MEDICATION DISCREPANCIES ASSOCIATED WITH DIABETES MELLITUS IN COMMUNITY DWELLING PRIMARY CARE OLDER ADULTS

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Medication management issues in persons with diabetes (PWD) are well documented. Few studies have examined community-dwelling older PWD in primary-care provider (PCP) practice setting to determine what medications PCPs prescribe and what patients actually take.

This secondary analysis, guided by Donabedian's structure-process-outcome framework, examined medication discrepancies (MD) in community-dwelling PWD (n = 142), 65 years of age and older, in the PCP setting. The aims were to (1) characterize the sample, (2) characterize the discrepancies associated with prescribed medications, and (3) identify potential correlates of medication discrepancies. This study used de-identified baseline data (n = 533) from a parent study (NIH/NIA AG023129), which examined the utility of cognitive function testing of older adults in the PCP setting. The Donabedian structure component included variables for subject characteristics such as sociodemographic variables, health information, and neuropsychological variables. The process component included data from a comprehensive medication review, which generated a complete and accurate list of the subject's current medications and allowed a comparison of the patient-generated list with the provider-generated list present in the subject's medical record.

In 95% of the subjects, MD were present. Among subjects with the same number of health problems, those with a higher number of medications were more likely to exhibit MD compared to the subjects with a lower number of medications. Among patients with the same number of medications, those who had a higher number of health problems were less likely to have a MD compared to the subjects with fewer health problems.

Polypharmacy and the number of health problems were the most significant correlates of a medication discrepancy. While not significant, a trend was observed for diminished cognitive function and the presence of a MD ($p = 0.056$). Despite a high MMSE mean score (27.9 ± 1.9) and positive correlations with neuropsychological scores, mild cognitive impairment was discovered in 44% of the sample—and four or more depressive symptoms in 69.72% of the sample.

The pervasiveness of medication discrepancies and health problems in a population of PWD at risk for cognitive impairment and depressive symptoms has significant health care implications that deserve further study.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

I would like to thank the influential and motivating individuals who believed in me during the course of this endeavor. First, grateful appreciation to the members of my dissertation committee, Judith Erlen, Lisa Morrow, Jennifer Lingler, and Dianxu Ren, for their dedication to this dissertation.

Many grateful thanks to my dissertation mentor and chair, Dr. Judith Erlen, for sharing her valuable time, and offering constructive guidance: Her support and understanding throughout this process was invaluable. I consider her my friend and my first true mentor. Drs. Lisa Morrow and Judith Saxton granted access to their data, provided guidance, and support, which made this dissertation a reality; for that I have utmost gratitude. Additionally, while not a committee member, I owe utmost gratitude to Dr. Wendy Henderson, my colleague and dear friend, for always being a resource, a reviewer, a champion motivator, and my greatest source of support throughout this endeavor. I want to recognize Joe Brun, in the School of Nursing, for his assistance through the years.

I am grateful to my family and friends who supported my persistent efforts through the years to achieve this milestone in my life. I wish to thank my son Warren, the light of my life, for always being supportive. We shared countless life events during the course of this dissertation process that kept my life priorities in check. The best gift I could offer him was the

completion my dissertation. It is my belief that he came to appreciate that perseverance and determination was rewarding and could be life changing. Thank you to the countless individuals that were not mentioned. This work was due to the involvement of many people, and I am thankful for each person's contribution.

1.0 INTRODUCTION

1.1 STATEMENT OF THE PROBLEM

The value of pharmacologic therapy to achieve and maintain diabetes mellitus (DM) control has been clearly established (Diabetes Prevention Research Group, 2002; Buchanan, T.A., Xiang, A.H., Peters, R.K., et al 2002; Chiasson, J.L., Josse, R.G., Gomis, R., et al, 2002). Yet, the ability to adequately manage DM has remained elusive and control of DM has remained suboptimal in the United States (Stratton et al., 2000). A direct relationship between adherence and glycemic control has been documented (Asche, LaFleur, & Conner, 2011; Rozenfeld, Hunt, Plauschinat, & Wong, 2008); the World Health Organization (WHO) declared adherence to be the cornerstone of metabolic control (World Health Organization, 2003). Medication adherence is defined as taking 80 to 120% of the medication prescribed (Avorn et al., 1998; Hope, Wu, Tu, Young, & Murray, 2004; Monane et al., 1996; Sackett et al., 1975). Yet, in a review article, Rubin (2005) reports that more than 20 studies found that adherence to oral medication for type 2 diabetes mellitus (T2DM) ranged from 65% to 85%. Medication discrepancies (discordance between the prescribed regimen and the medications actually taken each day) further limited treatment efficacy (Bedell et al., 2000; Grant, Devita, Singer, & Meigs, 2003b; Wagner & Hogan, 1996; Yang, Tomlinson, & Naglie, 2001), hence negatively affecting glycemic control.

Elderly DM patients have often required multiple medications to treat DM and associated comorbidities (Bailey & Kodack, 2011). In a review of DM medication adherence, Odegard and

Capoccia (2007) reported the mean number of medications ranged from 4.1 to 10.2 and the number of medications increased with the number of comorbidities. In a large (n = 30,000) study of adults 65 years of age and older, Field et al. (2007) corroborated this finding and reported that adverse drug events (ADEs) due to patient-generated errors was associated with polypharmacy and identified patient-generated medication errors most often involve hypoglycemic medications (28.7%) and led to 129 ADEs. Factors identified within the DM patient population have increased the complexity of therapeutic regimens, thus placing patients at greater risk for medication errors including adverse drug reactions, drug-drug interactions, and non-adherence.

Prevention of medication errors was the impetus behind the push for medication reconciliation which was championed by the Institute of Medicine and identified as a prominent intervention in the 100,000 Lives Campaign (Berwick, Calkins, McCannon, & Hackbarth, 2006). To promote patient safety and decrease medication errors, the medication reconciliation process became a vital component of the health care process across all trajectories of care. Medication reconciliation is a comprehensive evaluative process for generating a complete and accurate list of a patient's current medications and comparing the patient-generated list to those in the provider-generated list within the patient's medical record. The intention of medication reconciliation was to promote patient safety by identifying errors of omission, duplication, incorrect doses or timing, and the potential for ADEs ("Using Medication," 2006). The medication reconciliation process has been shown to be an effective means to reduce the number of medication errors (Pronovost et al., 2003; Rogers et al., 2006). Yet, failures in the medication reconciliation process have led to medication errors (Santell, 2006).

Determination of a medication error often has relied on the existence of a single, discrepancy free medication list, or *gold standard* for medications a patient should be taking (Coleman, Smith, Raha, & Min, 2005). For patients who received care from more than one

provider, such a list rarely existed (Frei, Huber, Simon, Bonani, & Lüscher, 2009). Unlike medication errors in the acute care setting, medication management and medication reconciliation processes in the community have not been comprehensively studied. Healthcare providers were often not aware of medication changes that occurred during hospitalizations or other care transitions (Layson-Wolf & Morgan, 2008). When medication reconciliations were conducted at discharge or within 72 hours of discharge from the hospital, at least one medication discrepancy was noted in those patients positive for a discrepancy (Coleman et al., 2005; Unroe et al., 2010). Within 72 hours of discharge in community dwelling adults 65 years of age and older, approximately 50% of medication discrepancies were categorized as patient-associated and the other 50% were categorized as system-associated. For patients with medication discrepancies, 14.3% were re-hospitalized at 30 days compared with 6.1% having no medication discrepancy (Coleman et al., 2005). Studies in the community setting reported medication reconciliation discrepancy rates ranging from 30% to 66% (Barat, Andreasen, & Damsgaard, 2001; Bloom, Frank, Shafir, & Martiquet, 1993; Coleman et al., 2005; Gleason et al., 2004; Gonski, Stathers, Freiman, & Smith, 1993; McKinley, Mulhall, & Jackson, 2004; Moore, Wisnivesky, Williams, & McGinn, 2003).

Medication discrepancies identified during the reconciliation process were perceived as a source of error, an indicator for potential medication nonadherence, and a risk for potential ADE and negative outcomes. Likewise, the discovery of a medication discrepancy may lead to corrective actions among patients, and providers, and within the healthcare system to promote more positive outcomes than otherwise may have been realized.

1.2 PURPOSE AND AIMS

The overall purpose of this secondary data analysis was to examine medication discrepancies associated with DM in adults 65 years of age and older who were community dwelling primary care patients. The specific aims were to (1) characterize the sample of older community dwelling patients with DM, (2) characterize the discrepancies associated with prescribed medications, and (3) identify potential correlates of medication discrepancies. The main outcome measure was the presence of discrepancies based on the process of comparing provider-recorded medications and patient self-reported medications.

2.0 BACKGROUND AND SIGNIFICANCE

Medication management issues in the treatment of diabetes have been well documented, but less is known about the pervasiveness and factors contributing to medication discrepancies associated with diabetic patients 65 years of age and older living in the community and utilizing a primary care provider. Avedis Donabedian, a physician and health services researcher, recognized the importance of evaluating the quality of health care and proposed a direct relationship between quality of the care provided and patient safety (Donabedian, 1966).

2.1 CONCEPTUAL MODEL

Donabedian (1966) introduced the structure-process-outcome (SPO) conceptual framework; the foundation for modern healthcare quality measurement. He proposed that good structure promoted appropriate processes of care and better patient outcomes.

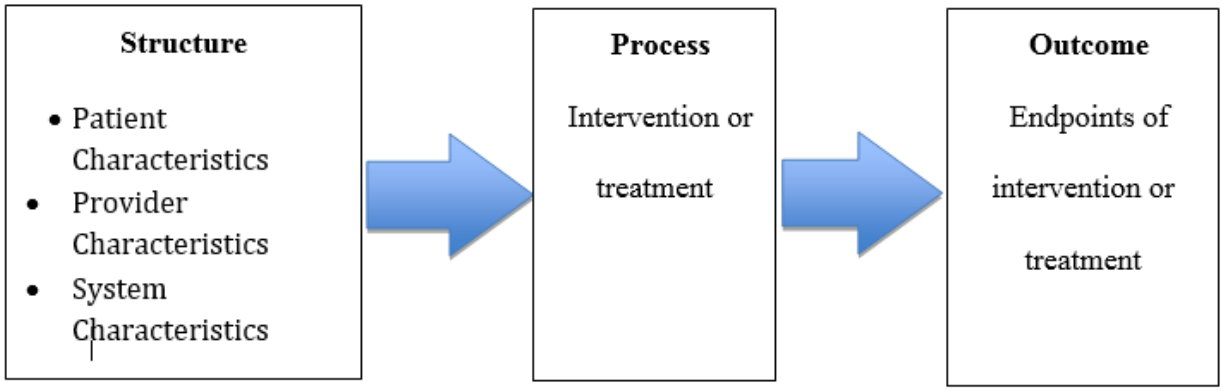

Figure 1. *Donabedian Conceptual Framework*

Structural categories considered important in assessing the quality of structure are (1) client or patient characteristics, (2) provider characteristics, and (3) system characteristics. The process component focuses largely on the intervention or treatment process, what is done for the patient; it includes interpersonal process factors and technical skill in the delivery of services. Interpersonal process refers to the way providers relate to patients. Technical skill refers to the specific services used and the way in which providers manage the care, which includes continuity of care and its coordination. Outcome is the final component of the framework, and is the ultimate test of the effectiveness of healthcare. Outcomes are the endpoints or results of an intervention or healthcare practice, such as RN staffing and outcomes of hospital related mortality and adverse patient events.

Donabedian's (1966) conceptual model, heretofore identified as the SPO model has been used by both health services and quality improvement researchers (Romano & Mutter, 2004). In health care studies guided by the SPO model, research findings have verified links between structural measures and processes and outcomes of care (Mitchell & Shortell, 1997). Health services research, guided by the SPO model, typically utilize either process or outcome measures

but not all three components of the model. The rationale for choosing one measure over the other was due to limitations within the data. Therefore, health services research that utilizes existing data sets not only is primarily tailored to either process or outcome measures, but also rarely combines both types of measures. Utilization of process measures have been prevalent in quality improvement and health policy research (Crombie & Davies, 1998). Process measures have been used in intervention studies to assess how providers evaluate and treat patients (Romano & Mutter, 2004). Outcome measures, primarily studied by health services researchers, have been indicative of end results of care (Crombie & Davies, 1998). Other outcome studies utilizing the SPO model have investigated patient assessments of health care (Oropesa, Landale, & Kenkre, 2002; Westaway, Rheeder, Van Zyl, & Seager, 2003).

Donabedian's (1966) SPO model presumed high-quality healthcare environment indicators were linked to patient safety. Health care researchers used the structure-outcome components of the SPO model to investigate patient safety. Adverse events at the patient care unit or care team level versus the hospital/system level were investigated as outcome measures to evaluate quality. Those researchers reported positive relationships with quality (Blegen & Vaughn, 1998; Naveh, Katz-Navon, & Stern, 2006; Pollack, Koch, & Network, 2003). Studies of quality improvement (QI) that utilized structure-outcome components also found positive relationships with quality (Aiken & Sloane, 1997; Aiken, Sloane, & Lake, 1997). Studies of QI utilizing structure-process components found no relationship with quality (Gill, Ryan, Morgan, & Williams, 2000; Kanse, van der Schaaf, Vrijland, & van Mierlo, 2006) with the exception of Brundage et al.,(1999) who found a positive relationship. Quality improvement studies using process-outcome components found positive relationships with quality (Curley, 1998; Glasson et al., 2006; Merlani, Garnerin, Diby, Ferring, & Ricou, 2001).

None of the above studies utilized the SPO model or mixed components of the SPO model to investigate the process of medication reconciliation with resulting medication discrepancies in a primary care setting for persons with diabetes. It remains important to gain insight about the influence of structural components (i.e., patient characteristics) on the medication reconciliation process and the resulting medication discrepancies.

