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Understanding Medication Self-Management Capacity among Older Adults Living in Low-Income Housing Communities

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Understanding Medication Self-Management Capacity among Older Adults Living in Low-Income Housing Communities

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LIST OF ABBREVIATIONS

ADLs – Activities of Daily Living
ARDS – Acquired Respiratory Distress Syndrome
BMI – Body Mass Index
BMI – Body Mass Index
CC – Correlation Coefficient
CDC – Center for Disease Control and Prevention
CI – Confidence Interval
COPD – Chronic Obstructive Pulmonary Disease
ECF– Executive Cognitive Function
ER – Emergency Room
FCI – Functional Comorbidity Index
HHS – Department of Health and Human Services
HUD – Department of Housing and Urban Development
IADLs – Instrumental Activities of Daily Living
LTSS – Long-Term Services and Support
MCI – Mild Cognitive Impairment
Meds – Medications
MI – Myocardial Infarction
MMC – Medication Self-Management Capacity
MRCI – Medication Regimen Complexity Index
OTC – Over-the-Counter Medications
PCP – Primary care Physicians
RHWP – Richmond Health and Wellness Program
Rx – Prescription medications
SD – Standard Deviation
SE – Standard Errors
SPM – Supplemental Poverty Measure
TIA – Transient Ischemic Attack
U. S. – United States of America

ABSTRACT

Background: Medication self-management capacity (MMC) is an individual's cognitive and functional ability to self-administer a medication regimen as prescribed. Poor MMC is an issue in older adults often resulting in negative health outcomes and loss of independence. Therefore, understanding low-income older adults' capacity to manage their medications may help identify individuals who are at risk for developing medication mismanagement and guide future intervention strategies based on individual need to promote safe medication use and healthy aging in place in the community.

Objectives: 1) To determine the cognitive and physical functional deficiencies in MMC among low-income older adults, 2) To identify variables that predict deficiencies in MMC in this population, 3) To determine the impact of using pharmaceutical aids/services on MMC, and 4) To examine the association between MMC and emergency room (ER) visits.

Methods: This was a cross-sectional study of older adult residents living in low-income housing buildings served by the RHWP. At a study interview, information on demographics, medical history, and medication use was collected. MMC was evaluated using the Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE) tool. Cognitive and functional status, health literacy and depression symptoms were assessed. ER visits were determined retrospectively over the last six months Descriptive analyses were performed to identify cognitive and physical functional deficiencies in MMC. Linear regression analysis was conducted to identify variables that predict MMC and assess the relationship between MMC and using pharmaceutical aid/service. Logistic regression analysis was used to examine the association between ER visits and MMC.

Results: A total of 107 participants were included, and 89% were African-American with an average age of 68.54 years (±7.23). They had an average of 4.92 (±2.85) comorbidities and used

approximately 8 (±4.12) medications on a regular basis. The mean total deficiency in medication management was 3 (±2.00) as assessed by MedMaIDE. Lacking medication knowledge was common among the participants: 69.16% could not name and 46% state the indication of all of their medications, and 38.32% did not how and when all of their medications should be taken. When controlling for ADLs and falls, the mean total deficiency score in MedMaIDE increased among those with an educational level equal to high school or less compared with participants who had a higher educational level than high school [β=1.32, 1.24, p= 0.0195, 0.0415, respectively], and participants who reported difficulty reading prescription medication labels or opening medication bottles compared with those who did not report any difficulties [β=1.18, 1.43, p= 0.0036, 0.0047, respectively]. About 20.56% of participants were receiving assistance with medications from someone, and 79.44% used at least one pharmaceutical aid/service. However, receiving assistance with medications and using pharmaceutical aid/service were not significantly associated with MMC [p= 0.5334, 0.0853, respectively]. The participants reported a total of 23 (21.5%) ER visits within six months. The adjusted model for age, educational level, number of comorbidities, and ADLs suggested that for every one-unit increase in the total deficiency score, the odds of ER visits increased by 1.23 (p=0.1809) times.

Conclusion: Many older adults who lived in low-income housing had impaired capacity to manage their medications independently. They appeared to have inadequate medication knowledge, which affects their cognitive ability to manage medications. Low educational level and health literacy and reporting trouble reading labels or opening medication bottles were predictors to deficient MMC. Future studies are needed to confirm whether or not MMC predicts those who may not able to remain living independently safely or who may need additional support with medications to remain independent.

CHAPTER ONE

INTRODUCTION

1.1 Older Adult Population and Poverty in the United States

In the United States (U.S.), there has been tremendous growth in the older adult population since the baby boomer generation turned 50 in the mid of 1990s. In addition, advances in medical care services with increased evidence for using a multiple medication regimen to manage chronic diseases has contributed to older adults living longer independently with good health status.[1] According to a U. S. Census Bureau report, the older adult population age 65 years and older accounted for approximately 15% (47.8 million) of the total American population in 2015, and the older adult population increased by 1.6 million since 2014.[2] By 2060, older adult population is expected to represent about 25% (98.2 million) of the total population and 19.7 million of this number will be people age 85 years and older. This means nearly one in four of the American residents will fall in this age group in 2060.[2, 3]

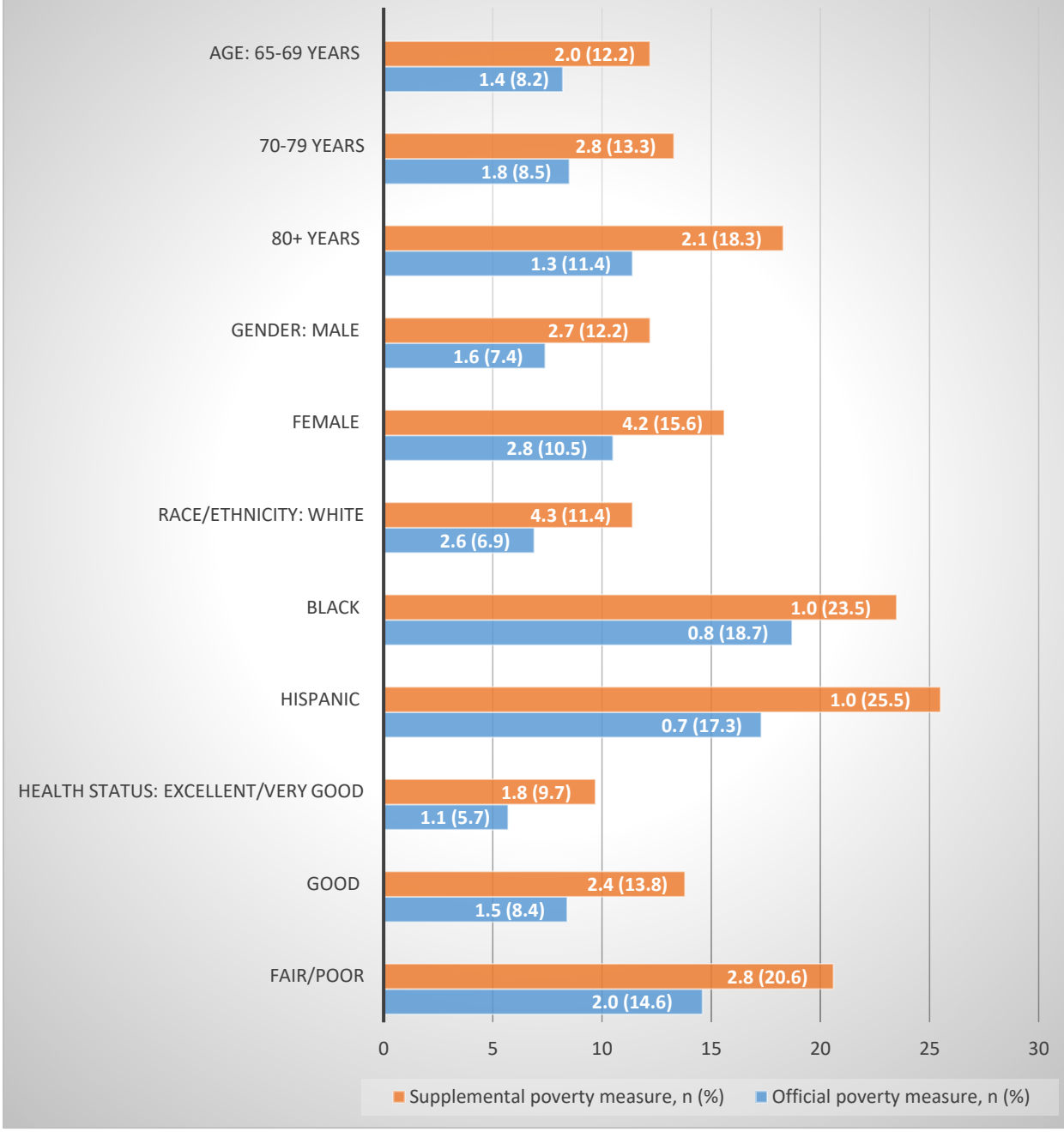
Because of this population level trend, the total dependency and old-age dependency ratios are estimated to increase. The dependency ratios represent the potential burden of the dependent population, those under 18 years and those 65 years and over, on those in the working-age population (18 - 64 years). The total dependency ratio is the sum of youth and old age dependency ratio, which calculated by dividing the number of people in the dependent age groups (youth or older adults) by the number in the working-age group and then multiplying by 100.[3,4] The total dependency ratios declined between 1990 and 2010 as the youth dependency ratio declined because the baby boomer generation reached adulthood. However, the total dependency ratio is proposed to rise from 59% in 2010 to 65% and 75% by 2020 and 2040 respectively, as the older adult population and the old-age dependency ratio is continuing to increase.[3]

Rapid growth in the older adult population will likely substantially increase the numbers of low-income older adults. However, the median household income increased between 2015 and 2016 across all age groups and those with householders of 65 and older had median income increased by 1.5%, from $41,501 in 2015 to $42,113 in 2016. Yet, many older adults live on a limited income in the U.S. Half of all Medicare beneficiaries had incomes below $26,200 and 25% had incomes below $15,250 in 2016.[5]

Policymakers in the U.S. aim to enhance economic security and independence and reduce poverty rates among older adult people. Therefore, the U.S. Census Bureau created an alternative measure of poverty, known as the Supplemental Poverty Measure (SPM) to overcome the concerns that the (traditional) official poverty measure is outdated and does not accurately reflect resident's financial resources and geographic variations in housing costs. Unlike the official measure, the SPM reflects out-of-pocket medical spending including premiums, which is specifically significant for older adult people, who spend a larger amount of their household incomes on health care costs than younger people.[4,5]

In 2017, the poverty threshold was $11,756 for an individual age 65 or older, and the official poverty rate was 9.2% in the U.S. However, the SPM rate was 14.1% among older adults, which results in over seven million older adults living below poverty rate based on SPM, compared to 4.7 million based on the official measure. The higher poverty rate under SPM is mainly because the SPM takes into account out-of-pocket medical expenses. Under both the official and supplemental measures, the national estimates of poverty rate among older adult increased with age and were higher among female, Black and Hispanic groups, and people with relatively poor health. Figure 1 illustrates the national estimates of poverty rates under both the official measure and SPM among older people by age subgroup, sex, race, and health status in 2017.[5]

Figure 1.1 National Estimates of Poverty Rates Among People Ages 65 Years and Older in 2017



Note: Numbers in millions (%)
Adapted from the Kaiser Family Foundation analysis of current Population survey, 2016-2018 Annual Social and Economic Supplement.

