	9	7	5	5	9	2	3	3	3		60	7
1J		1	3	1	1	1				1	1	1	1	11	20
2A							1							1	
2B			1	1	1				2					5	
2C				2	1									3	
2D	1	6	4		1			1		1	1			15	17
3A	2	4	4	1	4	3		3	2	1	1		3	28	12
3B		1												1	
3C	1				3		1	1			1			7	
3D	3	3	3	2	1	3			3	4				22	16
3E			1											1	
4A	1	3	1	1		1	1	1		2	2	1	1	15	18
4B					1								1	2	
4C		3		1	1		2	1	1					9	
5A	1	2	1		1	1		1			1			8	
5C		1	1				1	2	1		1			7	
6A		3	1	3		1			2	2	3	5	4	24	15
6B		4	3	5	5	2	8	7	2	1	6	2	2	47	10
6C	2	3	3	2	4	3	8	9	3	5	3	5	4	54	8
7A	8	11	8	9	4	6	6	10	4	4	3	3	4	80	5
7B	15	43	15	37	23	26	26	21	23	24	22	12	6	293	1
7C	5	11	10	8	6	9	9	4	4	3	3	5	2	79	6
7D	2	4	2	4	1	5		2	5		1	2		28	11
7E	7	24	15	12	7	12	6	9	3	5	8	4	3	115	4
8A	4	2	1	3	1	2	2	3	3	2	2	1	2	28	13
8C	1		1	1	1		2	1		3	1			11	21
8E		1			3	2	1	1						8	
Total Cases	55	115	96	92	86	81	90	89	71	69	69	53	36		
Total Meaning Units	82	190	128	142	117	129	125	129	103	96	94	69	56	1459	