2.2 OPERATIONAL MODEL

The operational model guiding this study, which addresses patient factors and medication reconciliation, is depicted as follows:

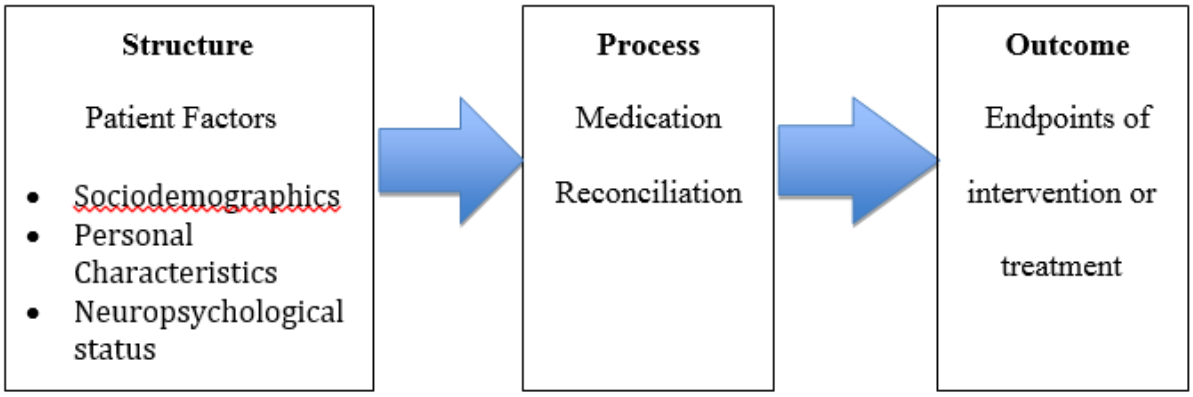

Figure 2. *Operationalized Donabedian SPO Model*

2.2.1 Structure: Potential factors associated with medication discrepancies

Medication discrepancies have numerous causes and sources. The National Council on Patient Information and Education (NCPIE) categorized factors that contributed to the medication problems as patient-related and medication-related factors, government impediments, as well as prescriber and pharmacy related factors (National Council on Patient Information and Education, 2007).

Independent community dwelling older adults faced multiple challenges when managing a complex medication regimen (Ahrens, Feldman, & Frey, 2002; Davis et al., 2006; Kairuz et al., 2008; Russell et al., 2006). Researchers identified many factors associated with an increased risk of medication errors. Patient characteristics of age, gender, living arrangements, social support, physical function, and neuropsychological status were identified as pertinent predictors, which contributed to medication discrepancy errors.

Patient Factors

Age was consistently cited as a factor related to medication discrepancies (Bedell et al., 2000; Gilbert, Luszcz, & Owen, 1993). Marek (2008) reported that older adults present with decreased comprehension of medication instructions and adherence. In a study of individuals aged 75 and older, Barat, Andreasen, and Damsgaard (2001) found that knowledge of medication for treatment was poor and non-adherence ranged from 20%–70%. Multiple physiologic and metabolic processes, including drug absorption, distribution, metabolism, and excretion of medications were affected by aging (Beers, Baran, & Frenia, 2000).

The 2011 CDC National Diabetes Fact Sheet reported an increasing prevalence of DM in the United States from approximately nine percent in 1980 to approximately 20% for those above the age of 65 years in 2010; and the prevalence increased with increasing age, to more than 11 times that of people younger than 45 years of age as reported in 2010 (Centers for Disease Control and Prevention, 2011). The prevalence of DM increased across age groups: men aged 65–74 years had an increased prevalence from 9.4% to 23.2%, and over the age of 75 the increase was from 7.6% to 23.8% between 1980 and 2010. Women aged 65–74 years had an increased prevalence from 8.9% to 18.6%, and over the age of 75 the increase was from 9.6% to 17.7% between 1980 and 2010, indicating that males had a higher prevalence of diagnosed DM

than females. Twenty-one percent of new persons with diabetes were diagnosed between the ages of 65–79 years but the majority of new diagnoses (63%) occurred between the ages of 40 and 64, leading to a conclusion that older adults had a longer duration of disease. (Centers for Disease Control and Prevention, 2011). While the prevalence of DM in older males was higher than in females, the female gender was predictive of medication discrepancies in the outpatient setting (Bedell et al., 2000; Wolff, Starfield, & Anderson, 2002).

Comorbidities

Multiple chronic diseases were common in 65% to 80% of the elderly population (Britt, Harrison, Miller, & Knox, 2008; Weiss, Boyd, Yu, Wolff, & Leff, 2007; Wolff et al., 2002). Almost 75% of adults with diabetes had two or more comorbid conditions which accounted for much of the morbidity and mortality in those patients (Halanych et al., 2007; Howard et al., 2006; Kerr et al., 2007). Caughey et al. (2010) reported a mean of five comorbidities in the persons with diabetes over 65 years of age. A higher disease burden due to comorbidities was reported to increase the risk for poorer cognitive functioning (Patrick, Gaskovski, & Rexroth, 2002; Proctor et al., 2003). Greater than eight medical comorbidities and a family history of dementia was associated with lower cognitive function (Morrow, Snitz, Rodriquez, Huber, & Saxton, 2009). An increased number of comorbid conditions were related to decreased treatment prioritization of diabetes in relation to other diseases, and decreased the ability of persons with diabetes to self-manage their disease (Halanych et al., 2007; Kerr et al., 2007).

Polypharmacy

Associated with comorbidity was the use of multiple medications in the older adult (Ciechanowski, Katon, & Russo, 2000; Miksch et al., 2009), and specifically in persons with diabetes (Caughey et al., 2010; Good, 2002; Odegard & Capoccia, 2007). In a study of T2DM

and hypertension in 44 primary care clinics, polypharmacy was common with more than one-half of patients taking five or more medications (Hunt, Kreiner, & Brody, 2012). In a study (n = 18,968) of elderly persons with diabetes, the median number of unique medicines dispensed was 10 (IQR 7–14) and over 70% of the patients were dispensed five or more unique medications (Caughey et al., 2010). This supported the findings of 4.1 to 10.2 medications, proportional to the number of comorbidities, in a systematic review of medication adherence in diabetes by Odegard & Capoccia (2007) not isolated to elderly adults. Polypharmacy has been associated with an increased risk of inappropriate prescribing and adverse drug reactions, resulting in an increase in adverse outcomes, such as falls, hospital admissions and mortality. Yet, counter to current treatment guidelines, early and aggressive polypharmacy in T2DM patients was recommended to modify the disease and aim for tight glycemic control which also would modify other outcomes related to comorbidities (Wright, Stonehouse, & Cuddihy, 2010).

Living Arrangements

In a systematic literature review spanning the years 1948 to 2001, DiMatteo (2004), found strong evidence of a relationship between social support, living arrangements, and patient adherence to medical regimens. Greater social support (e.g., family and living arrangements) and enhanced medication adherence was related to decreased medication errors (DiMatteo, 2004). Living arrangements were important to the elderly adult due to involvement with managing medications. A lack of social support with monitoring may have led to medication errors (Barat et al., 2001; Dunbar-Jacob, Bohachick, Mortimer, Sereika, & Foley, 2003).

Sensory Changes

Sensory changes have been recognized in older adults. Auditory and visual impairments can interfere with the ability to follow instructions given by healthcare providers. Visual (Mehuys et al., 2012) and hearing impairment (Cárdenas-Valladolid et al., 2010) were both identified as

sensory deficits negatively affecting adherence in studies (n = 338 and n = 327, respectively) of community dwelling older adults.

Neuropsychological status

In the "Action to Control Cardiovascular Risk in Diabetes-Memory in Diabetes (ACCORD-MIND)" trial, Cukierman-Yaffe et al. (2009) concluded higher A1C levels were associated with lower cognitive function in T2DM individuals with cardiovascular risk factors. Moreover, diabetes has been recognized as a potentially modifiable risk factor for cognitive compromise (Luchsinger et al., 2011). Similarly, Tuma (2007) reported that persons with diabetes had an increased risk of developing cognitive impairment in comparison to the general population and cognitive dysfunction was associated with poorer ability in diabetes self-care and decreased adherence to antidiabetic treatments. Additionally, patients with cognitive decline were reported to have increased healthcare utilization as evidenced by an increase in PCP visits (Fowler et al., 2012).

The Mini-Mental State Examination (MMSE) was developed as a practical method of grading cognitive impairment of elderly individuals in the clinical setting (Folstein, Folstein, & McHugh, 1975) and widely used as a screening tool for detecting changes in cognitive skills (Tombaugh & McIntyre, 1992). Surveys of health professionals reported the MMSE was the most commonly utilized cognitive test used by nine out of 10 specialists (Davey & Jamieson, 2004; Shulman et al., 2006). The MMSE has been used in clinical trials to measure cognitive decline in persons with diabetes (Bruce et al., 2008; Ravona-Springer et al., 2010; Williamson et al., 2007). In a study of 396 patients aged 65 years or older with known diabetes mellitus, those with MMSE scores less than 23 fared worse on measures of self-care and ability to perform activities of daily living (Sinclair, Girling, & Bayer, 2000). Yet, despite the reports

demonstrating the association of diabetes with cognitive decline, cognitive assessment has not been consistently performed as part of the routine evaluation and follow-up of patients in the primary care setting (Ganguli et al., 2004).

Memory Related Issues

In 1993, the incidence of healthy, nondemented older adults over the age of 75 years reporting subjective memory complaints (SMC) was 35–40% (Grut et al., 1993). SMC is how one interprets, feels, or thinks about his/her own memory and the (formal or informal) reporting of that memory (Pearman & Storandt, 2004; Ramakers et al., 2009; Siersma, Waldemar, & Waldorff, 2013; Wong et al., 2006). Subjective memory complaints in the absence of psychiatric or neurological disorders have been increasingly reported among healthy older adults (de Groot et al., 2001; Metternich, Kosch, Kriston, Härter, & Hüll, 2010), and SMCs were associated with a 60% increase in health care utilization cost over a three year period (Waldorff, Siersma, & Waldemar, 2009). In a population-based study (n = 2,146), poor psychological well-being, depressive symptoms, and hearing impairment were reported to be the strongest predictors of SMCs (Benito-León, Mitchell, Vega, & Bermejo-Pareja, 2010). Associations have been found between memory complaints and cognitive impairment on testing, even after adjustment for depressive symptoms (Waldorff et al., 2009). In a study of 140 participants over the age of 60 years in a residential facility assessed clinically for dementia, the sensitivity and specificity of several instruments were measured using receiver operating characteristic (ROC) analysis (Ramlall, Chipps, Bhigjee, & Pillay, 2013). Subjective Memory Complaint Clinical, MMSE, and Clock Drawing Test (CDT) were found to be “moderately accurate” in screening for dementia with an area under the curve (AUC) > 0.70. Associations between SMCs and

depression and MMSE scores were also reported (Schmand, Jonker, Geerlings, & Lindeboom, 1997).

Depressive Symptoms

The prevalence of depression and health care utilization in single and multiple morbidities was investigated in a population-based cohort study (n = 299,912); concurrent diabetes, coronary heart disease, and stroke were linked to a high prevalence of depression (men 23%, women 49%) (Bhattarai, Charlton, Rudisill, & Gulliford, 2013). Persons with diabetes were reported to be twice as likely to have depression (Munshi et al., 2006), and even low levels of depressive symptomatology were associated with nonadherence to important aspects of diabetes self-care (Gonzalez & Esbitt, 2010; Gonzalez et al., 2007). Persons with diabetes having three to eight comorbidities were at particular risk of depression (Caughey et al., 2010). Therefore, depression was associated with more diabetic complications, lower medication adherence, and poorer self-care of diabetes (Lin et al., 2006).

2.2.2 Process: Medication Reconciliation

Medication reconciliation was the process designed to improve patient safety by decreasing medication errors of omission, commission, duplication, incorrect doses or timing, and adverse drug-drug or drug-disease interactions. During medication reconciliation a list of all medications a patient is taking is created and maintained—including drug name, dosage, frequency, and route—that list is then used to guide therapy (Institute for Healthcare Improvement, 2011). The process of medication reconciliation was a core component of The Institute for Healthcare Improvement's (IHI) 5 Million Lives Campaign.

In 2002, The Joint Commission (TJC) established the National Patient Safety Goals (NPSGs) program; the first set of NPSGs was effective January 1, 2003 (The Joint Commission, 2006). In July 2004, to promote patient safety and decrease medication errors, TJC announced the 2005 National Patient Safety Goal #8 to "accurately and completely reconcile medications across the continuum of care" (p. 38). The steps in the process were to (1) develop a list of current medications, (2) develop a list of medications to be prescribed, (3) compare the medications on the two lists, (4) make clinical decisions based on the comparison, and (5) communicate the new list to appropriate caregivers and to the patient (The Joint Commission, 2006).

During October 2009, TJC formed focus groups with ambulatory health care, behavioral health care, critical access hospitals, hospital, home care, long-term care, and office-based surgery customers to discuss the medication reconciliation National Patient Safety Goal (NPSG). The groups discussed the components of a medication reconciliation process; the points in the care process that needed to be addressed; and the ideal elements for the medication reconciliation goal. The NPSG was subsequently revised and the medication reconciliation process was streamlined to place a spotlight on critical risk points and became three steps: (1) Verification (collection of the medication history); (2) Clarification (ensuring that the medications and doses are appropriate); (3) Reconciliation (documentation of changes in the orders). It became effective July 1, 2011 (The Joint Commission, 2011).

A study of patients in four academic, ambulatory primary care internal medicine clinics tested interventions to provide performance feedback and training to the health care team, and increase patient awareness and participation in the medication reconciliation process. Completeness of medication lists improved from 20.4% to 50.4% ($p = 0.001$). Correctness of

medication lists improved from 23.1% to 37.7% (p = 0.087). Patient participation in the medication reconciliation process increased from 13.9% to 33% (p = 0.001). The medication list accuracy improved from 11.5% to 29% (p = 0.014) (Nassaralla, Naessens, Chaudhry, Hansen, & Scheitel, 2007). Multiple definitions of medication discrepancy were found in the literature. According to Tjia (2009), medication discrepancies were unexplained differences among documented regimens across different sites of care. In an outpatient setting, Bedell et al. (2000) defined medication discrepancy as "the difference between the list of medications in the medical record (referred to as recorded medications) and what a patient actually took, based on medication bottles and on self-reports (referred to as reported medications)" (p. 2131).