As the low-income older population increases, many of them are living in subsidized housing to overcome the financial burden. The U.S. Department of Housing and Urban Development (HUD) estimates that nearly 800,000 older adults live in low-income housing settings and receive federal support to pay the rent.[6] Generally, older adults who are eligible for residing in low-income housings are more likely to have physical and behavioral health issues, chronic conditions, and report fair or poor health compared to other older population. Moreover, this population is less likely to have an education beyond high school compared to other older people in the community. For instance, it has been reported that 40% older adults residing in low-income housing had limited mobility and are in need of assistance with everyday activities such as toileting, eating, bathing, and dressing compared to 19% of other older homeowners. Moreover, one study reported that 66% of low-income older adult residents were overweight or obese and 25% had diabetes.[6]

1.2 Age-Related Changes in Cognitive and Physical Functional Abilities

Changes or declines in physical functional ability and cognitive function are part of the aging process.[7,8] These age-related changes substantially limit individual ability to perform one or more essential activities of independent living. Despite this fact, the number of older adults living in the community with difficulties in hearing, vision, cognition, ambulation, self-care, or independent living rises with age.[1,3] According to the U.S. Census Bureau's American Community Survey report (2008-2012), about 38.7% (15.7 million) of older adults reported one or more disabilities, and those aged 85 or older represented about 25% of them.[9] Table 1.1 summarizes the prevalence of disability among the older adult population in the U.S. by type of disability and age. Among the older adult population with disabilities, 12.6% of them were living in poverty, and

older Blacks with the disability had the highest poverty rate (23.7%) compared to other race groups.[9]

Table 1.1 Prevalence of Disabilities among American Older Adult Population in 2008-2012 [10]

Type of Disability	Total	Age n (%)		
		65-74 years	75-84 years	85+ years
Ambulatory*	10,467 (66.5)	3,696 (63.6)	3,861 (65.2)	2,911 (72.8)
Independent living*	7,523 (47.8)	1,978 (34)	2,796 (47.2)	2,749 (68.7)
Hearing	6,354 (40.4)	2,030 (34.9)	2,400 (40.6)	1,924 (48.1)
Cognitive*	4,529 (28.8)	1,311 (22.6)	1,655 (28)	1,562 (39.1)
Self-care*	4,468 (28.4)	1,177 (20.2)	1,595 (26.9)	1,697 (42.4)
Vision	3,028 (19.2)	959 (16.5)	1,075 (18.2)	994 (24.9)

Note: Numbers in Thousands (%)
* Ambulatory – Having serious difficulty walking or climbing stairs
* Independent living – having a difficulty doing tasks alone, such as visiting a doctor's office or shopping
* Cognitive – having difficulty remembering, concentrating, or making a decision
*Self-care – having difficulty bathing or dressing

Another way to measure disability is using the ability to perform both basic activities of daily living (ADLs) such as bathing/showering, getting in/out of bed/chairs, dressing, eating, walking and using the toilet, and instrumental activities of daily living (IADLs), such as preparing meals, managing money, shopping for groceries, or managing/taking medication. Indeed, both are essential for safe independent living. The Medicare Current Beneficiary Survey analysis in 2013 shows that approximately 30% of the beneficiaries in the community sittings reported at least one limitation ADLs and 12% reported having one or more limitations in IADLs.[4]

In general, aging is a significant risk factor for cognitive decline including dementia and mild cognitive impairment (MCI). Dementia is a cognitive condition that is characterized by a decline in one or more cognitive function such as, loss of memory, attention, or language or executive functioning.[10] Older adults may experience a significant decline in these cognitive functions that may interfere with independent living, specifically in performing IADLs.[7,10] Unlike dementia, MCI may sometimes interfere with basic activities, but it may not be severe enough to affect older adults' ability to perform IADLs. The prevalence of dementia is increasing by age. It

was estimated that 5% of older adult ages 71 to 79 years had dementia and this number increased to 24% by ages 80 to 89 years, and 37% by ages 90 years and older. Another study showed that the prevalence of dementia in Black adults age 71 years and older was about 21% compared with 11% of whites in the same age group. Dementia is more prevalent among females than males, it affects approximately 16% of older adult females compared to 11% of males.[10]

Typically, the ability to perform day-to-day activities (ADLs and IDALs) requires a complex integration of multiple physiological systems such as the psychomotor, musculoskeletal, and the cardiorespiratory systems. Most of these systems are altered by age and presence of chronic conditions. In addition, the ability to perform ADLs and IADLs is affected by an individual's cognitive ability, specifically executive cognitive function (ECF).[7,8] ECF refers to the individual's cognitive ability to engage in independent, appropriate, and self-caring behavior that involves coordination of simple tasks and ideas into more complex ones.[7,8] An example of ECF is coordinating between planning, organizing, and problem-solving activities to perform medication management/administration, shopping, and dressing. Previous studies found that 40% to 80% of older adults who had Mini-Mental State Exam (MMSE) scores indicating normal cognitive function experienced executive cognitive dysfunction.[8]

Consequently, older adults with physical and cognitive limitations will face challenges that affected their abilities to live independently in the community. The U.S. Department of Health and Human Services (HHS) estimates that about 7% of residents who reach the age of 65 will need some form of long-term care such as community-based long-term services and support (LTSS) which is mainly covered by Medicaid.[1]

1.3 Multimorbidity and Polypharmacy among Older Adults

Multimorbidity has become more prevalent among older adults as life expectancy has been increasing and the population has aged. Multimorbidity is defined as co-occurrence of two or more chronic conditions/diseases that are not cured but can be controlled through pharmacological or non-pharmacological treatments.[11,12] In 2008, 67% of Medicare beneficiaries in community settings reported living with two or more chronic conditions compared to 33% that reported none or one chronic condition. The prevalence of multimorbidity increased with age from 62% for those aged 65-74 years to 75.7% for those aged 75-84 years, and to 81.5% for those aged 85 years and older. Moreover, females had a higher prevalence of multimorbidity among all age groups compared to males. The most common chronic conditions among community-dwelling older adults were hypertension (56%), hyperlipidemia (42.8%), and ischemic heart disease (26.6%).[11]

Specific combinations of chronic diseases are associated with increased risk of disability and functional limitations, including limitations in physical and cognitive function and ADLs.[11] For example, having a stroke with diabetes, osteoporosis, or hip fracture, visual impairment with osteoporosis, and heart disease with cancer may lead to increased risk for disability. While, having a combination of heart failure with chronic obstructive pulmonary disease, depression, osteoarthritis, or cognitive impairment may lead to an increased risk of functional impairment.[11] Moreover, older adults with multimorbidity are at higher risk of reporting poor quality of life, polypharmacy, adverse drug events, and other adverse outcomes such as hospitalization and death.[11,12]

As the number of people with multimorbidity increases substantially with age, polypharmacy is often prevalent and unavoidable among the older adult population. There is growing evidence for using a multi-drug regimen to manage and control chronic diseases. For

example, a 79 year old woman with osteoporosis, osteoarthritis, type 2 diabetes, hypertension, and chronic obstructive pulmonary disease may require up to 12 medications and 19 doses scheduled in five different times daily based upon clinical practice guidelines.[12] In the U. S., older adults are the major consumers of prescription drugs, accounting for about 34% of pharmacy expenditures. A recent Centers for Disease Control and Prevention (CDC) report showed that approximately 89% of community-dwelling older adults reported using at least one prescription medication in the last 30 days, whereas almost 67% reported using three or more, and 50% reported using five or more prescription medications.[13]

Although using multiple-medication regimens is an important health intervention to manage multimorbidity, polypharmacy may cause or contribute to potential negative consequences, especially among older adults who live independently in the community. Unlike hospitals or nursing homes, older adults in the community often do not receive needed support or help from family members, caregivers, or professionals to prevent the potential consequences of medication misuse/mismanagement. This results in an increased risk of unintentional medication-related problems which can lead to serious consequences, such as nonadherence, hospitalization, emergency room (ER) visits, and a loss of independence.[16-18]

1.4 Medication-Related Problems among Older Adults

Medication nonadherence is one of the significant health problems among all age groups in terms of healthcare cost and utilization. Medication nonadherence is contributing to more than $100 billion in costs to the U.S. healthcare system annually and it is associated with more than 125,000 deaths per year.[14] Although using complex and multiple medication regimens to manage chronic diseases has been recommended by most current clinical guidelines, such complexity increases the potential for unintentional medication nonadherence. It has been estimated that more

than 50% of older adults do not take their prescription medications as prescribed.[15] Previous studies showed that 27% of adverse drug events among older adults were preventable. Among these preventable events, 20% were related to medication nonadherence. Other studies also found that approximately 28% of hospital admissions, over 70% of medication-related emergency room (ER) visits, and 23% of nursing home replacements were secondary to medication nonadherence.[15,16]

Research has established that decline in cognitive and physical skills required for optimal independent medication management can lead to unintentional medication nonadherence and medication errors.[15,17] Many older adults have difficulty opening different types of prescription medication vials/packages, which is one of the required physical skills for independent medication management.[17,18] In addition to older age, many other factors have been associated with the inability to open medication containers including Parkinson's disease, rheumatoid arthritis, cognitive impairment, and impaired vision. Studies have shown that over 60% of older adults were unable to break a tablet, about 14% had difficulty opening a screw-top bottle, 45% a flip-top bottle, 21% a blister pack, 24% a Dosett dose administration aid, and 64% a child-resistant bottle.[17]

Reading or interpreting instructions or labels on medication packaging is one of the essential cognitive skills for independent medication management.[17,18] However, it is not only older adults with vision impairment who are unable to read instructions on medication packaging. Even those with corrected vision report the same issue resulting in reduced medication management ability and adherence. Prior studies reported that self-treatment, lack of coordinated healthcare, recent hospitalization, impaired cognitive status, low socioeconomic status, and a complex medication regimen are factors contributing to poor medication self-management capacity in older adults.[19,20]

Despite these facts, the majority of community-dwelling older adults maintain the responsibility for managing their own medications. One study found that approximately 80% of community-dwelling older adults were responsible for managing their medications with no or little help from family members or caregivers while they experience a decline in their physical and cognitive abilities.[20] Moreover, another study showed that only 27% of older adults who had physical difficulty opening their medication containers were getting assistance with their medications.[17] Consequently, there has been a concern about medication self-management capacity among older adults because they are commonly using multiple medication regimens while they experience an age-related decline in their cognitive and physical abilities that are required for managing medication independently.

1.5 Medication Self-Management Capacity (MCC)

Numerous terms, including medication management capacity and medication self-management/administration skills or capacity, are routinely used in the literature to describe a person's ability to take his/her own medications. MMC has been defined as "an individual's cognitive and functional ability to self-administer a medication regimen as it has been prescribed."[8] A new conceptual model has defined MMC as, "the extent to which a patient takes medication as prescribed, including not only the correct dose, frequency, and spacing but also its continued, safe use over time."[14] According to these two definitions, MMC represents an individual's ability to self-administer a medication correctly and safely, when this person has the desire to follow the medication regimen as prescribed by healthcare providers.

Managing a medication regimen is one of the self-care activities that require a high level of integration and coordination between cognitive and physical skills. A wide range of cognitive and physical skills have been identified in the literature as requirements for optimal medication

management including, but not limited to, correctly identifying medications, opening and removing the medication from packaging, scheduling the medication regimen, and obtaining medication from the pharmacy or physician office.[8,17] Table 1.2 includes the most frequent skills assessed by different validated instruments of MMC.

Table 1.2 Most Frequent Skills Assessed by Different Validated Instruments of MMC[17]

Medication Self-Management Skills*	
Physical skills • Open medication packaging • Remove medication from packaging • Fill a dose-administration aid (pill box) • Re-cover medication container • Split tablet • Measure a dose of liquid medication • Swallow pills or water • Administer non-oral dosage form • Access pharmacy and/or doctor to obtain medication	Cognitive skills • Read standard medication label • Describe indications & dosage regimen of own medications • Demonstrate setting out 24 hours of medication • Read and interpret additional instructions • Name and identify all of own medications • Judgment and consequences (e.g. know what to do in missing a dose situation) • Perform calculations • Differentiate medication by color, size or shape

* The exhaustive list of medication management skills was reported in a review paper that identifies instruments used in clinical practice to assess patients' ability to manage medications.