Murphy and colleagues (2009) were of the opinion that until medication discrepancies could consistently and accurately be identified, the risks of medication errors and ADEs would continue. They proposed that the concept of medication discrepancy and the processes used to both prevent and correct medication discrepancies were poorly understood and hindered a proper medication reconciliation process. Therefore, when Murphy et al. (2009) conceptualized medication discrepancy in the context of patient safety, the initial step in the medication reconciliation process was identified as being the critical landmark for identifying the discrepancies between two or more medication lists. Further review of the literature revealed prescribing issues and patient adherence to regimens as two aspects of discrepancies within the context of medication management.

Multiple studies demonstrated discrepancies from 30% to 94% in what medications were ordered by the prescribing provider and the actual medications the older adult was taking (Barat et al., 2001; Bedell et al., 2000; Bloom et al., 1993; Coleman et al., 2005; Corbett, Setter, Daratha, Neumiller, & Wood, 2010; Gonski et al., 1993; McKinley et al., 2004; Moore et al., 2003). Corbett et al (2010) investigated a sample of 101 older adults recently discharged from

the hospital who were living at home and identified 69% of the participants as having system-level discrepancies and 40% with patient-level discrepancies. A meta-analysis by Tam et al. (2005) estimated that 27% to 54% of patients suffer at least one unintentional medication discrepancy due to medication history errors.

Providers were often unaware of all prescribed medications their patients were taking (Barat et al., 2001; Bonner & Carr, 2002; Fineman & DeFelice, 1992; Torrible & Hogan, 1997), particularly when multiple providers were involved due to multiple patient comorbidities. A direct relationship was identified between the number of prescribing providers and the presence of medication discrepancies (Bedell et al., 2000; Malhotra, Karan, Pandhi, & Jain, 2001; Tamblyn, McLeod, Abrahamowicz, & Laprise, 1996; Tulner et al., 2009). Additionally, a direct relationship was found between the number of medications and the number and type of discrepancies elicited by comparing pharmacy records and a *brown bag* medication review (Caskie, Willis, Warner Schaie, & Zanjani, 2006).

Medication discrepancies related to providers in acute care settings were categorized as intentional and unintentional discrepancies and were used in research involving the classification and prediction of errors related to inpatient medication reconciliation (Pippins et al., 2008). These researchers reported a prevalence of unintentional medication discrepancies (average of 1.4 per patient) with potential for patient harm. Most of the medication errors were due to omission and the majority of potential ADEs occurred at discharge rather than admission. Discrepancies of these types were not distinguished in outpatient or primary care studies involving medication reconciliation.

When a discrepancy existed between the use of a medication and the prescription directions, the drug-taking behavior was deemed nonadherent. Intentional nonadherence was investigated in elderly patients (Cooper, Love, & Raffoul, 1982); 90% of nonadherence was

found to be related to underuse; 73% of nonadherence was intentional and was more likely to occur in patients who used two or more pharmacies and two or more physicians. Stack et al. (2010) reported intentional nonadherence in community dwelling T2DM patients on oral antidiabetic medications and found it to be unrelated to the number of prescribed medications.

Grant et al. (2003a) conducted a randomized control trial in persons with diabetes to improve adherence and reduce medication discrepancies. Medical regimen discrepancies were identified in 44% of the patients randomized to the intervention arm; 60% of the discrepancies were resolved by corrections in the medical record and 7% were resolved by patient corrections. Medication discrepancies were reported to be important contributors to adverse drug events (ADEs) among hospitalized and recently discharged patients (Cornish et al., 2005; Schnipper et al., 2006).

According to TJC, when medication errors resulted in death or major injury, 63% were related communication breakdowns, and approximately half of those would have been avoided through effective medication reconciliation. The U.S. Pharmacopeia began to capture types of errors involving medication reconciliation failures (CAPSLink, 2005). Early studies reported that at least one-half of all patients had at least one potential ADE identified during the reconciliation process (Cornish et al., 2005; Gleason et al., 2004; Lau, Florax, Porsius, & De Boer, 2000; Rozich et al., 2004).

The terms medication error, medication discrepancy, potential adverse drug event, adverse drug event, and preventable adverse drug event have been used interchangeably in the literature. The Institute of Medicine (IOM) in conjunction with the Committee on Data Standards for Patient Safety adopted the following definitions as proposed by Bates et al. (1995): a medication error is any error occurring in the medication use process and an adverse drug event is any injury attributed to medication error. Medication error was identified as one of the most

frequent forms of medical error and was associated with significant medical harm (Santell, 2006). A medication error can originate at system, provider, and patient levels. It was reported that diabetes-related medical errors in outpatient practice were common and costly, with approximately 80% of persons with diabetes experiencing at least one error in their diabetes care during a year (O'Connor, Sperl-Hillen, & Klein, 2007).

Based on the above definition of medication error, a medication discrepancy is an error. A subset of patients were identified as being responsible for "patient-related" medication errors causing ADEs in a large study of 30,000 Medicare enrollees followed over a 12-month period (T. S. Field, K. M. Mazor, B. Briesacher, K. R. Debellis, & J. H. Gurwitz, 2007). The majority of patient errors leading to ADEs (n = 129) occurred in administering the medication (31.8%), modifying the medication regimen (41.9%), or not following clinical advice about medication use (21.7%). Possibly, the latter two patient-related errors may have been detected as medication discrepancies during a medication reconciliation process, thus potentially avoiding ADEs. Patient-related errors in this study most often involved hypoglycemic medications (28.7%), followed by cardiovascular medications (21.7%), anticoagulants (18.6%), and diuretics (10.1%) (Field et al., 2007). These findings support other studies linking polypharmacy and comorbidities in older adults to increased risk for nonadherence, medication errors, ADEs, and increased utilization of healthcare resources due to medication discrepancies.

Adverse drug events were defined as injuries due to a medication, and potential ADEs were defined as medication errors with the potential to cause an injury (Field et al., 2007). Adverse drug events were identified as a direct consequence of clinical care and were a key focus of the $1 billion federal initiative Partnership for Patients—the goal of which was to reduce harm to patients and reduce health care costs by decreasing the number of preventable rehospitalizations by 20% by the end of 2013 (Kocher, Emanuel, & DeParle, 2010). Most

emergency hospitalizations for recognized adverse drug events in older adults resulted from a few commonly used medications, 40% of which were antidiabetic medications. Therefore, improved management of antidiabetic medications had the potential to significantly reduce hospitalizations for ADEs in older adults (Budnitz, Lovegrove, Shehab, & Richards, 2011). In a national epidemiologic study, an estimated 265,802 emergency department visits for ADEs occurred annually from 2007 through 2009 among adults 65 years of age or older, of which 37.5% required hospitalization (Budnitz et al., 2011). Medications commonly implicated in emergency hospitalizations for older adults in the United States were insulin and oral hypoglycemic agents, ranked second (n = 13,854) and fourth (n = 10,656) respectively (Budnitz et al., 2011). Jha et al. (2001) identified hospital admissions due to adverse drug events using a computer-based monitor and found that among 3238 admissions, 76 (2.3%) were caused by an ADE, of which 78% were severe and 28% were preventable. Estimated costs were $16,177 per ADE, and $10,375 per preventable ADE; costs to the hospital were $6.3 million per year for all ADEs, and $1.2 million for the preventable ADEs.

Phillips et al. (2008) reported an increase in the fatal medication error rate in the outpatient setting of 564 percent over the past 20 years. Estimates are that ambulatory medication errors are expected to continue to increase exponentially with per-capita prescription use (Catlin, Cowan, Hartman, Heffler, & Team, 2008), and result in hospitalizations as Americans live longer, and have greater numbers of chronic conditions (Budnitz et al., 2011).

Identification of potential correlates of medication discrepancies in the older primary care diabetic population may improve the process of medication reconciliation. The results may lead to improved adherence, decreased medication error rate, and decrease ADEs.

2.3 GAPS IN THE LITERATURE

Based on the large number of studies regarding adherence and diabetes, more is known about adherence factors in the general primary care setting for persons with diabetes and much less about medication discrepancies specific to elderly patients with diabetes. Among the medication discrepancy studies published in outpatient or primary care settings, limited patient, provider, or system characteristics were investigated; patient-specific medication discrepancy characterizations were absent in a review of the diabetic population literature.

In prior studies of medication discrepancies in community dwelling adults, sociodemographic variables were limited to age and gender (Bedell et al., 2000; Orrico, 2008). Characteristics which may be implicated in predicting potential factors related to medication discrepancies include educational attainment, functional status, income level, employment status, insurance status, and social support; these were not investigated as potential correlates of medication discrepancies in prior studies. Additionally, limited information was collected for provider or system characteristics, particularly the specialization of other prescribing providers, and provider actions when potential ADEs were identified. While the type and number of comorbidities may affect the complexity of treatment regimens and have an impact on medication management, there was little to no information regarding the impact of comorbidities and associated sequelae on medication discrepancies specifically in the diabetic population.

Comorbidities were not collected in other outpatient or primary care medication discrepancy studies (Bedell et al., 2000; Orrico, 2008) and the influence of comorbidities on medication discrepancies could not be assessed. Studies which investigated depressive symptomology, subjective memory complaints, or cognitive function did not include an

assessment of medication discrepancies in a single study of community dwelling elderly persons with diabetes over the age of 65 years.

Therefore, gaps existed in the literature for the collection of structure variables that may affect the identification of potential descriptive correlates of medication discrepancies. The aforementioned limitation in prior research is particularly true in diabetic patients over the age of 65 years who are seen in the primary care setting.

This secondary data analysis captured many pertinent patient characteristics, including neuropsychological assessments, together with measures previously not explored in a single study to describe the sample. The quantity and quality of structure variables provided more complete information about potential correlates of medication discrepancies in diabetic persons greater than 65 years of age previously not documented from a single sample in the primary care setting.

3.0 METHODS

3.1 RESEARCH DESIGN

3.1.1 Introduction

This study was a secondary analysis of data prospectively collected at baseline during an experimental longitudinal trial that investigated the relationship between standard neuropsychological evaluation and patient outcomes in primary care. The current study was guided by the SPO model as set forth by Donabedian (1966, 1980, 1988) and used to guide health services research, quality improvement and patient safety research. See Figure 1 on page 5.

The investigator was familiar with limited variables from the parent study; having exposure to some measures while assessing reliability and validity of a novel memory test. A secondary data analysis was an appropriate method for research because the parent study had data to address the questions surrounding medication reconciliation. Additionally, the method diminished research expenditures, was time-efficient, eliminated recruitment and retention challenges, and participant burden was nonexistent.

3.2 PARENT STUDY OVERVIEW

The parent study, "Cognitive Assessment of Elderly Primary Care Patients," was supported by a National Institute on Aging Grant 1R01 AG023129 (Principal Investigators: Judith Saxton, Ph.D. and Lisa Morrow, Ph.D.). The experimental longitudinal study sought to investigate the usefulness of cognitive testing (in primary care provider [PCP] offices) for clinical practice and clinical outcomes over a 2-year period.

3.2.1 Parent Study Setting and Sample

The study was conducted by investigators from the University of Pittsburgh. Subjects were initially referred by their PCP in the greater Pittsburgh metropolitan area of southwestern Pennsylvania if they were aged 65 and older and did not have a medical chart diagnosis of dementia. The study took place from 2006 to 2010 and consented 533 patient subjects and 24 PCPs; 423 subjects received a second neuropsychological assessment at 24-month follow-up.

3.2.2 Parent Study Inclusion and Exclusion Criteria

Parent study patient subjects were included for that study when subjects were aged 65 years and over and exhibited a Mini Mental State Exam (MMSE) score greater than 18. Subjects were excluded if sensory deficits were present which would preclude cognitive testing (e.g., limited vision and hearing impaired). Subjects were also excluded if there was a documented diagnosis of dementia. Neither reports nor observations of memory problems were exclusion criteria. The inclusion/exclusion criteria were inclusive regarding actual level of cognitive function (e.g.,

investigators expected some participants to score within the range of dementia on neuropsychological testing, given the low rates of dementia detection in PCP settings). In cases of a MMSE score of 18 or less, the study blind (randomized to neuropsychological feedback group or treatment as usual (TAU) was broken and the PCP was notified of the individual's cognitive status. All patient and physician participants provided written informed consent.

3.2.3 Parent Study Procedures

The patient subjects were asked to complete a series of paper and pencil tests and computerized memory tests that measured memory and other intellectual abilities. They also completed forms about their emotions and ability to conduct their usual activities. Interview, questionnaires, and a review of the medical record captured patient and provider characteristics, and medication-related data. Patient subjects were rescreened with the same process and measures two years later.

3.3 STUDY DESIGN

3.3.1 Sample

Inclusion/exclusion criteria for this secondary data analysis included only subjects with diabetes who were part of the 533 subjects enrolled in the parent study.

3.3.2 Measures

The current study was limited to structure and process variables collected during the baseline visit of the parent study.

3.3.2.1 Structure Variables

3.3.2.1.1 Sociodemographic factors

Subject factors that were assessed included: sociodemographic variables, personal characteristic information, and neuropsychological status. Variables included age, gender, race, years of education, marital status, current employment status outside of the home (active in work force or retired), insurance status, social support or living arrangement, as well as standardized neuropsychological test scores.

3.3.2.1.2 Personal characteristics

Medication Management

Medication management was assessed by responses to the structured interview from the "Medication Review" form. Responses to the following questions were captured: "How do you remember that it is time to take your pills? How do you check that you have taken your pills? Of the meds that you are taking now, where do you get your prescriptions filled? Do you have any problems paying for your medications?"

Comorbidities

Comorbidities were measured by the presence of a listed medical problem code as defined in the parent study, which were obtained from chart reviews by a study nurse at baseline

and at six month intervals. The main categories were: psychiatric; neurological; heart; vascular; endocrine/metabolic; hematopoietic (blood, blood vessels, cells); respiratory (lungs, bronchi, trachea); eyes, ears, nose, throat (EENT); liver and renal; upper and lower gastrointestinal (GI); genitourinary; musculoskeletal / integument (muscles, bone, skin); and miscellaneous, which included medication issues. Each of the above categories had subcategories with specific codes.

Polypharmacy

Polypharmacy, the use of multiple medications or the administration of more medications than are clinically indicated (Hajjar, Cafiero, & Hanlon, 2007), was measured by the total number of unique medications the individual was taking as captured from the Chart Review, 2 Years Prior to Baseline Testing, item 17C, "What are the current meds?"

Sensory Changes

Sensory changes were defined as self-reported auditory or visual impairments. The Subject Demographics Form, item 14 captured visual impairment status by asking, "Do you wear eyeglasses or contact lenses?" followed by the fixed responses eyeglasses, contact lenses, both, or neither. Item 16 reads, "Can you see well enough to read newspaper print wearing corrective lenses?" The fixed categorical responses were yes or no. Hearing impairment was captured from the categorical yes/no responses to item 15, "Have you ever worn a hearing aid?" and the categorical yes/no response to item 17, "Can you hear well enough to carry on a conversation in a quiet room?"

Neuropsychological status

Neuropsychological assessments included cognitive function across multiple domains for memory, learning, attention/psychomotor, spatial, and executive function. Additional measures

of subjective memory complaints, depressive symptomatology, and activities of daily living were obtained.

Cognitive function

Overall cognitive function was assessed by the score on the Mini-Mental State Examination (MMSE). The MMSE is an instrument developed for grading the level of cognitive impairment of elderly patients in a clinical setting (Folstein et al., 1975). The MMSE has been used as a screening instrument for cognitive impairment associated with specific medical conditions (Mitchell, 2009; Munshi et al., 2006). The MMSE is a 30-point scale consisting of individual tests of eleven domains: orientation (10 points); registration and recall (6 points); attention (5 points); multi-step command (3 points); two naming tasks (2 points); repetition task (1 point); reading comprehension (1 point); written sentence (1 point); and a visual construction task (1 point). Internal consistency is reported as Cronbach's alpha ranging from 0.54 to 0.96 (Tombaugh & McIntyre, 1992) depending on the specific patient population. A practice effect was reported with repeat administrations (Galasko et al., 1997). Mitchell (2009) conducted a meta-analysis of 39 studies related to the accuracy of the MMSE in the detection of dementia and mild cognitive impairment (MCI) and reported modest accuracy with best value for ruling out a diagnosis of dementia in community and primary care. In the primary care setting the pooled sensitivity was 78.4%, specificity 87.8%, positive predictive value 53.6%, and negative predictive value 95.7%. The MMSE in non-specialist settings was best at ruling out dementia, with approximately 29/30 correct reassurances and less than three false negatives out of every 100 screens.

Subjective Memory Complaints

Subjective memory complaints in this study were measured by standardized questions developed to assess various aspects of subjective memory performance (Ganguli et al., 2004). The assessment includes general questions related to current functioning and change over the past year. Respectively, these questions are "In general, how good do you feel your memory is for a person your age?" (scaled response is limited to "poor," "fair," "good," and "excellent") and "In general do you feel you remember things less well than you did a year ago?" (which received a categorical "yes/no" response).

Depressive Symptoms

Depressive symptoms in this study were measured by the modified version of the Center for Epidemiological Studies—Depression (mCES-D) Scale (Ganguli, Du, Dodge, Ratcliff, & Chang, 2006) (Ganguli et al., 1995). The mCES-D differs from the CES-D in that it is interviewer-administered and asks the patients if symptoms are present (scored as 1) or absent (scored as 0) "most of the time" (defined as three or more days) during the preceding week. The maximum possible score is 20, with higher scores representing increased depressive symptoms. Ganguli et al. (2002) used a score of 5 on the 20-point scale as the cutoff point, as it defined the 10% of their study cohort with the highest number of depressive symptoms in a sample of 1422 participants aged 65 years and older in southwestern Pennsylvania. The parent study of this secondary data analysis used a score of 4 on the 20-point scale because nearly everyone in the 75^{th} percentile reported at least 4 depressive symptoms (Fowler et al., 2012).

Mild Cognitive Deficits and Pre-dementia Cognitive Changes

All participants completed a neuropsychological test battery of 14 standard cognitive

tests tapping multiple domains of memory, executive function, spatial ability, language, and attention/psychomotor speed. The test battery was designed to detect mild cognitive deficits.

Memory tests used were the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) Word List Learning Test (WLL) (Morris et al., 1989) with delayed recall, the Wechsler Memory Scale- Revised (WMS-R) Logical Memory (LM) I and II (D, 1987), and the modified Rey-Osterrieth (mR-O) figure immediate and delayed recall (Becker, Boller, Saxton, & McGonigle-Gibson, 1987). Executive function tests used included the Wechsler Adult Intelligence Scale-Revised (WAIS-R) Backward Digit span (Wechsler, 1981), the controlled oral word association test (FAS) (Spreen & Strauss, 1998), the Clock Drawing Test (Spreen & Strauss, 1998), the Trail Making Test Part B (Reitan, 1958), and the WAIS-R Digit Symbol (Wechsler, 1981). Tests of spatial ability were the modified WAIS-R Block Design (Wechsler, 1981) and the modified Rey-Osterrieth Copy (Shin et al., 2006). Tests of language abilities included the Boston Naming Test (Kaplan et al., 2001), letter fluency (number of letters starting with "F," "A," and "S" in 60 seconds each; FAS) and semantic fluency (animals) test (Spreen & Strauss, 1998). Tests of attention and psychomotor speed included WAIS-R Digit Span Forward 25 and Trail Making Test Part A (Reitan, 1958), and Wechsler Adult Intelligence Scale-Revised (WAIS-R) Digit Span Forward (Wechsler, 1981).

A total score of each domain was generated by obtaining a standardized z-score and summing tests within each domain. Additionally, a cognitive function total score was derived by adding all total scores across domains and dividing that score by five, which represented the total number of domains assessed. For this study, negative *z*-scores indicted worse performance when compared with the mean. The cognitive tests used in the parent study have reported validity and reliability statistics and have been used in older patient populations.

3.3.2.2 Process Variable

Medication Reconciliation

Medication reconciliation was a comprehensive evaluative process for generating a complete and accurate list of a patient's current medications and comparing the patient-generated list to those in the provider-generated list within the patient's medical record. The provider-generated list for this study included the drug name and dose variables collected from item 17C on the Chart Review—2 Years Prior to Baseline Testing form, as the information was gleaned from the patient's medical record. The patient-generated medication list was defined as the patient's current medications and number of tablets or doses captured on the *Medication Review* form. The form documented responses during a structured medication review conducted by the parent study nurse in a *brown bag* interview with the participant. Documentation of medication information during the structured interview was taken from the bottles brought in for the appointment (participants were requested to bring all medications to the clinic in a bag), self-report from the participant, or from a medication list provided by the patient. During the interview, the participant was asked a series of questions related to each medication on the patient-generated list: "Who prescribed this?" (responses were coded by medical specialty); "Why do you take this medication?"; "How much and how often do you take this medication?"; "Is this an over the counter medication?"; "Are you taking this medication as you are supposed to?" with follow up question "If no, why not?" Additionally, the participant was questioned as follows, "Are there any other medications that you take every day or only when you need them that you did not bring in today?" If so, those medications were added to the list.

Medication discrepancies were measured by the presence or absence of concordance between the provider-generated list in the medical record and the patient-generated medication

lists. The main outcome measure for this secondary data analysis was the presence or absence of medication discrepancies based on the medication reconciliation process of comparing the provider-generated list with the patient-generated list. Any inconsistency discovered during the reconciliation process was classified as a medication discrepancy.

When comparing the provider-generated list and the patient-generated list, a medication discrepancy was categorized as follows: 0-OK / in agreement (if total daily dose was the same); 1-A medication the subject is taking that is NOT on the PCP list; 2-A medication the subject is NOT taking that is on the PCP list; 3-A difference in dosage (if a combined medication dose is wrong, code as discrepant); 4-A difference in schedule (if provider orders to take HS, patient must take QD or HS); 5-Data entry code for when items 3 and 4 are coded simultaneously; and 6-Medication in agreement but dose and / or frequency is missing. Missing medication data was coded as -1 (see Appendix).

3.4 DATA COLLECTION PROCEDURES

Overview of the Data Collection Procedures

Approval for an exempt study was obtained from the University of Pittsburgh Institutional Review Board (IRB). IRB approval is included in the Appendix. Once IRB approval was obtained, the data manager for the parent study extracted and de-identified data prior to providing data files to this investigator for the secondary data analysis.

The parent study collected data longitudinally at two time points, at baseline and at two years. This secondary analysis utilized baseline data from the parent study collected between

2006 and 2008. De-identified data for 533 subjects were provided electronically on an excel spreadsheet for ease in isolating specific variables under investigation during this secondary analysis.

During a meeting with the parent study principal investigator and the data manager identified for this study, a review of the main parent study file (MPSF) revealed that specific variables of interest related to medications were not present in the file provided. The variables of interest related to specific subjects and their specific medication data was subsequently located in a different electronic data file identified as parent study medication file (PSMF) and provided as de-identified data to this researcher.

The architecture of the two data files provided was not conducive to a file merge. The MPSF had one row per subject with variables labeled horizontally across the top of the sheet, as is customary. Variables in the PSMF were labeled in a horizontal method as is customary, however each subject had multiple rows based on the number of medications per subject.

The MPSF and the PSMF both had variables for 533 subjects. The MPSF was sorted by a diabetes problem code as the first step to identify diabetic subjects for this study. The second step included a cross-validation and review of the PSMF to identify the prescribed medications each subject was taking for diabetes. The final step in the determination of a diabetic subject was accomplished based on a review of the coded diabetes problem code in the MPSF and by a review of the data from the PSMF indicating a subject was taking a medication indicated for the treatment of diabetes and the patient's self-report of diabetes as the rationale for taking the medication. Data were exported from the Excel files and merged into a common file for analysis using IBM®PASW® Statistics v.20.0 (Armonk, NY). Variables maintained the same coding as

reflected in the parent study parent study codebook. The primary study file for this proposal was then generated which isolated diabetic subjects (n = 142) from the MPSF.

In the PSMF, each subject had each type of medication discrepancy noted as absent or present by type of discrepancy for each medication documented; hence, there were multiple rows per subject. To accomplish a transfer of this information from the PSMF to the primary data file utilized for this secondary analysis, each medication discrepancy type (n = 6) was created as a single variable in the primary data file and coded for absence or presence across all medications associated with each unique subject. Therefore, the presence of a type of medication discrepancy by subject, regardless of the number of medications, was coded as a single variable for 142 subjects.

3.5 DATA SCREENING PROCEDURES

Pre-Analysis Data Screening: Exploratory analysis was conducted to determine the final data set and sample size as described above. Preliminary data analysis included computation of means, modes, medians, frequencies, ranges of scores, standard deviations, and tests for normality and linearity. Scatterplots, histograms, and stem and leaf diagrams were created to visualize influential data points. Both parametric and nonparametric statistical procedures were utilized based upon the tests for normality. This included checking each of the variables for outliers by using scatterplots and stem and leaf diagrams. The degree to which the missing data may have been problematic was assessed by examining the pattern of the missing data within and across

variables. Data transformations were performed as deemed necessary. In addition to evaluating descriptive statistics for data screening, correlations were examined and screened for multicollinearity in considering the possibility of data reduction. A correlation table was generated and analyzed to examine the correlation coefficients for each independent variable using the Pearson product-moment correlation and the Spearman rho. Collinearity statistics, including tolerance and the variance inflation factors (VIF), were examined.

3.5.1 Missing data

Multiple techniques were considered to address missing data. The pattern of missingness was assessed, random versus nonrandom, which included listwise and pairwise deletion.

3.6 DATA MANAGEMENT AND ANALYSIS

Sample size: The procedure for determining the sample involved an iterative process to merge data from the main parent study data file and the separate medication review data file for the parent study. The following criteria had to be met prior to combining the data from the two data files into one singular data file with all the DM subjects represented. The first criterion involved assessment of the main data file from the parent study (n = 533). Based upon a documented diagnosis code for diabetes, data for 139 subjects were selected. The second criterion involved a cross-validation with the parent study medication data file. A subject was included in the sample when one or more medications indicated for the treatment of DM were documented in the medication data file and the subject self-reported that the medication was

prescribed for the treatment of DM. The cross-validation yielded an additional three subjects. The sample size for the secondary data analysis was determined to be 142.

3.7 ANALYSIS OF STUDY AIMS

3.7.1 Primary Aim 1

Characterize the sample of older community dwelling patients with DM.

Descriptive statistics were analyzed to examine the characteristics of the sample. Means, standard deviations, and ranges were computed for all continuous variables. Categorical variables were analyzed and presented as frequencies and percentages.

3.7.2 Primary Aim 2

Characterize the discrepancies associated with prescribed medications.

Descriptive statistics were used to examine the presence and type of categorical medication discrepancy variables and were reported as frequencies and percentages.

3.7.3 Primary Aim 3

Identify potential correlates of medication discrepancies.

Given that the dependent variable, medication discrepancy, was categorized as absent or present, logistic regression was the primary statistical approach used to assess the relationship between

patient characteristics and medication discrepancy. Univariate (bivariate) and multivariate logistic regression analyses were conducted to investigate which independent variables were significant predictors of the presence of medication discrepancy. In the univariate analysis, each independent variable of interest was assessed separately as a potential correlate for the presence of a medication discrepancy. The variables included age (in years), race (white or other races), education (in years), gender (male or female), marital status (married/living as married, widowed, or other), living situation (alone or with other), employment, number of unique health problem codes, and number of medications per patient. Additionally, neuropsychological variables were assessed; these included MMSE, mCES-D, subjective memory complaints (yes or no), total scores from the five domains (memory, spatial, attention, language, and executive) measured in the neuropsychological battery of tests utilized to assess cognitive function, and a cognitive function total score. The total scores for each domain in the cognitive function test battery were used for the analysis based on a high correlation of the individual tests within each domain (L. Morrow, personal communication, February, 10, 2014). Pearson product-moment correlation and Spearman's rho correlation coefficients were examined and possible collinearity between independent variables was evaluated by collinearity statistics, i.e., tolerance and the variance inflation factors. In the multivariate analysis, the combined effect of all the independent variables on the probability of medication discrepancy was investigated. Several multivariate logistic regression models were built to investigate how different subsets of the predictors affected the probability of medication discrepancy and to identify the best subset of predictors.