This study will be guided by the conceptual model of medication self-management.[14] This model provides a better understanding of the tasks associated with the optimal management of medications and sustaining safe and correct use over time in community settings. The authors of this model deconstruct medication self-management into a series of six steps that a patient must perform to successfully manage their medications independently (Figure 1.2). These steps are fill, understand, organize, take, monitor, and sustain. The authors also highlighted the lack of a comprehensive measure of MMC that can be used to evaluate the full range of skills required by patients to successfully manage medication regimens.[14]

The term medication adherence is generally used to describe the patient's' medication-taking behavior over time. It is defined by the World Health Organization defines medication adherence as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider."[21] There are many different factors that affect medication adherence such as medication factors, patient factors, physician factors, system-based factors.[21,22] Non-adherence behaviors are broadly categorized into two types, intentional and unintentional non-adherence. Intentional non-adherence occurs when the patients purposely decide not to take or comply with the medication instructions, despite having the ability to take medications as instructed. This type of non-adherence is related to patients' beliefs, attitudes and expectations that influence patients' motivation to take and sustain taking medications as prescribed.[21,22] In contrast, unintentional non-adherence occurs due to capacity (i.e. forgetfulness, vision impairment, and dexterity deficiency) or resources (i.e. problems of accessing prescriptions or cost) limitations that prevent patients from complying with medication instructions.[21,22] Therefore, the current medication adherence measures are often focused on measuring whether you actually take medications or not. However, medication mismanagement usually occurs unintentionally by patients due to lack or insufficient skills that are necessary for optimal medication management regime.[14] Therefore, measurements of MMC typically determine factors of whether or not the patients can manage medications independently.

Assessing older adults' capacity to manage their medication independently is not routinely performed in clinical practice. Previous studies used measures of medication adherence such as self-report, pill count, and pharmacy claims data to evaluate MMC.[15, 21] However, measures of medication adherence provide limited insight on subsequent tasks associated with successful

medication self-management and are generally focused on how often medications are taken or refilled. On the other hand, evaluating patients' capacity to manage a medication regimen, using a standardized MMC assessment tool, provides information about how the medication is taken by patients (i.e. the accuracy of medication use).[15, 21] While several instruments have been developed to evaluate older adults' MMC, most were designed to identify cognitive and physical barriers to safe and accurate medication use. Additionally, there is a variation in medication management skills that are assessed in these instruments. However, the most frequently assessed skills are opening and removing the correct dose from medication packaging, reading standard medication labels, and recalling information, which is not a comprehensive evaluation of MMC.[17,18,23]

The majority of MMC instruments utilize two types of assessment methods, either using the patient's own medications or using simulated medication regimens, each with strengths and limitations. The simulated approach may help standardize the assessment process and it is useful when the patient's own medications are not usually available or the patients are reluctant to bring in their medications for testing. However, using the patient's own medications approach is preferred because it causes less stress on older adults, and it reflects what they do routinely in real life (home) compared to using an unfamiliar simulated approach.[17,18,23]

Figure 1.2 Model of Medication Self-Management[14]

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CHAPTER TWO

LITERATURE REVIEW

Measuring Medication Self-Management Capacity

2.1 Introduction

Managing a medication regimen is one of the self-care activities that is important for safe and independent living. Patients should have sufficient capacity to self-manage medication to attain positive outcomes and maintain independence. The capacity of self-managing medication refers to a patient's cognitive and physical skills to self-administer medications as prescribed. Typically, it is a measure of a patient's ability to follow the prescription directions, when they have the desire to do so. Whereas medication non-adherence may be a result of intentional or unintentional factors, this is not the case in medication mismanagement. Poor or limited ability to manage medications normally occurs unintentionally due to functional limitations, which can be cognitive, physical or both. This could be a consequence of health deterioration or aging, which negatively affects individuals' self-care ability. As the patients' medical and therapeutic needs increase, self-care ability decreases.[1,2] The importance of assessing patients' ability to manage medications, using an objective and validated tool, has been elucidated in the literature. It can be used as a guide to target medication interventions based on patients' needs to enhance the correct and safe use of medications among geriatric patients with chronic diseases. Additionally, it can be a significant indicator of self-care or cognitive function deficits that lead to loss of independence.[1-5]

However, assessing patients' capacity to manage medications independently is not routinely performed in clinical practice. Usually, healthcare providers assess a patient's ability to manage their medication using professional judgment based on the patient's medical conditions or

caregiver report. This method is subjective and biased which may lead to over or under estimating the patient's ability to manage medications. Additionally, some health professionals use medication adherence measures, either subjective or objective, as a proxy for a patient's ability to manage medications. Most adherence measures are limited to how often the medications are taken or refilled rather than how the medications are taken by the patient. Even the use of functional assessments such as MMSE, ADL, or IADL, which can predict patients' cognitive or physical ability, may not necessarily assess the required skills for optimal managing of medications. [2,6]

Therefore, there are numerous tools that have been developed to assess patients' capacity to manage medications independently. These assessments have been subjected to a varying level of validity and reliability testing. However, none of the previously published assessment instruments have been recommended as a gold standard to be used in clinical practice or research studies. Previous literature reviews identified and evaluated those available instruments assessing patients' functional ability to manage medications in outpatient settings.[2–5] However, there has been more recent innovation and expansion in the area of instrument development assessing patients' ability to manage medications. There have been newly published instruments that were not included in previous literature reviews. For this review, the included instruments were limited to those based on with direct observation.

The aim of this review was to identify the available assessment instruments designed to assess patients' ability to manage medications independently and identify reliable and valid tools that could be used in clinical practice and research. Reviewing the medication management assessment instruments can help healthcare professionals to select the appropriate tools to be used based upon the tools' characteristics and psychometric evaluation of its performance. Assessing patients' ability to manage their own medications using a validated instrument may help to identify

barriers for the appropriate and safe use of medications. Also, it helps to plan the intervention to enhance their performance and safe use of medications based on the potential needs. This may ensure that older adult patients are aging safely and independently in their own homes as long as possible.

2.2 Methods

Literature Search

To review the existing medication management assessment instruments, a comprehensive literature review was conducted using the following electronic databases: PubMed/MEDLINE, CINAHL Complete, PsycINFO, Embase, and International Pharmaceutical Abstracts (IPA). A broad search was conducted due to the lack of a standard definition and terminology of patients' capacity to self-manage medication in the literature. The relevant published studies were targeted using combinations of key words and medical subject headings (MeSH) in PubMed. The search strategies used in the other databases were built to reflect similar keywords and MeSH terms used in the PubMed search as described in Table 2.1. This review was limited to articles published in English and after 2009 to capture any tool that were not included in the previous review papers. The final search strategy was performed in October 2018. Bibliographies of the selected articles were also screened to identify any other relevant articles.

Review Process

The final search yielded a combined total of 3,856 articles. After eliminating the duplicate studies (n=1,360), a total of 2,496 articles remained for initial screening by title and abstract. Two authors (Slattum, P.W. & Badawoud, A.M.) reviewed the titles and the abstracts for all the retrieved articles independently. The following criteria were used to identify all relevant articles:

1. Preliminarly study introduced/proposed an assessment instrument developed to assess patients' or informal caregivers' capacity to manage their medication in outpatients or intend to assess the patients ability to self-manage of medications after hospital discharge.
2. Assessed the required skills to successfully manage a whole/complete medication regimen.
3. Discussed the psychometric evaluation of the instrument performance, which may include reliability, validity, or both data.
4. Provided sufficient required details to be replicable in clinical practice.

Any articles that: 1) were not relevant to the review topic, 2) introduced an assessment measure for adherence, self-care, disease management, or inpatient self-medication program, 3) introduced an assessment tool to assess medication management among pediatric patients or formal caregivers managing the medications of another person, or 4) described a tool to assess patients' ability to manage one specific complex dosage forms, such as inhalers, or injectable medications.

2.3 Results

A total of 16 papers were identified, which corresponded to 4 literature reviews and 12 new studies. The flow chart in Figure 2.1 illustrates the screening and review process. Of the 16 papers identified describing development and/or validation of instruments that were designed to assess patients' medication management capacity, 26 instruments were identified. While 17 instruments were obtained from the review papers[7–23], 9 were newly published (3 were described in 2 separated papers) since the published reviews.[24–35] These 26 instruments are listed in Table 2.2.

Characteristics of the Studies

The primary validation study for each instrument is described in Table 2.3, illustrating instrument name (authors), design, aim, sample and psychometric evaluation. Of the 26 studies reviewed, 20 were conducted in the U.S., three in Canada, and one each in United Kingdom (Scotland), Sweden, and South Korea. The design of almost all studies were cross-sectional (25), except one (DRUGS) which was initially validated in a cross-sectional study then followed by a prospective study.[8] Most of the validation studies included a reasonable sample size of > 30 subjects, except studies with five instruments that assessed small sample sizes (<30) (Home-Rx, Show Back, Patient's barriers to compliance, SM Task, S-5).[17, 19, 24, 28, 32]

Content Validity

Of the 26 studies reviewed, studies with 24 instruments were subjected to some sort of content. However, the studies with two instruments (Show Back and S-5) reported only content validity.[28, 32] In both studies, the content validity was conducted simply among a panel of experts and a sample of older adult patients.

Construct Validity

Most of the instruments were designed to assess outpatients' capacity to take their medications except two of them (PA and S-5).[15, 32] The S-5 and PA instruments were developed to determine the readiness of hospitalized patients to self-manage their medications before they were discharged.[15, 25] Of the 25 studies, 18 studies included a sample of apparently healthy older adults with an average age of ≥ 65 years. The other seven studies assessed medication management capacity among patients with HIV (MMT and MMT-R),[22, 23] schizophrenia (MMAA and

VRAMMA),[9, 13] Parkinson's disease (PillQ),[29] stroke (S-5),[32] and Alzheimer 's disease and dementia (Pillbox Test).[27]

In 20 studies, the correlation between the subject's ability to manage medications and cognitive function was tested in order to validate the ability of the proposed instrument to assess cognitive medication management skills. In six studies, patients' performance on ADL, IADL, or both tests was used to correlate the physical medication management ability with functional status (DRUGS, HMS, MAT, MedMaIDE, MMT-R, PillQ).[7, 8, 10, 11, 16, 23, 29] Additionally, patients' dexterity of handling medication bottles (RAT) and grip strength (SM Task) were used to correlate physical function with medication management ability.[19, 35] Eight studies examined the correlation between inability to manage medications independently and both physical and cognitive functional impairment (DRUGS, HMS, MAT, MedMaIDE, SM Task, MMT-R, PillQ, and RAT).[7, 8, 10, 11, 16, 19, 23, 28, 35] These analyses confirm that medication management ability decreases when cognitive or physical functional status deficits increase.

The significant association between medication management performance and medication-related outcomes (e.g. medication adherence, medication related-problems, medication regimen complexity, and the number of medications taken) was reported in studies with nine instruments. The association between medication management capacity and self-reported adherence was assessed in five studies (MMPT, MAI SM task, MMT, and SMAT).[12, 14, 19, 22, 33, 34] Objective measures of medication adherence (e.g. pill count, medication refills) were used to validate two instruments (MMAA and MedMaIDE).[9,16] The performance on the ManageMed instrument was associated with the number of medications taken; PA instrument was associated with medication related-problems; SMAT was associated with medication regimen complexity.[15, 31, 33, 34]

In studies with five instruments, medication management performance was compared with other measures of medication management capacity. The performance as measured by the DRUGS and MMPT instruments was significantly associated with self-reported medication management capacity.[7, 8, 12] The patients' performance as measured with the PA instrument was compared with self-medication ability during hospital admission.[15] In addition, the comparison between two objective measures of medication management was reported in primary validation studies with two instruments, the VRAMMA instrument was compared with MMAA, and Home-Rx was compared with ManageMed. [13, 31]

Reliability

The reliability data was not reported for 14 instruments, while 12 of them were subjected to some sort of reliability testing (i.e. internal consistency, inter-rater and/or test-retest reliability).[7-10, 16, 20-23, 28, 31, 33-35] Only studies with two instruments reported complete and acceptable reliability evidence including inter-rater and test-retest reliability, and internal consistency (MedMaIDE, SMAT).[16, 33, 34] Studies with five instruments reported only internal consistency (MMAA, HMS, MM Test, and RAT).[20, 9, 10, 35] All instruments that reported internal consistency had acceptable Cronbach's alpha coefficient values (i.e. > 0.70), except the HMS instrument, which had low internal consistency (0.38).[10] Show Back and RACT instruments were subjected to only test-retest reliability.[21, 28]

Selected Instrument Characteristics

Table 2.2 provides details of each instrument, illustrating its purpose as reported by the authors, number of items, medication management abilities and skills assessed, scoring scale, and time for administration. Of the 26 instruments, both validity and reliability data were reported for

12 instruments,[7-10, 16, 20-23, 28, 31, 33-35] two of which tested validity using simply content experts' and patients' opinion (Show Back and S-5).[28, 32] Only two instruments had been subjected to content and construct validity testing as well as full reliability testing (MedMaIDE, SMAT). [16, 33, 34]

Almost all the identified instruments (25) were designed as performance-based assessment tools, where the patients' medication management skills were observed during face-to-face interviews.[6-28, 31-36] One self-reported instrument was identified where the patients were asked to describe their medication regimen and colors and shapes of the tablet (PillQ).[29, 30] The identified instruments are categorized according to the administration method used: a) performance-based instruments using patients' own medications [5 instruments], b) self-reported instrument using patients' own medications [1 instrument], c) performance-based instruments using simulated medication regimen [14 instruments], d) performance-based instruments using both simulated and patients' own medication regimens [4 instruments], e) performance-based instruments using a pillbox [2 instruments].

The main purpose of almost all of the instruments was to assess older adult patients' ability to take medications independently at home,[6-14, 16-31, 33-35] except for the PA tool, which was designed to assist with discharge-planning decisions in hospitals and the S-5 tool used to assess patients' readiness to self-medicate after stroke.[15, 32] Most of the identified instruments covered both cognitive and physical abilities to manage medications. [6-12, 14-25, 27, 28, 31-35] There were three instruments assessing only the cognitive ability to manage medications (VRAMMA, Medi-Cog, and PillQ).[13, 26, 29] Sensorial ability to manage medication was assessed in eight instruments, and these instruments covered cognitive and physical abilities as well (Patient's barriers to compliance, MMEI, MMAA, S-5, MAI, PA, SMAT, Pillbox test).[14, 15, 17, 18, 27, 32 -34]

The number of items included in each instrument varied from four to 44 items/questions and that was based upon the number of medication management skills that were assessed in each instrument. The medication management skills that were assessed varied per instrument. However, the most frequently assessed skills were identifying medications by reading the labels or recalling the name or appearance, opening and removing the correct dose from packaging, reading standard medication labels, and stating dosing time. In the instruments that used patients' own medications, cognitive ability to manage medications was assessed by asking the patients to identify/name all medications and state why and when each medication is taken. Physical ability was assessed by asking the patients to open/close medication vials/bottles, and removing the required dose from packaging. The instruments that used a simulated medication regimen tested patients' cognitive ability to manage medications by asking them to read and interpret prescription labels (in standard font size or in different font sizes) and/or organize a pillbox and perform some simple calculations. Physical ability was determined by assessing patients' ability to open/close child-resistant caps and/or different sizes of vials, and the ability to remove pills from vials. The other instruments determined the cognitive medication management ability by assessing what the patients knew about their medications (name, dose, indication, and timing) and assessed physical ability using standardized kits of prescription vials/bottles. Medi-Cog assesses only the cognitive function as patients are asked to fill in the correct number of "pills" in the correct compartments of a pillbox using a paper and pencil.[26] In contrast, the Pillbox test assesses both cognitive and physical ability by requiring patients to read standard prescription labels on five pill bottles containing colored beads (standard pill size) to fill a weekly pillbox.[27] Sensorial ability to manage medication was assessed primarily by asking patients to distinguish tablets by color and/or shape in all instruments.

The scoring system varied among instruments, however, most of them utilized the response format of yes and no (able and unable) and summed up all the yes or no responses at the end of the assessment. The scoring system was not reported for four instruments (MAI, patient's barriers to compliance, SM Task, and RACT)[14, 17, 19, 21] The VRAMMA and Pillbox Test had multiple scoring systems, and the SMAT instrument had five scales, and each one was scored differently.[13, 27, 33, 34]

The administration time may vary based upon the number of medications the patients were taking when patients' own medications were used for testing. Additionally, patients with cognitive impairment may take a longer time to complete the assessment in all types of instruments. The administration time was not reported in studies of eight instruments (PillQ, RACT, MMPT, VRAMMA, ManageMed, SMAT, Medi-Cog, Pillbox Test).[12, 13, 21, 26, 27, 29, 31] The administration time for the instruments that used patients' own medications ranged from 5 to 45 minutes. Most instruments that used standardized medication regimens for assessment were reported to take less than 20 minutes to complete with the exception of the MMAA instrument, which reported 45-60 minutes to complete.[9] The instruments assessing medication management skills by using both patients' own medications and standardized medication regimen took about 30 minutes to complete.

2.4 Discussion & Conclusion

Discussion

Recently, the area of developing a standardized instrument to quantify medication self-management capacity has been growing. A number of instruments have been developed to assess the medication management skills required by patients for safe and accurate use of medications.

Although some of the instruments identified for this evaluation were reviewed in previous papers, nine newly published instruments were identified. Most instruments were designed to identify cognitive and physical barriers to successful medication management. Despite this common rationale, there was inconsistency among the instruments in the specific skills that should be assessed. In addition, some of the instruments have not generated reliability evidence and some of them reported limited evidence of reliability. Because medication management is a complicated construct involving several skills and behaviors, a wide variety of measurements and comparisons were used to validate the instruments. Most of the instruments were validated by testing its association with at least one related construct measure such as cognitive function, ADL, IADL and/or adherence. Consequently, the evidence is insufficient to recommend a single instrument to be used in clinical practice or research as a "gold standard."

Clinical Applicability

Despite this wide range of attempts to develop a reliable and valid instrument assessing medication management capacity, none of the instruments has enough evidence to be recommended as a standard measure in clinical practice or research. A couple of earlier reviews nominated some instruments as promising measures for future studies based on the current reliability and validity evidence, and/or other characteristics such as length of the instrument, administration method, scoring system, and skills assessed. However, the recommendations made in the earlier reviews were inconsistent. Both reviews selected DRUGS, MedMaIDE, and MMAA, but there was controversy about recommending MMPT, HMS, MAT, MM Test, and MMEI.[3,4]

Therefore, it is important to propose specific desirable characteristics for a suitable measurement instrument intended to be used in clinical settings and studies. In Table 2.4, a list of ideal assessment instrument characteristics was created based on the findings of this review and

previous reviews. Regardless of the purpose of the instrument, the ideal assessment instruments share some basic characteristics. In general, the ideal instrument should be valid and reliable, objective and quantitative, easily administered with an uncomplicated scoring system and provide clear and interpretable results. In addition, it should be brief, administered in less than 30 minutes with minimal training and materials. The ideal instrument assessing medication management should assess both cognitive and physical abilities, but at the same time should not be overwhelming for the patient (Table 2.4). [2–4]

Using the patient's own medication regimen to assess MMC causes less stress on older adults (non-threatening), and reflects what they do routinely in real life (home) compared to using an unfamiliar simulated approach. Sometimes, patients are reluctant to bring their medications for review, especially older adult patients who may anticipate that poor performance may cause loss of independence. In contrast, using a simulated medication regimen for assessments needs special training and preparation of a standardized kit of medication labels and bottles. As a result, those instruments may not be easily portable. However, it is useful when patients' medications are not available, and helps to standardize the assessment process to compare between different groups and/or changes over time.[2,4]

Based on the current evidence, several cognitive and physical skills were recommended to be assessed for successful medication management, regardless of the methods each instrument uses to assess these skills. The ideal assessment instrument should assess some basic cognitive and physical tasks required to be performed by patients to manage medications independently in real-life. In terms of cognitive skills, the patients should be able to identify medications by whatever means (i.e. reading the label or recognize the appearance of medication), state indications, and describe dosing time and medication instructions. Additionally, knowing how and when to order

more medications (i.e. refills) was considered one of the basic cognitive skills that should be assessed by ideal medication management instruments. According to the medication self-management capacity model, the patients should be able to sustain the safe use of medication by being aware of the ongoing supply of medications.[36] However, MedMaIDE is the only instrument that determines patients' knowledge of how to get their medications. In term of physical skills, patients' ability to open their medication packaging and remove the required doses should be assessed. Most of the instruments assessed patients' ability to open child-resistant vials because they were developed in the U.S. where it is the most common type of packaging in the pharmacy community.

When managing complex and multiple medication regimens, some assessment measures require that patients be able to split the tablets and be able to handle and administer non-oral medications (such as different types of inhalers, injectable medications, eye and ear drops, and nasal sprays). However, few instruments assessed patients' ability to manage non-oral dosage forms and none of the instruments used a standardized method for assessing the required skills to manage non-oral medications. In addition, dose administration aids such as pillboxes are commonly used by patients required to take multiple medication regimens. Therefore, when the patients depend on a pillbox to organize their multi-drug regimens, their skills to correctly organize and fill the pillbox or use a pillbox filled by a caregiver should be assessed.

Based on this review, instruments utilizing the patients' own regimen are more applicable for use in clinical settings. DRUGS and MedMaIDE met most of the proposed characteristics for ideal instruments designed to assess medication management capacity. In addition, they reflect what the patients do routinely in real life (at home), do not require special preparation or materials, and cause less stress on patients compared to using an unfamiliar (simulated) approach.

MedMaIDE is the instrument that demonstrates the most promise for use in future research studies. It is the most comprehensive instrument compared to other identified instruments; the items included in MedMaIDE consolidate the required tasks associated with managing prescription. It is the only instrument that determines a patient's knowledge of how to get their medications, and is not limited to oral medications. In addition, it is reasonable in length, taking approximately 30 minutes to administer.

This literature review has several limitations. This review is limited to English language publications. In addition, the methodological quality of validation studies was not systematically assessed or reviewed. The list of the ideal instrument characteristics proposed is somewhat subjective, however, it was adapted from previous literature. The selection of instruments based on the proposed criteria is subjective and suited to studies done in clinical settings. There might be other factors that affect patients' capacity to manage medication (such as motivation for take medications, patients' perception about medication, and financial ability) that are not addressed in the current tools. These factors were beyond the scope of this review. Finally, only the initial validation studies were discussed in this review, which might omit some details or validation evidence studied later by the same group who developed the instrument or another independent group.

Conclusion

A number of instruments assessing medication management capacity have been published recently. However, the medication management skills assessed and the methods used to assess these skills varies between instruments. The majority of available instruments may help to determine cognitive and physical barriers to safe and accurate medication use, and guide the interventions based on potential patient needs. DRUGS and MedMaIDE demonstrate the most

characteristics consistent with the proposed criteria for an ideal instrument designed to assess medication management capacity that are applicable for clinical use.