Bivariate logistic regression analysis was conducted for each of the six types of medication discrepancy to determine what characteristics are associated with a specific type of medication discrepancy. This analysis provided evidence regarding the uniformity or the

differences in type's medication discrepancies.

Results of the analyses include significance (p values), odds ratios, and the 95% confidence interval for odds ratios. The level of significance was set to be 0.05. The analyses were done using IBM®PASW® Statistics v.20.0 (Armonk, NY).

3.8 PROTECTION OF HUMAN SUBJECTS

This study was a secondary data analysis of existing data/documents/records collected at baseline from the parent study. The data were de-identified by the parent study data manager according to the Complete Health Insurance Portability and Accountability Act (HIPAA) of 1996. This descriptive study met criteria for an exempt study with expedited approval by the University of Pittsburgh IRB in accordance with the Health and Human Services regulation in 45 CFR 46.101(b)(4). The IRB approval and consent form appear in the Appendix. No potential risks existed to human subjects in this study as the data are not identified; the data that were provided were in compliance with HIPAA regulations.

3.9 LIMITATIONS

A secondary data analysis was conducted on a study that had been completed and utilized variables collected for a different research question. There were inherent limitations when conducting this research using a secondary data analysis approach. The researcher obtained approval from the principal investigator and ascertained data availability. Once the researcher

provided documentation of IRB approval and specified the variables of interest, the parent study's data manager was approached to obtain the data. A limitation of this secondary data analysis involved access to the data. The parent study had concluded and was no longer funded; hence the parent study research staff was no longer employed on the parent study. Partial files and data were housed on a computer not easily accessed by the honest broker. Paper files were stored at an external facility; therefore, some data were unavailable.

The honest broker for this secondary analysis had access to sufficient, but not all electronic data required for this secondary analysis. Data with limited or no access included the following:

- Diabetes health problem code did not specify Type I versus Type II diabetes.
- Neither sensory acuity nor insurance information was available in the electronic files provided.
- Item responses were not available for the MMSE assessment.
- Item responses were not available for the mCES-D.
- Medication interview (qualitative response) data was not available in the electronic files provided.
- There was a discordant formatting present on multiple data files due to the type of data (main data file and medication-related data file). Thus, no straightforward merge of the data files was possible. Data reduction was required and extrapolation from one type of file were required prior to the information being imported into SPSS format.

In this secondary data analyses, the study population and measures collected during the parent study limited the type and scope of the proposed research. The variables available for

analysis within the conceptual framework were limited to structure and process; therefore, it was not possible to include the outcome construct in the current study. The parent study was a longitudinal study, and some data collected later in the study was not available at baseline. One example of data collected later in the study but not at baseline occurred during the medication interview process when the subject was questioned about the ability to pay for medications. Another example was the lack of biophysiologic measures, such as HgA1c, to assess glycemic control.

4.0 RESULTS

This study examined medication discrepancies in community dwelling adults with diabetes mellitus over the age of 65 years who were being followed by a primary care healthcare provider. After an initial review of the data sampling procedures, this chapter provides the results of the three primary aims posited in chapter one: the characteristics of the sample; second, the characteristics of the medication discrepancies associated with prescribed medications; and third, identification of potential correlates of medication discrepancies. Because this was a secondary data analysis, the number of subjects with DM that met criteria for this analysis was not known *a priori*. Therefore, the procedure and results of the inclusion criteria are outlined below. All screening and analytic procedures were conducted in IBM®PASW® Statistics v.20.0 (Armonk, NY) by the principal investigator. Missingness, outlier examination, and checking of statistical assumptions were performed prior to analysis.

4.1 PROCEDURES

4.1.1 Determining the Sample

The procedure for determining the sample involved an iterative process to merge data from the main data file and the separate medication review data file of the parent study. The following

criteria had to be met prior to combining the data from two data files into one singular data file with all DM subjects represented. The first criterion involved assessment of the main data file from the parent study (n = 533). Based upon a documented diagnosis of DM, data for 139 subjects were selected. The second criterion involved a cross-check with the medication data file. A subject was included in the sample when one or more medications prescribed for the treatment of DM were documented in the medication data file and the subject self-reported that the medication was prescribed for the treatment of DM. The cross-validation yielded an additional three subjects for a total of 142 subjects with DM in the final data set. Baseline data in the primary study were collected between 2006 and 2010.

4.2 DATA EXPLORATION STATISTICS

Exploratory statistical analyses were conducted to screen for missingness, outliers, normality, collinearity, and homeoscedasticity. There was minimal missing data. Each of the five domains in the neuropsychological battery of tests had three randomly missing variables. Across all screenings, outliers were found for years of education, unique health problems, number of prescription medications, mCES-D, cognitive function total score and for each domain in the neuropsychological battery of tests for cognitive function. All neuropsychological variables were negatively skewed. Due to the sample size, nonlinearity, non-normal data distribution, and dichotomous dependent variables, bivariate and multivariate logistic regression were performed.

4.3 PRIMARY AIMS

4.3.1 Primary Aim 1

Characterize the sample of older community dwelling patients with DM.

During the preliminary data screening the selected subject characteristics were determined for the entire sample (see Tables 1–3). Overall, there were a greater number of females than males (54.93% female; 45.07% male). There were significantly more participants who self-reported their race as *white* (93.66%). Marital status assessment revealed 60.56% were married, 28.87% were widowed, 6.33% were divorced, and the remaining 4.23% were either never married or categorized as *other*. Sixty-nine percent of subjects reported living with someone, either a spouse or partner, or a relative or friend. Subjects who reported living alone comprised 29.58% of the study sample. Working outside of the home was reported by 21.83% (Table 1). Health status, as a personal characteristic, revealed the presence of polypharmacy, comorbidities, and health problems. The range of scores on the mCES-D was 0–12 and n = 99 (69.72%) had scored greater than 4. A score of 4 on the 20-point scale was used as the cutoff point for depressive symptomology because in the parent study nearly every subject in the 75th percentile reported at least four depressive symptoms. The mean number of health problems was reported as 9.94 (SD 4.15); the prevalent comorbidities (active or past) and their percentage of the sample included: hypertension (86.62), hypercholesterolemia (83.10), and arthritis (62.68). Eight subjects had a note in the medical record indicating the presence of memory loss. (Table 2). Mild cognitive impairment was identified in 44.37% of the sample. Subjects with subjective memory complaints represented 10.56% of sample. The MMSE mean score was 27.94 with a range of 21–30. Mean scores across the domains (executive function, memory, spatial, language,

attention/psychomotor) in the neuropsychological test battery were all below zero, negatively skewed, with two to nine outliers per domain. (Table 3).

Table 1. *Descriptive Statistics for Subject Personal Characteristics*

Variable	Overall (N = 142)	Group	
		Discrepancy Present (N = 135)	Discrepancy Absent (N = 7)
Age, years*	73.32 (5.29)	73.39 (5.33)	72.08 (4.76)
Education, years*	13.46 (2.61)	15.00 (3.11)	13.38 (2.57)
Sex**			
Female	78 (54.93)	75 (96.15)	3 (3.85)
Male	64 (45.07)	60 (93.75)	4 (6.25)
Race**			
White	133 (93.66)	126 (94.74)	7 (5.26)
Other race	9 (6.34)	0 (.00)	9 (100.0)
Marital status**			
Married	86 (60.57)	82 (95.35)	4 (4.65)
Widowed	41 (28.87)	39 (95.12)	2 (4.88)
Divorced	9 (6.34)	9 (100.00)	0 (.00)
Never married	5 (3.52)	4 (80.00)	1 (20.00)
Other	1 (.70)	1 (100.00)	0 (.00)
Living situation			
Spouse/partner	87 (61.27)	83 (95.40)	4 (4.60)
Alone	42 (29.58)	39 (92.86)	3 (7.14)
Relative/friend	11 (7.74)	11 (100.00)	0 (.00)
Other	2 (1.41)	2 (100.00)	0 (.00)
Work outside home			
Yes	31 (21.83)	29 (93.55)	2 (6.45)
No	111 (78.17)	106 (95.50)	5 (4.50)

Note. *Standard deviations appear in parentheses with means.

**Percentages appear in parentheses with counts.

Table 2. *Descriptive Statistics for Subject Health Status Characteristics*

Variable	Overall (N = 142)	Group	
		Discrepancy Present (N = 135)	Discrepancy Absent (N = 7)
Mood*			
Modified CES-D			
< 4 depressive symptoms	43 (30.28%)	42 (97.67%)	1 (2.33%)
≥ 4 depressive symptoms	99 (69.72%)	93 (93.94%)	6 (6.06%)
Number of medications*	9.68 (4.56)	9.94 (4.51)	4.71 (1.70)
Number of health problems*	9.94 (4.12)	9.88 (4.15)	11.14 (3.44)
Hypertension **	123 (86.62)	116 (94.31)	7 (5.69)
Hypercholesterolemia**	118 (83.10)	111 (94.07)	7 (5.93)
Arthritis**	89 (62.68)	85 (95.51)	4 (4.49)
Coronary Artery Disease*,	55 (38.73)	54 (98.18)	1 (1.82)
Cancer diagnosis**	36 (25.35)	35 (97.22)	1 (2.78)
Chronic Obstructive Pulmonary Disease**	20 (14.08)	19 (95.00)	1 (5.00)
Myocardial Infarction**	17 (11.97)	15 (88.24)	2 (11.76)
Stroke**	17 (11.97)	17 (100.00)	0 (.00)
Memory loss**	8 (5.63)	8 (100.00)	0 (.00)

Note. *Standard deviations appear in parentheses beside means.

**Percentages appear in parentheses beside counts.

Table 3. *Descriptive Statistics for Subject Neuropsychological Status Characteristic Measures*

Variable	Overall (N = 142)	Group	
		Discrepancy Present (N = 135)	Discrepancy Absent (N = 7)
Cognitive Status			
Normal cognition*	73 (51.40)	67 (91.78)	6 (8.22)
Mild Cognitive Impairment*	63 (44.37)	62 (98.41)	1 (1.59)
Dementia*	6 (4.23)	6 (100.00)	0 (.00)
Subjective memory complaints			
Yes*	20 (14.08)	20 (100.00)	0 (.00)
No*	122 (85.92)	122 (85.92)	0 (.00)
MMSE score**	27.91(1.83)	27.87(1.84)	28.57 (1.62)
Cognitive function total score**	-.90 (.82)	-.94 (.83)	-.32 (.47)
Executive function	-.83 (1.02)	-.87 (1.03)	-.16 (.32)
Memory	-.98 (.96)	-1.00 (.97)	-.48 (.67)
Spatial	-.97 (.96)	-.99 (1.18)	-.69 (.62)
Language	-1.03(1.30)	-1.07 (1.31)	-.16 (.46)
Attention/psychomotor	-.61 (1.07)	-.64 (1.14)	.03 (.94)

Note. *Percentages appear in parentheses beside counts. **Standard deviations appear in parentheses beside means.

Associations among the Patient Characteristics

Given that the data were non-normally distributed, Spearman's rho correlation coefficient was used. The standardized skewness coefficients for the MMSE and the five neuropsychological domains (represented by the global cognitive function score) justified the choice for utilizing the Spearman's rho correlation coefficient. The Spearman's rho correlation coefficient revealed a statistically significant relationship between cognitive function total score and the individual domains, which were components of the cognitive function total score. Additionally, the Spearman's rho revealed a statistically significant negative relationship between age and MMSE and the global cognitive function score. A significant positive relationship was noted between education and the MMSE and the global function cognitive score. Moreover, a significant positive relationship was present for the number of medications with the number of health problems. The number of health problems had a significant negative correlation with the memory domain and the global cognitive function score but not with other domains. MMSE was significant for positive correlations across all cognitive domains. Squaring the correlation coefficients indicated that the variances between the above differences minimally explained the relationships. The correlation matrix is presented in Table 4.

Table 4. Associations Among Measures of Subject Characteristics, Health Status, and Neuropsychological Variables

	Age	Education (yrs)	Medications	Health problems	MMSE	Memory	Spatial	Attention	Language	Executive function	Global Cognitive Function
Age	1.000										
Education (yrs)	-.021	1.000									
Medications (#)	.027	-.125	1.000								
Health problems (#)	.097	-.077	.390**	1.000							
MMSE	-.238**	.349**	-.055	-.083	1.000						
Memory	-.296**	.182*	.004	-.185*	.492**	1.000					
Spatial	-.195*	.221**	-.056	.052	.441**	.386**	1.000				
Attention	-.402**	.239**	-.179*	-.089	.383**	.301**	.336**	1.000			
Language	-.261**	.218**	-.051	-.088	.375**	.429**	.289**	.368**	1.000		
Executive	-.323**	.332**	-.132	-.109	.490**	.508**	.461**	.611**	.405**	1.000	
Global cognitive function	-.391**	.321**	-.104	-.168*	.600**	.844**	.601**	.628**	.613**	.803**	1.000

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

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

4.3.2 Primary Aim 2

Characterize the discrepancies associated with prescribed medications.

Medication discrepancy was evident in n =135 (95.07%) of subjects. The seven subjects without a medication discrepancy were not prescribed nor were they taking a medication to treat DM.

Presence of self-reported medication discrepancies was categorized as:

- taking but not documented in the provider's list of medications;
- not taking yet documented in the provider's list of medications;
- combined dose is different than the combined dose documented in the provider's list of medications;
- administration time is different than the provider's list of medications;
- medication dose and schedule is different from the provider's list of medications; and lastly,
- a given medication is congruent with the provider's list but the dose and/or the frequency is missing.

Table 5 presents the type of discrepancy for all medications and the frequency.

Table 5. *Medication Discrepancy Types and Frequencies (n = 135)*

Type of discrepancy as assessed through patient self-report	**N (%)**
Taking medications that were not documented in the provider's list of medications	93 (68.89)
Not taking a medication that was documented in the provider's list of medications	0 (0%)
Combined dose was different than the combined dose documented in the provider's list of medications	55 (40.74)
The administration time was different than the provider's list of medications	43 (31.85)
Medication dose and schedule was different from the provider's list of medications	21 (15.56)
Medication was congruent with the provider's list but the dose and/or the frequency was missing	89 (65.93)

Note. *Percentages appear in parentheses.

4.3.3 Primary Aim 3

Identify potential correlates of medication discrepancies.

Univariate logistic regression revealed that the number of recorded medications was the only significant predictor of medication discrepancies (p = .003). For each additional medication, the odds of medication discrepancy increased by about 59% (OR = 1.59, 95% CI [1.17, 2.15]). There was a trend evident for diminished cognitive function as measured by the cognitive function total score and the presence of medication discrepancies (p = .053) (Table 6).

Table 6. *Univariate Logistic Regression Results for Presence of Medication Discrepancy*

			95% CI for Odds Ratio	
Variable	P value	Odds Ratio	Lower	Upper
Age	.52	1.05	.90	1.23
Race, white vs. other races	1.00	NC	NC	NC
Education, in years	.12	.81	.62	1.06
Gender, male vs. female	.51	.60	.13	2.79
Marital status, married vs. other	.74	1.46	.15	14.08
widowed vs. other	.79	1.39	.12	16.58
Living situation, alone vs. with other	.44	.54	.12	2.53
Employed, yes vs. no	.66	.68	.13	3.71
Number of health problems	.42	.94	.80	1.10
Number of medications	.003*	1.59	1.17	2.15
MMSE	.35	.78	.47	1.31

mCES-D score ≥ 4 vs. < 4	.363	.369	.043	3.162
MCI vs. normal	.117	5.55	.650	47.43
Subjective memory complaints, yes vs. no	1.00	NC	NC	NC
Cognitive function, memory	.16	.52	.21	1.30
Spatial	.52	.78	.37	4.65
Attention	.10	.40	.13	1.19
Language	.07	.41	.16	1.06
Executive	.054	.29	.08	1.02
Cognitive function total score	.053	.23	.52	1.02

Note. NC = not calculated due to zero counts for some categories. * Significant at the 0.05 level (2-tailed).

In the multivariate analysis, race, marital status, living situation, and subjective memory complaints were excluded due to the low or zero counts in some of the variables' categories. Cognitive function total score was also excluded since it was a combination of the five domains' scores of the cognitive function. The combined effect of age (in years), education (in years), gender (male or female), employment, number of unique health problems, number of medications per patient, MMSE, mCES-D, and scores from the five domains (memory, spatial, attention, language, and executive) measured in the neuropsychological battery of tests utilized to assess cognitive function was investigated. The findings showed that the number of medications ($p = .025$) and the number of unique health problems ($p = .011$) were significant in predicting the probability of medication discrepancy. For every additional medication, the odds of medication discrepancy increased by 118% (OR = 2.18, 95% CI [1.20, 3.95]), while all the other variables in the model were held constant. For every additional health problem, the odds of

medication discrepancy decreased by 33% (OR = .67, 95% CI [.47, .95]), while all the other variables in the model were held constant. Table 7 presents the results of the multivariate logistic regression for all the independent variables considered in the model to predict the probability of medication discrepancy (model 1).

Table 7. *Model 1. Multivariate Logistic Regression Results for Presence of Medication Discrepancy*

Variable	P value	Odds Ratio	95% CI for Odds Ratio	
			Lower	Upper
Age	.94	.99	.71	1.38
Education, in years	.14	.69	.42	1.13
Gender, male vs. female	.81	1.48	.06	36.70
Employed, yes vs. no	.99	.98	.07	14.18
Number of medications	.01*	2.18	1.20	3.95
Number of health problems	.03*	.67	.47	.95
MMSE	.41	1.38	.65	2.92
mCES-D	.40	1.22	.77	1.93
Cognitive function, memory	.33	.33	.03	3.16
Spatial	.48	2.34	.23	24.22
Attention	.40	.47	.08	2.77
Language	.28	.42	.09	2.04
Executive	.91	1.14	.12	10.89

Note. * Significant at the 0.05 level (2-tailed).

The number of medications and the number of health problems remain significant predictors when they were entered in the model along with age, education, gender, and cognitive

function total score only (model 2, Table 8) or along with age, education, gender, and the five domains of the cognitive function (model 3, Table 9). The magnitude of the effects of the significant predictors estimated with models 2 and 3 were OR = 1.97, and OR = 2.01, respectively, for the number of medications, and OR = .73, and OR = .71 for the number of health problems.

Table 8. *Model 2. Multivariate Logistic Regression Results for Presence of Medication Discrepancy*

			95% CI for Odds Ratio	
Variable	P value	Odds Ratio	Lower	Upper
Age	.92	1.01	.80	1.29
Education, in years	.19	.74	.47	1.17
Gender, male vs. female	.67	1.66	.18	15.13
Number of medications	.007*	1.97	1.21	3.20
Number of health problems	.03*	.73	.55	.97
Cognitive function, memory	.27	.31	.04	2.43
Constant	.59	71.06		

Note. * Significant at the 0.05 level (2-tailed).

Table 9. *Model 3. Multivariate Logistic Regression Results for Presence of Medication Discrepancy*

Variable	P value	Odds Ratio	95% CI for Odds Ratio	
			Lower	Upper
Age	.90	.98	.74	1.30
Education, in years	.17	.73	.46	1.15
Gender, male vs. female	.95	.92	.06	15.03
Number of medications	.01*	2.01	1.22	3.32
Number of health problems	.03*	.71	.52	.97
Cognitive function, memory	.31	.35	.05	2.62
Spatial	.25	3.26	.43	24.88
Attention	.54	.60	.12	3.04
Language	.35	.52	.13	2.04
Executive	.84	.81	.11	5.97
Constant	.45	1408.1		

Note. * Significant at the 0.05 level (2-tailed).

Since only the number of medications and the number of health problems were significant predictors, the best model of predicting the probability of medication discrepancy is the model having these two predictors. The results of this model (model 4) are presented in table 10. For every additional medication, the odds of medication discrepancy increased by 94% (OR = 1.94, 95% CI [1.28, 2.94]), while the number of health problems was held constant. For every additional health problem, the odds of medication discrepancy decreased by 38% (OR = .72, 95% CI [.55, .94]), while all the other variables in the model were held constant. Figure 3 shows the predicted probability of medication discrepancy by number of medications, when number of

health problems is 5, 10, and 15 respectively. As the number of medications increases, the probability of medication discrepancy increases for all three categories of health problems. Subjects with 15 health problems had lower probability of medical discrepancy compared to the group with five or 10 medical problems. For subjects with more than 10 medications, it was estimated that they are likely to have medication discrepancy regardless of the number of health problems (probability close or equal to 1).

Table 10. *Model 4. Significant Predictors for Presence of a Medication Discrepancy*

			95% CI for Odds Ratio	
Variable	P value	Odds Ratio	Lower	Upper
Number of medications	.002*	1.94	1.28	2.94
Number of health problems	.02*	.72	.55	.94

Note. * Significant at the 0.05 level (2-tailed).

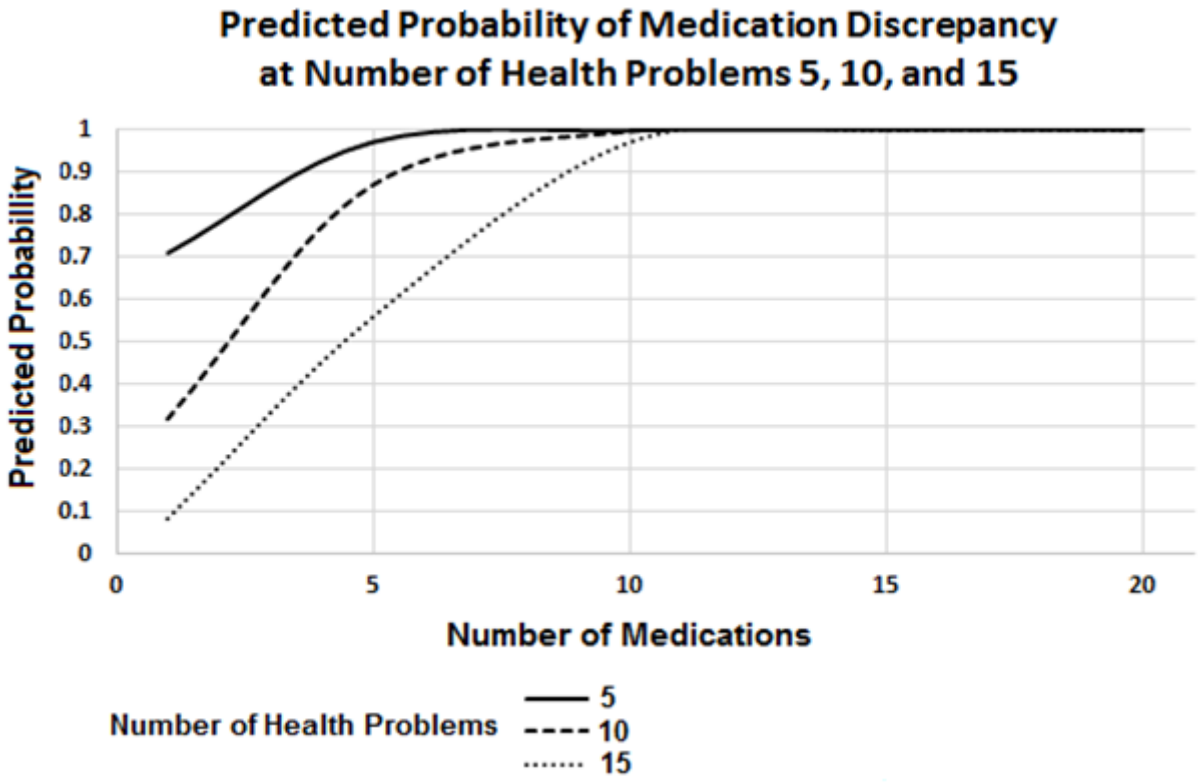

Figure 3. *Predicted Probability of Medication Discrepancy*

Each type of medication discrepancy was investigated for potential correlates with subject characteristics. Of the 135 subjects with a medication discrepancy, 93 (69%) had the medication discrepancy of *taking but not documented in the provider's list of medications*, none had medication discrepancy of *not taking yet documented in the provider's list of medications,* 55 (41%) had the medication discrepancy *combined dose is different than the combined dose documented in the provider's list of medications,* 43 (32%) had the medication discrepancy *combined dose is different than the combined dose documented in the provider's list of medications,* 21 (16%) had medication discrepancy *administration time is different than the provider's list of medications,* and 89 (66%) had medication discrepancy *an given medication is congruent with the provider's list but the dose and/or the frequency is missing.*

The significant findings are described below.

The medication discrepancy of *taking but not documented in the provider's list of medications* revealed the following significant patient characteristics. The number of medications in the subject's armamentarium (p =.002), and the number of unique health problems (p = .018) were significant predictors. For each additional medication, the odds of medication discrepancy of *taking but not documented in the provider's list of medications* compared to all the other types increased by about 18% (OR = 1.18, 95% CI [1.06, 1.31]). For each additional health problem, the odds of medication discrepancy of *taking but not documented in the provider's list of medications* increased by 14% (OR = 1.14, 95% CI [1.02, 1.27]).

The medication discrepancy *combined dose is different than the combined dose documented in the provider's list of medications* was associated with the number of medications (p = .005) and the number of health problems (p = .027). For each additional medication, the odds of medication discrepancy *combined dose is different than the combined dose documented in the provider's list of medications* increased by 13% (OR = 1.13, 95% CI [1.04, 1.23]). For each additional health problem, the odds of medication discrepancy *combined dose is different than the combined dose documented in the provider's list of medications* increased by about 11% (OR = 1.11, 95% CI [1.01, 1.21]).

The medication discrepancy *administration time is different than the provider's list of medications* was associated with the number of medications (p = .041). For each additional medication, the odds of medication discrepancy *administration time is different than the provider's list of medications* increased by 9% (OR = 1.09, 95% CI [1.003, 1.18]).

Examining the medication discrepancy *medication dose and schedule is different from the provider's list of medications*, the number of medications was not significant for this specific discrepancy (p = .105), nor the number of health problems (p = .174).

The medication discrepancy a *given medication is congruent with the provider's list but the dose and/or the frequency is missing* was associated with the number of medications (p = .029). For each additional medication, the odds of medication discrepancy a *given medication is congruent with the provider's list but the dose and/or the frequency is missing* increased by 11% (OR=1.11, 95% CI [1.01, 1.21]).

The results presented above indicate that medication discrepancies are present in persons with diabetes in the primary care setting and increase based on the number of health problems. A summary and discussion of the findings are presented in the next chapter.

5.0 DISCUSSION, CONCLUSIONS, AND IMPLICATIONS

This study focused on patient factors, particularly cognitive function, that to date have not been investigated in any study of medication reconciliation specifically in a diabetic patient population. Donabedian's structure-process-outcome model guided the aims for this secondary analysis. The study was descriptive and cross-sectional using baseline data from an experimental longitudinal trial to address structure and process variables. Outcome measures were not examined in this secondary data analysis. As such, this study did not assess the impact of medication discrepancy on patients' outcomes. Thus, it is not known if the medication discrepancies had a negative impact on patient outcomes and resulted in adverse events. This chapter reviews and discusses the main findings of this dissertation, describes the implications this work has for future research, and identifies limitations of the study.