Table 2.1 Search Strategy for Each Database

Databases	Research Strategy
PubMed/MEDLINE	(("Self Care"[MeSH] OR "Self Efficacy"[MeSH] OR "Self Administration"[MeSH] OR "Patient Compliance"[MeSH] OR "self care"[All Fields] OR "Medication Adherence"[MeSH] OR "self management"[All Fields] OR "self administration"[All Fields] OR "self medication"[All Fields] OR "self efficacy"[All Fields] OR "patient compliance"[All Fields] OR "medication adherence"[All Fields]) AND ("prescription"[All Fields] OR "prescriptions"[All Fields] OR "medication"[All Fields] OR "medications"[All Fields] OR "Medication Therapy Management"[MeSH] OR "medication management"[All Fields])) AND (“assessment”[ti] OR “assessments”[ti] OR “assess”[ti] OR “assessing”[ti] OR "validity"[ti] OR "validation"[ti] OR “validating” [ti] OR "reliability"[ti] OR "Psychometrics"[MeSH] OR "psychometric"[ti] OR "psychometrics"[ti])
CINAHL Complete	((MH "Self Care+" OR MH "Self Administration+" OR MH "Self Medication" OR "self care" OR "self efficacy" OR "self administration" OR "patient compliance" OR "medication adherence" OR "self management") AND (MH "Medication Management" OR MH "Medication Compliance" OR "prescription" OR "prescriptions" OR "medication" OR "medications" OR "Medication Therapy Management" OR "medication management")) AND TI (“assessment” OR “assessments” OR “assess” OR “assessing” OR "validity" OR "validation" OR “validating” OR "reliability" OR "psychometric" OR "psychometrics")
PsycINFO	((IndexTermsFilt: ("Self-Efficacy")) OR (IndexTermsFilt: ("Drug Self Administration")) OR (IndexTermsFilt: ("Self-Management"))) OR((Any Field: ("self care")) OR (Any Field: ("self efficacy")) OR (Any Field: ("self administration")) OR (Any Field: ("patient compliance")) OR (Any Field: ("medication adherence")) OR (Any Field: ("self management")))) AND(((IndexTermsFilt: ("Prescription Drugs")) OR (IndexTermsFilt: ("Drug Therapy"))) OR ((Any Field: ("prescription")) OR (Any Field: ("prescriptions"))OR (Any Field: ("medication")) OR (Any Field: ("medications")) OR (Any Field: ("Medication Therapy Management")) OR (Any Field: ("medication management"))))) AND ((title: ("assessment") OR title: ("assessments") ORtitle: ("assess") OR title: ("assessing") OR title: ("validity") OR title: ("validation") OR title: ("validating") OR title: ("reliability") OR title: ("psychometric") OR title: ("psychometrics")))
Embase	("self care" or "self management" or "self administration" or "self medication" or "self efficacy" or "patient compliance" or "medication adherence").mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] AND ("prescription" or "prescriptions" or "medication" or "medications" or "medication management").mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] AND ("assessment" or "assessments" or "assess" or "assessing" or "validity" or "validation" or "validating" or "reliability" or "psychometric" or "psychometrics").ti.
IPA	(("self care" OR "self efficacy" OR "self administration" OR "patient compliance" OR "medication adherence" OR "self management") AND ("prescription" OR "prescriptions" OR "medication" OR "medications" OR "Medication Therapy Management" OR "medication management")) AND TI (“assessment” OR “assessments” OR “assess” OR “assessing” OR "validity" OR "validation" OR “validating” OR "reliability" OR "psychometric" OR "psychometrics")

Figure 2.1 Screening and Reviewing Process

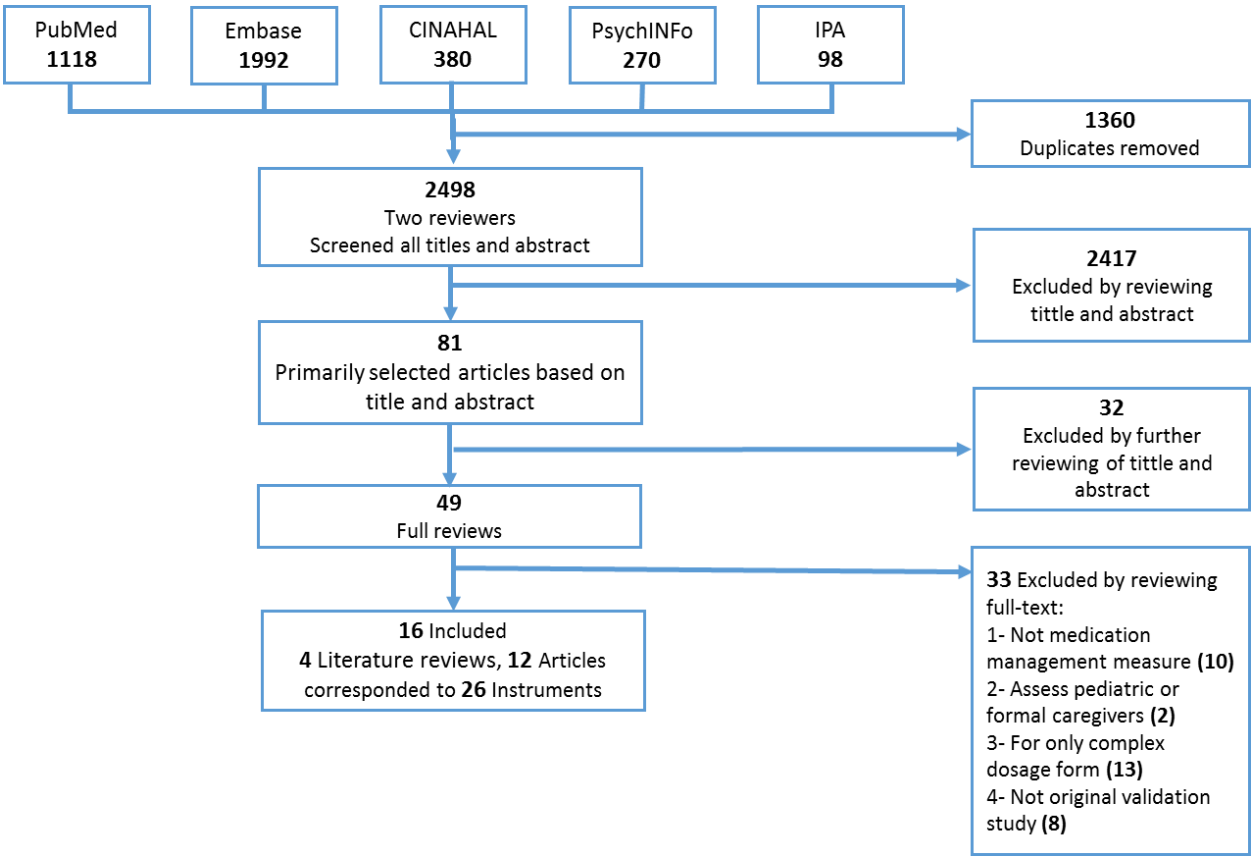

Table 2.2 Medication Management Capacity Assessment Instruments

			MM abilities assessed			MM skills assessed		
Instruments	**Purpose***	**# items**	**Cognitive**	**Physical**	**Sensorial**	**Skills assessed**	**Scoring Scale**	**Time (mins)#**
Performance-based instruments use patients' medication regimen								
DRUGS[7,8]	To examine the patient's capacity to manage his/her own medication regimen, and standardize the brown bag review	4	+	+		1) Identify meds, 2) open bottles/vials, 3) remove dose from package, 4) state time schedule	0-100	5-15
MedTake[6]	To quantify seniors' ability to take **oral** drugs safely, standardize the brown bag review	4	+	+		1) Identify meds & recall med names, 2) open bottles/vials & remove dose from package, 3) state indication, food/water coingestion, and 4) timing	0-100	30-45
MedMaIDE[16]	To identify the deficiencies in older adults' ability to take their medication at home • Assess different dosage forms	20	+	+		1) Medication knowledge (name all drugs and describe full regimen including indication, rout of administration, dose and time) 2) Medication taking ability (filling a glass of water, sip enough water, open bottles/vials, remove dose from package, and demonstrate admiration method for oral and non-oral dosage form) 3) Knowledge about ongoing supplies (identify existing refills, name of pharmacy or physician office, and available resources)	0-13	30
HOME–Rx[24,25]	To assess an older adult's ability to manage medication routines in the home and to identify at-risk behaviors by home health occupational therapists • Assess different dosage forms	16	+	+		knowledge of medications, Recall information, maniple of medication bottles and/or syringe (if used by pt), and calculate medication doses	1-16	30-45
Show Back [28]	To assess older adult medication self-management proficiency	5	+	+		1) Identifying meds, 2) explaining the indication, 3) Organizing pillbox, 4) describing the administration process for injectable and inhaled meds. or pills requiring cutting, 5) Describing the timing of doses	0-100	22

			MM abilities assessed			MM skills assessed		
Instruments	**Purpose***	**# items**	**Cognitive**	**Physical**	**Sensorial**	**Skills assessed**	**Scoring Scale**	**Time (mins)#**
Self-reported instruments use patients' medication regimen								
PillQ[29,30]	To assess decline in cognitive functioning and its impact on ADLs in patients with PD by asking patients or caregivers about whether patients can independently manage their medications	1	+			Ask the patients to clearly describe medications including doses (mg. or color of tablet) and medication schedule	0-3	
Performance-based instruments use standardized medication regimen								
Patient's barriers to compliance[17]	To assess functional abilities that can make compliance difficult for the older people	5	+	+	+	Recall, read small font, differentiate tablets by color and size, open different sizes of vials and liquid containers, and interpret instructions		< 10
MMEI[18]	To assess the patient's functional ability to take medication	5	+	+	+	1) Read Rx label, 2) Open and close a child-resistant & a non-child-resistant vials, 3) remove tablets from vails, 4) Interpret instruction, & 5) differentiate tablets by color.	0-5	< 5
SM Task[19]	To assess patients' ability to plan medication & successfully administer a new medication	5	+	+		1) Read the Rx label, 2) interpret the Rx instructions, 3) open the pill bottle; 4) cut pills when required, and 5) organize weekly pillbox		< 20
MM Test[20]	To assess high-level adaptive functioning in people with early dementia & MMC	17	+	+		1) Identify med, 2) Recall number of pills, 3) calculate days' supply, 4) explain med regimen, 5) know the indication, 6) open vial, 7) remove pills from the vial, & 8) describe the medication vial	0-46	< 5
RACT[21]	To assess patient's capacity to adhere to a medication regimen before its initiation	11	+	+		1) Read and interpret Rx & auxiliary labels, 2) open/close & remove/return pills from vials, 3) what should be done when missing a dose, or having adverse effects		
MMT[22]	To assess patients' ability to comply to anti-retroviral medication regimens	20	+	+		1) Organize weekly pillbox, 2) calculate day's supply, 3) read and interpret Rx & axillary labels, 4) what should be done when missing a dose, or having adverse effects	0-100	15-25
MMT-R[23]	To assess patients' ability to comply to anti-retroviral medication regimens	11	+	+		Same as MMT	0-10	10