5.1 SUMMARY OF THE STUDY

The purpose of this secondary data analysis was to examine subject characteristics and medication discrepancies associated with DM in adults 65 years of age and older who were community dwelling primary care patients and to determine if potential correlates existed between and among patient characteristics and medication discrepancies.

This secondary analysis used de-identified baseline data from a parent study (n = 533) that investigated the usefulness of cognitive testing in a primary care setting. The parent study baseline data collection occurred from 2006 into 2008. Exempt approval was obtained from the University of Pittsburgh Institutional Review Board (IRB) for a retrospective secondary analysis (IRB # PRO14010425, see Appendix). Data from two architecturally distinct databases from different software programs (Excel and SPSS) were combined in order to determine the sample of subjects with diabetes and conduct this secondary data analysis. The sample for this analysis was determined to be 142 subjects with DM.

5.2 SUMMARY OF THE FINDINGS

This study found that 95.07% of subjects displayed evidence of at least one medication discrepancy, indicating that there are a considerable number of community dwelling persons with diabetes 65 years of age and older who are being seen in a primary care setting and who have a medication discrepancy. All prescription medications were reviewed in determining the medication discrepancies. The different types of discrepancies measured were reflective of comparisons between the primary care medical record and a *brown bag* review of the subject's medications obtained at the baseline study visit. The types of discrepancies included: taking or not taking a medication that was evident in the medical record, dosing discrepancies, and schedule of administration discrepancies. The extent of medication discrepancies in this study was higher than the 30%–76% previously reported in outpatient studies (Barat et al., 2001; Bloom et al., 1993; Coleman et al., 2005; Gleason et al., 2004; Gonski et al., 1993; McKinley et al., 2004; Moore et al., 2003). This difference may have been related to the sample being limited

to persons with diabetes and the meticulous *brown bag* review and documentation by study personnel. Consistent with findings of Bedell and colleagues (2000), the probability of having a medication discrepancy was positively related to the total number of medications taken by the subject.

Much of the existing literature on medication use and misuse in older persons with diabetes focused on subject adherence, which assessed the failure of subjects to adhere to prescribed medications. The differences between the definitions of nonadherence and discrepancy notwithstanding, existing data on high rates of nonadherence in the DM population (Odegard and Capoccia, 2007; Field et al., 2007) are consistent with the present findings. This finding is in conflict with Grant et al., (2003) who reported high medication adherence rates and high prevalence of medication discrepancies, which appeared to reflect medication inaccuracies in the medical record rather than subject errors.

A unique aspect of this study includes assessment of cognitive function in a study of medication discrepancies involving DM patients. Many studies have evaluated cognitive function in the DM population, but none have assessed cognitive function as a potential predictor of medication discrepancies.

5.2.1 Specific Aim Findings

Aim 1. *Characterize the sample of older community dwelling subjects with DM*

Subject characteristics in this sample of older community dwelling persons with diabetes were described as structural constructs within the Donabedian model. This study included older (65 to 88 years of age) subjects with the majority being women. While not a significant predictor of medication discrepancy in this study, all subjects were above 65 years of age, which was

consistently cited as a factor related to medication discrepancies (Bedell et al., 2000; Gilbert et al., 1993).

The mean years of education was approximately 13, with a quarter of the subjects having greater than 12 years of education, and approximately half of those with more than 16 years of education, indicative of a highly educated sample for this study. Education has been cited as being a protective factor for cognitive decline; this may also have influenced the high MMSE scores in this study. There was a positive correlation for years of education and MMSE, memory, attention, language, and executive function, despite the lower mean scores in the neuropsychological battery of tests. MMSE scores overall were high, as represented by a mean score of about 28. This finding was expected, as individuals with dementia were excluded from the study. High MMSE scores were also evident in previous secondary analysis studies utilizing the same parent study (Fowler et al., 2012; Morrow et al., 2009; Snitz et al., 2008). As postulated in prior studies, this finding was due to the exclusion of potential participants with a diagnosis of dementia documented in the medical record.

Polypharmacy was evident with a subject having, on average, about 10 medications prescribed. A quarter of the subjects took more than 12 medications. This finding supported earlier studies, which identified polypharmacy (Grant et al., 2003b; Coleman et al., 2005; Caskie et al., 2006) as a variable or factor contributing to medication discrepancy errors. Polypharmacy was significantly correlated with the number of health problems; the higher the number of medications, the higher number of health problems.

The negative mean scores in the neuropsychological battery of tests, could be reflective of this DM sample, in addition to almost 45% of the subjects having mild cognitive impairment, which is slightly higher than the total parent study sample (n = 533). Ryan (2005) reported cognitive domains most frequently impaired in persons with diabetes were memory, attention,

psychomotor speed, and problem solving; which was supported by the findings from this study. The mean scores for this DM cohort were lower than the overall parent study sample indicating an increased prevalence of cognitive impairment in DM subjects. The global cognitive function score was reflective of cognition as a whole and included all domains measured (memory, spatial, attention, language, and executive function). The global cognitive function score was significant for negative correlations with age, and the number of health problems: and was significant for positive correlations with education and MMSE. Significant negative correlations were noted for memory and number of health problems; the number of medications was negatively correlated with the attention domain. Therefore, cognitive function, overall, was associated with age, education, number of health problems, and number of medications.

There were several unmodifiable characteristics of the sample, which are limitations. Subjects were recruited from southwestern Pennsylvania as participants for a larger study of cognitive function screening in primary care. The subjects were initially selected based on primary care providers also serving as study participants for determination of provider characteristics for the parent study. Therefore, because providers were also participants in the parent study, there may have been a bias in the sample. All patient subjects had health insurance coverage, as the lower age for inclusion was 65 years; yet, the source and type of health care coverage was not known. The percent of non-whites in the study was half of that estimated by the U.S. Census for the region, and was not representative of the general population in southwestern Pennsylvania. The provisional diagnosis of diabetes was based on a combination of self-report and objective medication data. It was not possible to determine Type I or Type II DM. Results from this sample may not necessarily be representative of an aging population based on race, education, and cognitive function level.

The measures used in this secondary analysis were those available from data files of the parent study. A potential limitation to this study was that the majority of the data was self-reported. However, the self-report data was confirmed through the medical record review in the parent study. Biological information, such as an HbA1c level, reflective of glycemic control, were not available in a sufficient number of subjects to be used as a potential correlate for medication discrepancies nor for the neuropsychological tests of cognitive function. Prior studies have associated inadequately controlled diabetes and declining cognitive function in older adults (Cukierman-Yaffe et al., 2009; Grober et al., 2011). Therefore, having a biophysiologic variable, such as HbA1c to measure diabetes control may have helped to explain this study's findings.

Analysis of the neuropsychological variables revealed negative *z*-scores across all domains in this diabetic sample. Negative scores indicated a worse performance when compared with the mean. Because these *z*-scores were compared with the mean from the parent study (Fowler et al., 2009), it was not possible to back-transform these scores specifically for this study in diabetic subjects nor to assess individual test results within a given domain of cognitive function.

Aim 2. *Characterize the discrepancies associated with prescribed medications*

When examining the medication discrepancies of the 142 subjects in this study, 95% of them had evidence of at least one medication discrepancy. This number is higher than the 76% reported by Bedell et al. (2000) in an outpatient study.

The types of medication discrepancies ranked by highest frequency included: taking medications that were not documented in the provider's list of medications (70%); medication that was congruent with the provider's list but the dose and/or the frequency was missing (67%); combined dose was different than the combined dose documented in the provider's list of

medications (42%); the administration time was different than the provider's list of medications (33%); medication dose and schedule was different from the provider's list of medications (16%). *Taking yet not documented in the provider's list of medications* as a discrepancy was not coded as being present in the medication data file for any patient.

The discrepancy *taking medications that were not documented in the provider's list of medications* was evident in 70% of subjects in this study. In other outpatient studies subjects taking medications that were not recorded was evident in 50% (Bedell et al., 2000) and 87% (Miller et al., 1992). One possibility for the lower percentage in Bedell et al. (2000) could be due to the research being limited to its own practice and not across multiple practices. The present study drew subjects from eleven different primary care practices. Additionally, the number of prescribing providers for subjects in this study likely extended to specialists in addition to the primary care provider due to the high number of reported health problems. A direct relationship was identified between the number of prescribing providers and the presence of medication discrepancies (Bedell et al., 2000; Malhotra et al., 2001; Tamblyn et al, 1996; and Tulner et al., 2009).

The discrepancy capturing differences in dosage was higher in the Bedell (2000) study (20%), compared to 16% for this study. The present study did capture instances where a limited number of subjects reported that the provider verbally communicated a medication dose modification. This communication may have been a reason for the dose discrepancy, as the medication bottle label would not have reflected this verbal communication.

Aim 3. *Identify potential correlates of medication discrepancies.*

Once medication discrepancies were identified as present in 135 subjects and absent in seven subjects, the sample was grouped accordingly. Sociodemographic covariates were not

predictive of medication discrepancies, whereas health status covariates, represented by the number of medications and the number of health problems, were predictive of medication discrepancies. While not significant, there was a trend for diminished cognitive function as evidenced by the cognitive function total score and the presence of a medication discrepancy. The effects of diabetes on neuropsychological function have been reported in the literature (Luchsinger et al., 2011; Kodl and Seaquist, 2008); yet, no investigations reported assessment of specific domains of cognitive function in a study of medication discrepancies. Rosen et al. (2003) reported a modest nonspecific association between metformin adherence and neuropsychological function. This study was not designed to analyze specific test results administered within individual neuropsychological domains, as the individual tests were not available for analysis. Therefore, the findings related to neuropsychological tests were limited by mean domain scores rather than by individual tests conducted within each domain.

Health status variables were predictive of medication discrepancies. The number of medications was significant in predicting the probability of medication discrepancy in addition to the number of health problems. This finding supports earlier studies that identified polypharmacy (Grant et al., 2003b; Coleman et al., 2005; Caskie et al., 2006) as a variable or factor contributing to medication discrepancy errors. While multiple health problems were contributing factors for the increased number of prescribed medications in the DM population (Caughey et al., 2010; Good, 2002; Odegard & Capoccia, 2007), medication discrepancies related to multiple health problems were not identified in the literature.

Among subjects with the same number of health problems, those with a higher number of medications were more likely to experience a medication discrepancy compared to the subjects with a lower number of medications. Among subjects with the same number of medications, those with a higher number of health problems were less likely to experience a medication

discrepancy compared to the subjects with a lower number of health problems. This novel finding was of particular interest as it had not been described elsewhere in the medication discrepancy literature.

Each type of medication discrepancy was investigated for potential correlates with subject characteristics. The predominant predictors for each type of discrepancy were the number of medications and the number of health problems. However, these were not predictive of the medication discrepancy *medication dose and schedule is different from the provider's list of medications*.

The present study found that the number of health problems was associated with different types of medication discrepancies. This relationship may be supported in the literature where the number of comorbid conditions has been associated with poorer cognitive function (Morrow et al., 2009). A higher disease burden places one at greater risk for poorer cognitive functioning (Patrick et al., 2002; Proctor et al., 2003), and possibly decreases the ability of patients to self-manage their diabetes (Halanych et al., 2007; Kerr et al., 2007). However, the present study found that subjects with a higher number of health problems were less likely to have a medication discrepancy compared to the subjects with a lower number of health problems when taking the same number of medications. Possibly, subjects realized that increased self-management was warranted due to increasing health problems.

The cognitive function total score was not a predictor of medication discrepancy in this study, but a trend was suggested by the study findings. This nonsignificant finding of a decrease in cognitive function may have influenced but did not predict the presence of medication discrepancies. It was not possible to discern errors of omission or commission, intentional versus nonintentional, or subject versus provider responsibility, for individual medication discrepancies.

5.3 CONCLUSIONS

This study contributed to the literature by describing specific types of medication discrepancies and the covariates in an older community dwelling population of persons with diabetes in a primary care setting in which almost half of the subjects were found to have cognitive impairment, a large number of health problems, and were prescribed a large number of medications. Ninety-five percent of the subjects had a least one medication discrepancy. This was a higher percentage than previously reported in the literature, and may have been due to the specific sample of older DM subjects.

The results of this study revealed that among subjects with the same number of health problems, those with higher number of medications were more likely to have a medication discrepancy compared to the subjects with a lower number of medications. Among subjects with the same number of medications, those with a higher number of health problems were less likely to have a medication discrepancy compared to the subjects with a lower number of health problems.

The pervasiveness of medication discrepancies and health problems in this older population of persons with diabetes may have significant health care implications that deserve further study, particularly with a trend noted for diminished cognitive function. The results qualify and extend implications of previous medication discrepancy studies.

5.4 IMPLICATIONS

Over the past decade, medication reconciliation became policy-driven and was a vital component of the health care process across all trajectories of care to promote patient safety by decreasing medication errors (Kocher, Emanuel, & DeParle, 2010). The U.S. Congress passed the Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (H.R. 4994/S. 2553) in September 2014, which was signed by the President of the United States and enacted in October 2014. The act will require, among other actions, the assessment of quality measures for medication reconciliation and cognitive function and will take effect in 2017 and 2019, respectively. The IMPACT Act will provide a mechanism for reimbursement for cognitive screening at geriatric well visits. To collect data for these quality measures discovered during the medication reconciliation process, it will be prudent to include variables, which have been shown to be potential structure and process predictors of medication discrepancies.

Findings from this research may contribute to modifications in geriatric curriculum development in the education of nursing students. Nurses who serve an elderly patient population need to assess patient's knowledge, understanding, and management of their medications to prevent adverse drug events and promote improved patient outcomes. The findings may also suggest further nursing research to understand the precise cognitive function deficits and the impact on medication discrepancies in an older community dwelling diabetic population. Future studies are warranted to examine longitudinal trends in medication discrepancies vis-à-vis the medication reconciliation process among older persons with diabetes. Future research should include assessments of health literacy in a racially and culturally diverse sample. Measurement of adherence and medication discrepancies should occur simultaneously and include biological measures, such as HbA1c, to assess glycemic control in persons with

diabetes. Future research should also focus on identification of the best neuropsychological assessment feasible in the primary care setting in order to determine whether different types and patterns of cognitive decline occur over time, which may subsequently affect medication management, and hence the control of diabetic symptoms.

APPENDIX A

STUDY FORMS

From: IRB
Sent: Tuesday, February 04, 2014 3:14 PM
To: Lea, Dawn Elizabeth
Subject: PI Notification: IRB determination

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To:	Dawn Lea RN
From:	Christopher Ryan , Ph.D., Vice Chair
Date:	2/4/2014
IRB#:	PRO14010425
Subject:	Medication Discrepancies in Community Dwelling Older Adults with Diabetes Mellitus

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The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section
45 CFR 46.101(b)(4) Existing data, documents, or records.

Please note the following information:

- If any modifications are made to this project, use the "**Send Comments to IRB Staff**" process from the project workspace to request a review to ensure it continues to meet the exempt category.
- Upon completion of your project, be sure to finalize the project by submitting a "**Study Completed**" report from the project workspace.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Q: (you have any problems paying for your medications? (*pleas rcle*) Y N

If yes, please specify problem: _____

Subject I.D. #: _____

Date of Testing: ___/__ |___

Visit 1 2

Interviewer Initials: _____

Entry Date: ___/___/___

Initials: _____

Cognitive Assessment of Elderly Primary Care Patients

Medication Review

Medication Name listed on bottle	Dose on bottle	Ordered by: *See codes below	**Patient**: Reason for taking Medication	**Patient**: How do you take this medication?	Is this what is documented in the chart? 0=No 1=Yes 2=Ordered by other M.D. 3=OTC 4=Free Sample 5=Other	**Patient**: Do you take this as ordered on the bottle? 0=No 1=Yes	**Patient**: If no, why not.	Taken from: 1=Bottle 2=Patient

***Codes for Specialists:**

1= general practice/family practice
2= internal medicine
3= cardiology
4= chiropractic
5= gastroenterology
6= rheumatology
7= endocrinology
8= oncology
9= orthopedics
10= gynecology
11= nephrology
12= dermatology
13=ophthalmology/optometry
14= ear/nose/throat
15= psychiatry
16= neurology
17= neurosurgery
18= urology
19= surgery
20= pulmonary
22= hematology
24=allergy/allergist
25=podiatry
26=Other

Medication Abbreviations

QAM – Every morning
QD – Every day
QOD – Every other day
QPM – Every evening
QHS –at Bedtime
BID – Twice a day
TID – Three times a day
QID – Four times a day
AC – before a meal
PC – after a meal
PRN – as needed
O.S. – left eye
O.D. – right eye
O.U – Both eyes

Revised 8/2/06

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Department of Neurology

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Approval Date: March 7, 2008
Renewal Date: April 4, 2009
University of Pittsburgh
Institutional Review Board
IRB Number: 0503124

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY
Consent Form for PCP Patients

TITLE: Cognitive Assessment of Elderly Primary Care Patients

PRINCIPAL INVESTIGATOR: Steven T. DeKosky M.D.
Chair and Professor of Neurology
Department of Neurology
University of Pittsburgh
3471 Fifth Avenue
Pittsburgh, PA 15213
(412) 692-4622

CO-INVESTIGATORS:

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Pittsburgh, PA 15261
(412) 242-0374

SOURCE OF SUPPORT: National Institute on Aging

_____
Participant's Initials

Why is this research being done?

Dr. DeKosky and colleagues are conducting research on the identification of memory and thinking problems by Primary Care Physicians (PCPs). Many patients experience memory problems as they get older but the busy PCP usually does not have time to administer tests to determine whether the memory problems are part of normal aging or the result of a more serious disorder. Dr. DeKosky and his colleagues are conducting a study to see whether administering pencil and paper tests in the PCP office will help the PCP with early diagnosis of memory problems.

Who is being asked to participate in this research study?

Because you are a patient at a PCP office and you are over the age of 65 years you are being asked to enroll in this study. Between 900 - 1,000 male and female patients aged over 65 will be recruited into this study over the next two years. As part of your participation in the study you will take a series of pencil and paper tests designed to assess your memory and thinking abilities. In addition, you will answer some questions about your mood and your ability to carry out your everyday activities. You will be asked to return in two years time to retake the assessment. The evaluations will be performed at no cost to you or to your insurance company.

Your PCP will be randomly assigned to one of two physician groups; one physician group will receive a report from the researchers giving the results of the pencil and paper tests and the other physician group will not receive the results. This means that your PCP has a 50-50 chance (like the toss of a coin) of being in the group that gets a report of the tests. If your PCP is in the group that does not receive the results of the tests this means that your PCP will continue his or her usual treatment, there will be no change to how your PCP has managed your care. If your PCP is in the group that receives the results of the tests, this means that in addition to continuing his or her usual treatment he/she will be sent your test results and your PCP may use these results in making decisions about your care.

What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

Screening Procedures:

Procedures to determine if you are eligible to take part in a research study are called "screening procedures". For this research study, the screening procedures include:

Participant's Initials

Phone screen: You have already given your permission to your doctor for research staff to contact you by phone to learn more about the study. You may have also given your permission for the research staff to speak with your doctor/doctor's staff to verify that you meet all study entry criteria (that is, any vision, hearing, or memory problems). Your verbal permission for research staff to contact your doctor was documented and will be kept by the research staff. This documentation form may also be kept in your medical record with your doctor's permission. Patients who are under the age of 65 or with significant vision, hearing, or memory problems will not be allowed to take part in this study.

Experimental Procedures

Neuropsychological Tests: The paper and pencil tests will be used to measure memory and other intellectual abilities. Some tests will involve remembering information such as a shopping list or a picture. Other tests will assess language such as naming pictures of objects. You will also be given some tests in which you have to do two things at once. Finally, you will be asked to complete a short computer test. You do not need to have any experience with computers to be able to complete the computer test. The research staff will be available to answer any questions you may have.

Questionnaires: You will also be asked to complete some questionnaires about your emotions and how you are feeling at the moment. Other questionnaires will ask about your ability to conduct your usual daily activities. The complete evaluation will take about 2½ hours.

These studies are being conducted for research purposes and, if your PCP is in the research group that does not receive a report, neither your PCP nor you, will be told the results of the tests. However, if the results indicate that you have significant memory problems or significant depression your PCP and you will be told.

The assessment will take place at your PCP's office. In the event that you are unable to meet at your PCP's office, we will arrange to conduct the testing at another location where you will have privacy for testing. You will also be asked to give the researchers the name and contact information of a family member or friend that we can contact in case we can't get hold of you. If you are not available this person will be asked some questions about your health and thinking abilities. This person may also be told the results of the memory tests.

Review of your medical record: As part of this study, the researchers will review your medical chart from your PCP's office. The information that will be recorded will be limited to information concerning your past, current and future health history, including information about your mental health and medical status, for example, the medications you are taking, and any tests that the doctor may have ordered such as blood tests. The research staff will also try to obtain records of any inpatient hospitalization or Emergency Room visit, if these have occurred during your participation in this study. This information will be used for the purpose of evaluating your memory symptoms.

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Participant's Initials

Phone screen: You have already given your permission to your doctor for research staff to contact you by phone to learn more about the study. You may have also given your permission for the research staff to speak with your doctor/doctor's staff to verify that you meet all study entry criteria (that is, any vision, hearing, or memory problems). Your verbal permission for research staff to contact your doctor was documented and will be kept by the research staff. This documentation form may also be kept in your medical record with your doctor's permission. Patients who are under the age of 65 or with significant vision, hearing, or memory problems will not be allowed to take part in this study.

Experimental Procedures

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Questionnaires: You will also be asked to complete some questionnaires about your emotions and how you are feeling at the moment. Other questionnaires will ask about your ability to conduct your usual daily activities. The complete evaluation will take about 2½ hours.

These studies are being conducted for research purposes and, if your PCP is in the research group that does not receive a report, neither your PCP nor you, will be told the results of the tests. However, if the results indicate that you have significant memory problems or significant depression your PCP and you will be told.

The assessment will take place at your PCP's office. In the event that you are unable to meet at your PCP's office, we will arrange to conduct the testing at another location where you will have privacy for testing. You will also be asked to give the researchers the name and contact information of a family member or friend that we can contact in case we can't get hold of you. If you are not available this person will be asked some questions about your health and thinking abilities. This person may also be told the results of the memory tests.

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Participant's Initials

Re-evaluation: You will be asked to return in two years for re-evaluation. You can choose to stop participation at any time. These re-evaluations are an important part of the research program. The evaluation performed during the follow-up visit will include the same pencil and paper tests, the computer test, and the same questions about your emotions and activities of daily living. You will not be charged for the clinical evaluation or research tests. The follow-up evaluations take about 2½ hours. Even if your PCP did not receive the results of your initial evaluation he/she will be told the results of the follow-up evaluation.

Monitoring/Follow-up Procedures

Telephone Follow-Up: In between the visits, or if you are physically unable to return to complete the follow-up evaluation, the research staff will contact your caregiver or you by telephone approximately every 6 months. These telephone "check-ups" will include questions regarding your physical and mental condition, and review what medications you are currently taking. These telephone check ups should last approximately 20 minutes.

What are the possible risks, side effects, and discomforts of this research study?

Paper and pencil tests may be boring and, at times, frustrating. The research staff is trained in administering the tests and questionnaires and will try to make the assessment as pleasant as possible. Despite precautions to maintain confidentiality, it is still possible that the privacy of your results might be breached.

What are the possible benefits from taking part in this study?

There may be no direct benefits to you. If a previously unknown disorder is identified we will refer you to appropriate health and community services that may be helpful. In addition, you will be helping us with a study whose results may eventually be of use in providing services to older people with memory problems.

What treatments or procedures are available if I decide not to take part in this research study?

Screening tests for memory the thinking problems are not considered standard of care in primary care physician offices. If you decide not to take part in this research study, you may speak with your doctor about any concerns you have about memory problems. Your doctor may refer you to a specialist for additional testing.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any other information, either good or bad, develops during the course of this study which may cause you to change your mind about continuing to participate.

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Participant's Initials

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (that is, the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). You will be charged, in the standard manner, for any procedures performed for your routine medical care or services not connected with the study (for example, any co-payment, coinsurances, and deductibles for a well or sick visit to your doctor's office).

Will I be paid if I take part in this research study?

You will be paid $25.00 for completing the initial evaluation and another $25.00 for completing the two-year follow-up.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh investigators and their associates who provide services at the University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation to their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as the result of the research procedures being performed, you should immediately contact the Principal Investigator (412) 692-4920 listed on the cover sheet of this form. Emergency medical treatment for injuries solely and directly relating to your participation in this research will be provided to me by hospitals of the UPMC. It is possible that the UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to me. If your research-related injury required medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

Any information about you obtained from this research study will be kept as confidential (private) as possible. Any information about you obtained from this research will be kept strictly confidential and stored in locked files. Only authorized study investigators and staff will be allowed to look at these files. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. However, as mentioned previously, the results of your testing may be sent to your PCP and will appear in your medical records.

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Participant's Initials

Will this research study involve the use or disclosure of my identifiable medical information?

You will not be identified by name in any publication of research results unless you sign a separate form giving permission (release).

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (e.g., physician office) records. The information that will be recorded will be limited to information concerning your past and current health history, including information about your mental health and neurological status. This information will be used for the purpose of evaluating your memory symptoms.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable research information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Physicians are required to report the names of individuals who would have difficulty driving safely because of mental or physical disability to the Pennsylvania Department of Transportation. This is in accordance with the Pennsylvania State law (Title 67., Part I., Subpart A., Article IV., Chapter 83., S 83.5.). If your PCP determines that you are too impaired to drive safely, he/she would have to comply with this law.

Your doctor may be an investigator in this research study, and as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

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Participant's Initials

Authorized representatives of the sponsor of this research study, National Institute on Aging, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in this study. Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g. laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time.

May I have access to my medical information that results from my participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document that you have been provided you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider unless otherwise specifically stated below. You will only have access to information generated by this research that is part of your medical record, you will not have access to information that is part of your research record.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed in general to participate in this research study). Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent

Participant's Initials

for participation in this research study will not affect your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (however, if you withdraw your consent for the use and disclosure of your identifiable information for the purposes above, you will also be withdrawn, in general, from further participation in this research study). Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will not affect your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

If you agree to participate in this research study, you may be removed from the research study by the investigators without your consent in the event they believe it is in your best interest. For example, if the results of the testing indicate that you have a significant memory problem you will be withdrawn from the study and the results of your tests will be given to your PCP. You will also be referred to the appropriate clinical setting for follow-up. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you were withdrawn from the study may continue to be used and disclosed by the investigators for the purposes described above.

POTENTIAL USE IN PRODUCT DEVELOPMENT: One or more of the investigators conducting this research has a financial interest in or a patent for the development of the computerized assessment used in this study. This means that it is possible that the results of this study could lead to personal profit for the investigators and/or the University of Pittsburgh. This project has been carefully reviewed to ensure that your well-being holds more importance than any study results. Any questions you might have about this will be answered fully by Dr. Steven T. DeKosky at (412) 692-4622 or by the human subject Protection Advocate of the University of Pittsburgh (1-866-212-2668).

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_____
Participant's Initials

Approval Date: March 7, 2008
Renewal date: April 4, 2009
University of Pittsburgh
Institutional Review Board
IRB Number: 0503124

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. Questions regarding the study have been answered by Dr. DeKosky and colleagues. Any questions I have concerning my rights as a research subject will be answered by the Human Subjects Protection Advocate, Institutional Review Board (IRB) Office at 1-866-212-2668. A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this research.

_____
Printed Name of Participant

_____ _____
Date Time Participant Signature

CERTIFICATION of INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date

INFORMANT INFORMATION:

Please provide the name and address of someone we can contact to answer questions about your health status, mood, memory and everyday functioning, in the event that you are unavailable or unable to:

Name: _____

Address: _____

_____

Phone number: _____

Relationship to you: _____

_____
Participant's Initials

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