			MM abilities assessed			MM skills assessed		
Instruments	**Purpose***	**# items**	**Cognitive**	**Physical**	**Sensorial**	**Skills assessed**	**Scoring Scale**	**Time (mins)#**
MMAA[9]	To assess geriatric mental health patients ability to independently manage medications	4	+	+	+	1) recall information, 2) describe full regimen, 3) open/close, 4) remove the dose from vials, 5) differentiate tablet by color	0-25	45-60
HMS[10]	To test older adults' ability to understand and implement a routine prescription medication	2	+	+		1) Read Rx labels, 2) comprehend medication regimen, 3) plan a schedule for meds regimen, 4) open & close vails, 5) remove dose from vials, 6) organize pillbox.	0-11	15-30
MAT[11]	To aid in placement decisions regarding level of care bases on MMC	10	+	+		1) read Rx labels, 2) comprehend medication regimen, 3) open & close vails, 4) remove dose from vials, 5) organize pillbox	0-100	5-15
MMPT[12]	To identify visual, physical and cognitive barriers in MM in older adults	5	+	+		1) Read Rx labels, 2) open vials, 3) interpret medication instruction, 4) calculate days' supply	0-5	
VRAMMA[13]	To assess MM skills in patients with schizophrenia	4	+			1) Read Rx label, 2) interpret medication instruction	No specific	
ManageMed[31]	To quickly determine if someone can handle a moderately difficult medication routine	33	+	+		1) red Rx label, 2) recall information, 3) open/close vials, 4) perform calculations, 5) organize pillbox	0-42	15-20
S-5[32]	To screen the safety and readiness of self-medication after stroke.	16	+	+	+	1) Read Rx labels, 2) recall information, 3) interpret med instruction, 4) open different vails, 5) differentiate tablets by shape, color, & size, 6) describing the administration process for injectable med (if required)	Yes-no	4-6
Performance-based instruments use both standardized & patient's medication regimens								
MAI[14]	To evaluate patients' knowledge and skills to take medications and identify barriers to optimal MM	2	+	+	+	1) Read Rx & auxiliary labels, 2)open different vails, 3) differentiate tablets by color, 4) name all meds, 5) state indication, 6) duration med should be taken, 7) state dose and time		15 – 30
PA[15]	To identify barriers to medication self-administration and to assist discharge-planning decisions in hospital	28	+	+	+	1) Read labels, 2) open vials, 3) remove dose from vials, 4) differentiate tables by color, 5) organize pillbox, 6) describe a regimen, & 7) swallow pills	0-28	20

			MM abilities assessed			MM skills assessed		
Instruments	**Purpose***	**# items**	**Cognitive**	**Physical**	**Sensorial**	**Skills assessed**	**Scoring Scale**	**Time (mins)#**
SMAT[33,34]	To screen for MM deficits in older adults & facilitate targeted interventions	44	+	+	+	1) Read Rx labels, 2) recall information, 3) interpret medication instruction, 4) open vials, 5) remove tablets from packaging, 6) differentiate tablet by color, & 7) organize pillbox	Multiple scale	
RAT[35]	To assess elderly patients' needs for additional support in managing their medicines	13	+	+		1) Read Rx labels, 2) open different medication packaging, 3) manipulate with 5 ml spoon and eye or ear drop bottles	0-26	5-20
Performance-based instruments use only pillbox								
Medi-Cog[26]	To assess patients' ability to fill their own prescribed medications into a pillbox	3	+			1) Read Rx labels, 2) interpret medication instructions, 3) organize pillbox	0-10	
Pillbox Test[27]	To asses a four compartment of Executive Function through the real-time assessment of MM	5	+	+	+	1) Read Rx labels, 2) interpret medication instruction, 3) open vails, 4) differentiate tables by color, 5) organize pillbox	No specific	

MM = medication management, Meds = medications, DRUGS = Drug Regimen Unassisted Grading Scale, MedMaIDE = Medication Management Instrument for Deficiencies in the Elderly, HOME–Rx = In-Home Medication Management Performance Evaluation, PillQ = Pill Questionnaire, MMEI = Medication Management Evaluation Instrument, SM Task = Standardized Medication Task, MM Test = Medication Management Test, RACT = Regimen Adherence Capability Test, MMT = Medication Management Test, MMT-R = Medication Management Test-Revised, MMAA = Medication Management Ability Assessment, HMS = Hopkins Medication Schedule, MAT = Medication Administration Test, MMPT = Medication Management Performance Test, VRAMMA = Virtual Reality Apartment Medication Management Assessment, S-5 = Self-Medication Safety Post-Stroke Scale (S-5), MAI = Medication Assessment Instruments, PA = Pharmacy Assessment, SMAT = Self-Medication Assessment Tool, RAT = Self-medication Risk Assessment Tool

* Purpose stated as described by the developers

Reported administration time (minutes)

Table 2.3 Studies that Introduced a Medication Management Assessment Instrument

	Study description				Validity		Reliability		
Instruments (Authors, year)	**Design**	**Aim**	**Sample, n**	**Age, years mean (SD)**	**Content**	**Construct^**	**Inter-rater***	**Test-retest***	**Internal consistency****
Performance-based instruments use patients' own medications									
DRUGS (Edelberg H.K., et al., 1999) (Edelberg H.K., et al., 2000) U.S.	Cross-sectional Prospective cohort	To introduce DRUGS and examine the relationship between inability to take medications and cognitive impairment	Outpatient older adults, 59	84.20 (5.1)	+	Cognitive function (MMSE) Functional status (ADL & IADL) Self-reported MMC Health literacy	+ (>0.90)	+ (>0.90)	
MedTake (Raehl C.L., et al., 2002) U.S.	Cross-sectional	To quantify how seniors' ability to take oral drugs safely may correlate with age, sex, socioeconomic status, education, cognitive impairment, depression, and drug self-management	Outpatient older adults, 57	79.49 (7.26)	+	Cognitive function (MMSE) Educational level			
MedMaIDE (Orwig D., et al., 2006) U.S.	Cross-sectional	To describe the MedMaIDE and to provide results of reliability and validity testing	Outpatient older adults, 50	78.18 (7.21)	+	Cognitive function (MMSE) Functional status (ADL) Med. adherence (pill count)	+ (0.74)	+ (0.93)	+ (0.71)
HOME-Rx (Bolduc JJ, et al., 2015) (Murphy M.C., et al., 2017) U.S.	Cross-sectional	To develop a novel, performance-based medication adherence assessment, HOME–Rx	Community-dwelling older adults, 5 Experts, 7	75.6 (4.4)	+	Cognitive function (MoCA) MMC (MangeMed)			
Show Back (Kapoor A., et al., 2018) U.S.	Cross-sectional	To develop a standardized simulation to assess MM proficiency in older adult by home nurses and test reliability	Community-dwelling older Adults, 10	76 (7.1)	+		+ $		
Self-reported instruments use patients' own medications									
PillQ (Kim J.S., et al., 2013) South Korea	Cross-sectional	To evaluate the correlation between ability to MM and	Outpatient with PD, 208	66.4 (7.1)	+	Cognitive function (MMES, MoCA, CDR)			

		cognitive functioning in patients with Parkinson's disease				Function status (ADL)			
	Study description				**Validity**		**Reliability**		
Instruments (Authors, year)	**Design**	**Aim**	**Sample, n**	**Age, years mean (SD)**	**Content**	**Construct^**	**Inter-rater***	**Test-retest***	**Internal consistency****
Performance-based instruments use standardized medication regimen									
Patient's barriers to compliance (Hurd P.D., et at., 1986) U.S.	Cross-sectional	To understand the patient's barriers to compliance	Outpatient older adults, 14	75.5	+	Age			
MMEI (Meyer M.E., et al., 1989) U.S.	Cross-sectional	To develop a simple objective screening tool that assess the patient's functional ability to take medications.	In & outpatient older adults, 93	74.3 (10.1)	+	Cognitive function (CCSE)			
SM Task (Isaac L.M., et al., 1993) Canada	Cross-sectional	To describe the development of a method for assessing the relationship between cognitive function, comprehension, and compliance with medication	Outpatient older adults, 20	71.5 (5.8)	+	Cognitive function (neuropsychological battery) Function status (grip strength) Self-reported adherence			
MM Test (Gurland B.J., et al., 1994) U.S.	Cross-sectional	To measure high-level adaptive cognitive functioning in early dementia	Older adults, 259	Range (65-85)	+	Cognitive function (CARE) Dementia diagnosis			+ (0.82)
RACT (Fitten L.J., et al., 1995) U.S.	Cross-sectional	To develop an instrument that will facilitate and focus the assessment of a patient's capacity to adhere to a medication regimen before its initiation	In & outpatient older adults, 55	69.95 (7.46)	+	Cognitive function (MMES) Different patients group	+ (0.70)		
MMT (Albert S.M., et al., 1999) U.S.	Cross-sectional	To examine the relationship between neuropsychological status, MMT, and antiviral medication adherence.	HIV-positive patients, 61	42.25	+	Cognitive function (neuropsychological battery test) Self-reported adherence	+ (≥0.72)		+ (≥0.74)

	Study description				Validity		Reliability		
Instruments (Authors, year)	**Design**	**Aim**	**Sample, n**	**Age, years mean (SD)**	**Content**	**Construct^**	**Inter-rater***	**Test-retest***	**Internal consistency****
MMT-R (Heaton R.K., et al., 2004) U.S.	Cross-sectional	To evaluate the impact of HIV-associated NP impairment in HIV-infected patients	HIV-positive patients, 267	39.32 (7.52)	+	Cognitive function (neuropsychological battery test) Function status (IADL)		+ (0.96)	+ (0.72)
MMAA (Patterson T.L., et al., 2002) U.S.	Cross-sectional	To introduce MMAA, and compare its findings with adherence	Healthy participant, 33 vs. Schizophrenic patients. 104	63.10 (8.8) 56.10 (8.4)	+	Cognitive function (neuropsychological battery test) Adherence (Pharmacy data)			+ (0.96)
HMS (Carlson M.C., et al 2005) U.S.	Cross-sectional	To develop HMS and validate it	Outpatient females, 360	77.5 (2.8)	+	Cognitive function (MMSE) Functional status (IADL)			+ (0.38)
MAT (Schmidt K.S., et al., 2005) U.S.	Cross-sectional	To examine the construct and concurrent validity of the MAT	Community-dwelling older adults, 62	85.56	+	Cognitive function (MMSE) Functional status (IADL)			
MMPT (Beckman G.K., et al., 2005) Sweden	Cross-sectional	To uses performance tests of hand function, vision and medication competence to assess the limitations in these dimensions in a population-based sample of elderly people	Community-dwelling older adults, 492	82.9	+	Self-reported MM			
VRAMMA (Kurtz M.M., et al., 2007) U.S.	Cross-sectional	To validate VRAMMA as a tool for measuring MM skill in patients with schizophrenia	patients with schizophrenia, 25 & healthy people, 18	42.1 (10.5)	+	Cognitive function (neuropsychological battery test) MMC (MMAA)			
ManageMed (Robnett R.H., et al., 2007) U.S.	Cross-sectional	To introduce ManageMed and complete initial reliability and	Outpatient older adults, 67	76 Range (47-95)	+	Neurocognitive function (Cognistat)	+ (0.86-0.96)		+ (0.89)

		validity analyses on the ManageMed Screening				Number of meds taken			
S-5 (Kaizer F., et al., 2010) Canada	Cross-sectional	To develop and pilot test a S-5 to be used in screening for self-medication safety in individuals after stroke	Patients with stroke, 6	Range (50-70)	+				
Performance-based instruments use both standardized and patient's medication regimens									
MAI (Murray M.D., et al., 1986) U.S.	Cross-sectional	To examine the extent and correlates of noncompliance in community-dwelling older adults	Outpatient older adults, 140	71.59 (9.81)	+	Self-reported adherence			
PA (Romonko L., et al., 1992) Canada	Cross-sectional	develop an PA to better identify drug and patient-specific concerns and to then compare it to nursing and medical assessments utilized in geriatric	Hospital discharged patients, 51	80.9	+	Self-reported adherence Hospital self-medicated program Medication-related problems			
SMAT (Irvine-Meek J.M., et al., 2011) Canada	Cross-sectional	To evaluate the psychometric properties, as well as the usability, of the SMAT, an instrument designed to measure elderly patients' ability to manage their medications	Older adults patients, 121	81.5 (7.3)	+	Cognitive function (MMSE, CDT, CCT) Medication regimen complexity Self-reported adherence	+ (≥0.79)	+ (≥0.83)	+ (≥ 0.81)
RAT (Lubinga S.J., et al., 2011) U.K.	Cross-sectional	To determine scale reliability and validate the instrument against community pharmacists' assessment of patients' ability to manage their medicines	community dwelling elderly patients, 37	Median = 76 (IQR=72, 82)	+	Patient's comprehension and dexterity of handling the medications			+ (≥0.79)
Performance-based instruments use pillbox									
Medi-Cog (Anderson K., 2008) U.S.	Cross-sectional	to evaluate the association between the MMSE, Mini-Cog, MTS, or Medi-Cog cognitive screens with patients' ability to fill their own prescribed medications into a pillbox	Hospital discharged patients, 62	62.5 (13.5)	+	Cognitive function Correctly filled pills			
Pillbox Test (Zartman A.L., 2013) U.S.	Cross-sectional	To examine the construct validity of a new measure of EF, the Pillbox Test which is a real-time	Patients with Alzheimer'	68.63 (8.08)	+	Executive Cognitive Function measures			

		assessment of medication management	s Disease & dementia, 40 Healthy controlled group, 80						

DRUGS = Drug Regimen Unassisted Grading Scale, MedMaIDE = Medication Management Instrument for Deficiencies in the Elderly, MoCA = Montreal Assessment of Cognition, HOME-RX = In-Home Medication Management Performance, CDR = Clinical Dementia Rating Scale, CARE= Comprehensive Assessment and Referral Interview. CCSE = Cognitive Capacity Screening Examination, CDT = Clock Drawing Test, CCT = Cognitive Competency Test , SM Task = Standardized Medication Task, MM Test = Medication Management Test, RACT = Regimen Adherence Capability Test, MMT = Medication Management Test, MMT-R = Medication Management Test-Revised, MMAA = Medication Management Ability Assessment, PA = Pharmacy Assessment, HMS = Hopkins Medication Schedule, MAT = Medication Administration Test, MMPT = Medication Management Performance Test, VRAMMA = Virtual Reality Apartment Medication Management Assessment, S-5 = Self-Medication Safety Post-Stroke Scale, MAI = Medication Assessment Instruments, SMAT = Self-Medication Assessment Tool, RAT = Self-medication Risk Assessment Tool, MTS = MedicationTransfer Screen

* Reliability coefficient
** Alpha coefficient
^ Significant correlation or association
$ Interrater agreement was reported as κ values for identification (κ = 0.220, 95% CI = −0.142-0.584), explanation (κ = 0.837, 95% CI = 0.627-1.046), organization (κ = 0.840, 95% CI = 0.442 - 1.229), administration (κ = 0.633, 95% CI = 0.232-1.034), and timing (κ = 0.702, 95% CI = 0.409-0.997)

Table 2.4 Characteristics for Instruments Assessing Medication Management Capacity

	Using patients' own medications						Using standardized medication regimen														Using both patient's own medications and a standardized regimen				Using pillbox	
Characteristics	DRUGS	MedTake	MedMaIDE	HOME–Rx	Show Back	PillQ	Hurd	MMEI	SM Task	MM Test	RACT	MMT	MMT-R	MMAA	HMS	MAT	MMPT	VRAMMA	ManageMed	S-5	MAI	PA	SMAT	RAT	Medi-Cog	Pillbox Test
Assess cognitive & physical abilities	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X		X
Cognitive MM skills																										
Identify medications * /Or Read a standard med. label	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
State indications		X	X	X	X	X				X											X		X			
Describe dosing time	X	X	X	X	X	X	X			X	X			X	X	X					X	X	X			
Describe instructions on label		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Know how to get refills			X																							
Refill pillbox [$]					X				X			X	X		X	X			X			X	X		X	X
Physical MM skills																										
Open medication packaging	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X		X
Remove tablets	X	X	X	X						X	X	X	X	X	X	X			X			X	X	X		X
Split tablets [$]					X				X																	
Administer non-oral drug ^			X	X	X															X				X		
Other characteristics																										
Brief [§]	X		X	X	X		X	X	X	X		X	X	X	X	X			X	X	X	X		X	X	
Small & Portable	X	X	X	X	X	X																			X	
Objective	X	X	X	X	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
More than self-reported	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Uncomplicated scoring system	X	X	X	X	X	X		X		X		X	X	X	X	X	X		X	X		X		X	X	
Less overwhelming or threatening	X	X	X	X	X	X																				
Reliable [¥]	X		X																				X			
Valid [£]	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X
Sensitive to change in function over time	X														X											
Guide future intervention	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

* Identify medications by any means such as recalling medication name, distinguishing the appearance, or reading the label
^ Such as, measuring a dose of liquid medication, administering injectable medications, and using inhalers devices
¥ Having complete and acceptable reliability evidence including inter-rater, test-retest reliability and/or internal consistency
§ Reported administration time ≤ 30 minutes
$ If required or relevant
£ Having some sort of construct testing beside simple content validity

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CHAPTER THREE

SPECIFIC AIMS AND SIGNIFICNE

3.1 Hypotheses and Specific Aims

The overall goal of this line of research is to identify older adults living independently in low-income senior housing who are at risk of losing independence due to medication mismanagement by screening for medication self-management deficits. This will be achieved by addressing the following specific aims:

Specific Aim One: To determine the cognitive and physical deficiencies in MMC among older adults who live in low-income housing.

Hypothesis: A substantial number of older adults who live in low-income housing will have significant cognitive and physical functional deficiencies in their MMC (low capacity to manage their medication).

Specific Aim Two: To identify variables that predict low MMC among older adults who live in low- income housing.

2.1) Assess the relationship between MMC and demographic characteristics.

2.2) Assess the association between MMC and the number of medications and doses that are taken per day and medication-taking behavior.

2.3) Assess the association between MMC and comorbidities.

2.4) Assess the association between MMC and health literacy, cognitive and functional status, and depression symptoms.

Hypothesis: Lower MMC in older adults is associated with increased number of medications and doses taken daily, increased number of medical conditions, declined in cognitive and functional status, lower health literacy, and having depression.

Specific Aim Three: To determine the impact of using medication aids and specialized pharmacy services on MMC, with aids including medication cards/lists, organizers and reminders, and using specialized medication packaging, easy-to-open containers, large-print labels, medication synchronization, or prescription home delivery service.

Hypothesis: Using at least one specialized pharmaceutical service will increase the MM score.

Specific Aim Four: To determine the association between MMC and ER utilization over the past six months in this population.

Hypothesis: Older adults with low MMC will be at a higher risk of using the ER.

3.2 Significance

Living in a low-income community with age-related decline in cognitive and functional ability coupled with multiple comorbidities increases the demand for community-based long-term services and support (LTSS). LTSS provides assistance with daily self-care tasks such as eating, bathing, dressing, managing medication, and preparing meals. It is estimated that 70% of older adults will need LTSS at some point in their life.[1] Problems related to medication mismanagement are costly and may lead to serious complications such as hospitalization and institutionalization.[2,3] In fact, a study on the causes of hospitalization among community-dwelling older adults confirmed that the risk of hospital and long-term care admissions increased with lack of assistance when medication support was needed.[4] Moreover, the U.S. healthcare system could save as much as $2.6 billion by retaining community-dwelling older adults to age in their homes instead of transferring them to long-term care facilities.[5]

Therefore, understanding the challenges that low-income older adults face during routine management of medications may help identify targets for future intervention to ensure safe medication use. This indirectly will promote healthy aging in place and independence in this population. Consequently, healthcare utilization and the strain on community-based LTSS might be reduced as well.

This study seeks to identify factors among independently-living low-income older adults that may predict deficiencies with medication self-management, which could guide future interventions. First, by exploring the relationship between MMC and various factors, we will help identify individuals who are at risk for medication mismanagement. Second, determining cognitive and physical deficiencies in medication management could help healthcare providers (e.g. pharmacists) identify key targets for intervention strategies based on the individual's need, to enhance medication use. For example, providing counseling sessions for older adults who have limited knowledge about their medications or ordering non-child resistant or specialized packaging for those who have difficulty opening the bottles of their medication.

In summary, this study seeks to determine the medication self-management capacity among low-income older adults. In addition, it identifies risk factors that may predict deficiency in medication self-management capacity among this population, which helps to guide intervention based on their needs. This study will add evidence for the utility of using a standardized tool to assess MMC in outpatient settings and ultimately guide interventions to help older adult people to maintain their independence in their home.

3.3 References

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CHAPTER FOUR

METHODS

4.1 Study Design

This is an observational, cross-sectional study. The study data was collected during a semi-structured interview using a battery of assessments. These assessments were selected based upon the reliability and validity data supporting use in outpatient settings as well as the time required to be administered. The recruitment, eligibility screening and interviewing was performed by the study investigator (Amal Badawoud). All assessments were performed by the study investigator during a scheduled, face-to-face interview with each eligible participant. . The participants were asked to bring all of their current medication containers (i.e. all medications that they use regularly) to the interview, including prescription and over-the-counter (OTC) medications, vitamins and minerals, and dietary supplements (anything they used on a regular basis).

4.2 Study Setting and Participants

This study was conducted in five low-income apartment buildings that are served by the community-based Richmond Health and Wellness Program (RHWP). These buildings are designated for low-income people who are aged 55 years and older or individuals with disabilities. They are located in downtown Richmond, Virginia, and are considered as healthcare "hot spot" areas where the population lives with a high burden of chronic illnesses, and increased healthcare utilization such as unnecessary emergency room (ER) visits and ambulance use. Therefore, the overall goal of RHWP is to reduce unnecessary health care utilization through health and wellness promotion. It is designed to provide care coordination services to residents, as well as education, training, and research opportunities for healthcare students. For example, RHWP clinics provide medication management, geriatric assessments, follow-up and communication with primary care

providers, and blood pressure and glucose monitoring.[1] RHWP is based on a patient-centered care principle, where residents' needs determine the care and support provided by an interprofessional team. The team consists of three to four students ─ from the VCU Schools of Nursing, Pharmacy, Medicine, Social Work, and the Department of Psychology ─ who are overseen by licensed clinical faculty. The main goal is to improve residents' health outcomes, experience with the healthcare system, and quality of life in order to decrease healthcare costs. At the same time, this practice also improves students' performance.[1]

Approximately 247 residents live in Building 1, 137 live in Building 2, 105 residents live in Building 3, 77 live in Building 4, and 55 live in Building 5. A total of 348 residents were enrolled in RHWP from September 2012 through December 2016. The majority of RHWP enrollees are female (58%), African-American (72%), and with an average age of 74 years. Half of the enrollees have two or more chronic diseases. Most residents (84.5%) live independently (i.e. do not have help/aid in the home), and approximately 65% are unable to drive. Most of them use assistive devices, approximately 36% use a cane, 28% use walker, and 7% are in a wheelchair.[1,2]

Reviewing residents' medications is an important service provided by the RHWP. The most frequent interventions were individualized medication counseling (52%), and medication management (24.7%).[2] Most of RHWP enrollees (90%) are responsible for managing their medication independently, and approximately 80% of enrollees are responsible for ordering their medication refills. About 45% of them brought their medications to the RHWP clinics for review. Residents reported some medication-related issues including having difficulty reading prescription labels (18%), opening prescription bottles (16%), paying for medications (11%), and getting refills on time (12%).

Inclusion and Exclusion Criteria:

Residents living in buildings served by RHWP were recruited for this study based upon the following criteria: those who were: 1) living in one of the five apartments buildings served by RHWP, 2) aged 55 years or older, 3) currently taking at least one prescription or over-the-counter (OTC) medication, 4) living independently, 5) not relying on another person to administer medications (i.e. family members, friends, or caregivers), 6) able to read and converse in English, 7) not diagnosed with Alzheimer's disease or dementia, and 8) not taking any medications for memory such as cholinesterase inhibitors and memantine (i.e. inferred diagnosis of dementia).

Exclusion criteria included participants who were: 1) less than 55 years old, 2) not taking at least one prescription or OTC medication on a regular basis, 3) fully relying on a caregiver to administer medications, 4) not able to communicate in English, or 5) reported having a diagnosis of Alzheimer's disease or dementia or taking any medication for memory. For example: any participants taking cholinesterase inhibitors which include donepezil (Aricept®), rivastigmine (Exelon®), galantamine (Razadyne®, Razadyne ER®); memantine which include (Namenda®, Namenda Titration Pak®, Namenda XR®, or Namenda XR Titration Pack®); or taking combination of memantine and Donepezil (Namzaric®) were excluded. The Screening for Eligibility form is in Appendix 1.

4.3 Recruitment Strategy & Screening for Eligibility

The ideal sampling strategy would be a random selection of residents living in subsidized housing communities under HUD. However, it would be difficult to access HUD data due to ethical consideration and privacy concerns and policies to protect privacy, especially for the vulnerable older adult population. In addition, using this sampling stratgy would be very expensive and it might take a longer time for recrutiment.

Therefore, a nonprobability (non-random) sampling strategy, primarily a convenience sampling technique, was used to recruit the study participants. Convenience sampling is a type of nonprobability sampling where the target population meets certain predefined criteria, such as easy accessibility, availability at a specific period of time, or willingness to participate. In other words, the convenience sample is the population who is easily accessible to the researcher.[3] This sampling technique is convenient, easy, and affordable. Typically, the convenience sample is homogeneous because they are recruited from one target population. However, the main disadvantage of this sampling technique is limited generalizability; the results may not be representative of the entire population.

Furthermore, a snowball sampling technique was used where the study participants were asked to encourage other people to participate in the study. During the recruitment phase, those participants who completed the study interview referred their friends and neighbors in the buildings to participate in the study. Using this sampling technique helps to accelerate the recruitment process within a short period of time. Like convenience sampling, this sampling technique may lead to limited generalizability and selection bias.[3]Several recruitment methods were used in this study including 1) posting flyers around the apartment buildings and RHWP clinics, 2) distributing the brochure to residents in all buildings, and 3) introducing the study to residents during group education sessions given by RHWP providers. The study flyer and brochure included a brief description of the study and inclusion criteria and contact information for study investigators. The study recruitment flyer and brochure are in Appendix 2.

In order to partner with the housing buildings and gaining permission to post the study's flyers and distribute brochures, the study investigators shared the information about the study with the resident services coordinators at each building. In addition, the study investigators met with

RHWP clinic staff and discussed the study aims and methods with them to ensure that the conduct of the study was not disruptive to clinic operations but rather was complementary to the clinic. These are some of the important factors in successfully carrying out community-based research—getting buy-in from multiple stakeholders to drive success.

The study investigator was responsible for answering any questions about the study from the residents who were interested in participating in the study. The contact information of the investigator was given to the residents who had questions or wanted more information about the study. After getting all their questions about the study answered, participants signed the screening consent form. All residents who were interested in the study were screened for eligibility based on the inclusion criteria. To see if they were eligible to be in this study, they were asked about their age, medication history, whether they were living independently, able to manage their medication with no assistance, and whether they had been diagnosed with Alzheimer's disease, dementia or memory problems. This screening interview took approximately five minutes or less. Potential study participants had the option to complete this screening process over the phone or in-person. Both in person and telephone screening consent forms were developed by the investigator and approved by the VCU Institutional Review Board. The screening consent form included a brief description of the study, its purpose, voluntary participation, risks and benefits, confidentiality protections, and HIPAA authorization, as well as the contact information for the study PI. The in-person and telephone screening consent forms are in Appendix 3.

After screening for eligibility, the individual interview was scheduled by the investigator for each eligible participant. Eligible participants were asked to bring their current medication containers (i.e. all medications that they use regularly), including prescription and OTC medications, and vitamins and minerals. In addition, the investigator conducted a day-before reminder phone call

with eligible participants who provided their phone number. The script for the phone call reminder/message is in Appendix 4.

4.4 Interview Procedure

The investigator was available in the community area at each resident building during RHWP clinic hours. Many candidate participants came to the clinic with their medication, ready for the individual study interview. In this case, the investigator started the interview screening for eligibility and then proceeded with the study interview. Typically, the study interview procedure took about 30 to 45 minutes, and not more than 60 minutes. All study interviews took place in a private area during RHWP clinic hours. At the beginning of the interview, the investigator completed a Research Subject Information and Consent Form with each eligible participant. The Research Subject Information and Consent Form is in Appendix 5. Before asking the participant to provide their signature on the informed consent form, the investigator went over each section in the consent form with the participants and answered any remaining questions. The informed consent form was developed by the study investigator. It included detailed information about the study, its purpose and process, risk and discomfort, benefits, cost and payment process, confidentiality, voluntary participation and withdrawal, and HIPAA authorization. In addition, it included the full contact information for the study PI and the office of research at VCU. It was approved by the VCU IRB. A copy of the full informed consent form was provided for all participants as a reference for them.

After completing the consent process, the demographic information and medical history were collected. The participant was then asked to display all medication containers they brought with them and the investigator gathered all relevant information (see section 4.2 medication list). Using the complete and comprehensive list of medication taken, a participants' medication self-

management capacity was assessed using the Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE) Tool.[6] Following the MMC assessment, participants were asked questions related to their medication-taking behavior, using medication aids, ordering pharmacy services, and ER utilization in the last six months. Following that, additional assessments were administered with the following order: health literacy, cognitive function, functional status, and depression symptoms. Upon completing all assessments, each participant received $15 cash as compensation for their time.

4.5 Study Measures

Demographic Characteristics: Each participant was asked about his/her age, sex (male and female), race (Caucasian, African-American or Black, Hispanic, and Other), marital status (single, married, separated, divorced, and widowed), educational level (less than high school diploma, high school graduate/GED, some college, college degree completed), and type of insurance (Medicaid, Medicare, Dual Eligible, Veteran, other). In addition, the participants were asked to report their living arrangement (alone, or with other people), as well as how they would rate their health status in general (excellent, very good, good, fair, poor).

Medical History: The number of comorbidities was recorded using the Functional Comorbidity Index (FCI). It is a list of 18 clinical comorbidities validated for adjusting the impact of comorbidity on physical functional status. Participants were asked if they had any of the 18 medical conditions included in the FCI: arthritis, osteoporosis, asthma, chronic obstructive pulmonary disease (COPD) (or acquired respiratory distress syndrome (ARDS) or emphysema), angina, congestive heart failure (or heart disease), heart attack (or myocardial infarction), neurological disease (e.g., multiple sclerosis or Parkinson's disease), stroke (or transient ischemic attack (TIA)), peripheral vascular disease, diabetes types I and II, upper gastrointestinal disease (e.g., ulcer,

hernia, reflux), depression, anxiety or panic disorders, visual impairment (e.g., cataracts, glaucoma, macular degeneration), hearing impairment (i.e., very hard of hearing even with hearing aids), degenerative disc disease (e.g., back disease, spinal stenosis, or severe chronic back pain), or obesity and/or body mass index (BMI) > 30. The weight in pounds and height in inches were collected to calculate the BMI. Each listed medical condition is given one point if present and the final score for the FCI is the sum of all present conditions, which ranges from 0 to 18.[4]

Medication List: A medication list was created for all medications that were brought by the participant to the study interview. In the list, the investigator recorded information about each medication including name (brand or generic), strength, dosage form, dose, the route of administration, and frequency based upon the label on the medication bottle. The dose and frequency were not recorded for those prescription medications with a lost or unreadable label. A total number of medications was calculated as the absolute total count of medications brought by the participant during the study visit, including prescription and OTC medications, vitamins/minerals, and dietary supplements as well as as-needed medications (PRN). The number of daily doses was the count of total doses for these medications except for the PRN medications doses. For example, two tablets three times per day counted as three doses, regardless of the number of tablets taken for one medication dose.

Medication Regimen Complexity: The information collected in the medication list was used to calculate the complexity of the medication regimen for each participant using the Medication Regimen Complexity Index (MRCI) tool.[5] MRCI was selected because it has been widely used in research studies and validated among older adult patients. It is a reliable and valid tool designed to quantify the complexity of the prescribed medication regimen based upon the dosage form, dosing frequency, and the additional administration directions for each medication in the regimen.

It includes 65 criteria divided into three sections, and each item is assigned a weighted score corresponding to the relative degree of complexity it adds to the regimen. The first section includes the weighting score for different dosage forms (e.g. oral: capsules/tablets, liquids, sublingual sprays/tablets; topical: creams/gels/ointments, patches). The second section represents the weighting score corresponding to the dosing frequency for each medication in the regimen. The third section indicates the additional directions if present for each medication. The total MRCI score is the sum of the scores of the three sections. Since the total MRCI score is based upon how many prescription medications have been taken by the patient, the minimum total score could be 0 while there is no maximum score.[5] In this study, MRC was assessed for only the prescribed (scheduled and PRN) medications.

Medication Self-Management Capacity (MMC): The Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE) was used to assess the participants' MMC. It was selected based upon a comprehensive review conducted to identify the suitable, published MMC instruments that designed to assess both cognitive and physical ability of older adults to manage their medications independently. It was the instrument that demonstrates the most promise to be used in this study. It is a standardized performance-based instrument and has been validated in outpatient settings. It is the most comprehensive instrument compared to other identified instruments; the items included in MedMaIDE consolidate the required tasks associated with managing prescription medication and encompass all six steps of the model of medication self-management. It is the only instrument that determines patient's knowledge of how to get their medications, and is not limited to oral medications. In addition, it is short and quick, it takes approximately 30 minutes to administer.[6]

It was developed by a panel of experts in gerontology at the University of Maryland. Previous research has shown that MedMaIDE is a reliable [test-retest reliability (CC= 0.93), interrater reliability (CC= 0.74), and internal consistency (Cronbach's alpha = 0.71)] and valid instrument for identifying cognitive and functional deficiencies in managing medications among older adults in home settings using their own medications.[6,7] The assessment procedure is based upon observing the medication-taking ability and assessing the knowledge about the individual's own medications. It includes 20 items covering three important areas of medication self-management: 1) medication knowledge, 2) medication-taking ability, and 3) knowledge about the ongoing supply of medications. This medication knowledge was assessed by asking the person to name all medications; state when, how, why, and the amount of each medication that should be taken, and whether he/she can identify any problems after taking the medication. The functional ability was assessed by asking whether the person is able to fill a glass and sip enough of water to swallow the pills per dosage and asking them to demonstrate opening medication bottles and counting out the required number of pills, and asking them how they are supposed to administer their medications (e.g. pointing to the mouth for inhalers and pills, or describing how to draw up insulin). The third area assesses whether the person is able to obtain his/her medication and sustain the use of medications by asking about the existing refills, who to contact to get a new prescription, and whether or not they have the resources to obtain medications (like transportation).[6]

Each item scores as 0 (able) or 1 (unable), however, only 13 of the 20 items are scored (Table 4.1). The participant must be able to answer each question correctly for all medications to receive a score of able = 0. The total deficiency score is the sum of the three deficiency sub-scores. The maximum total score is 13, with a higher score indicating less ability for medication self-

management. [6] The non-scored items give more details to determine the overall ability to manage medication and identify the appropriate intervention to enhance medication use.

Table 4.1 Medication Management Instrument for Deficiencies in the Elderly (MedMaIDE)

Areas	Number of items	Number of scored items	Range of the scored items
First: Medication knowledge	8	5	0 – 5
Second: Medication-taking ability	6	5	0 – 5
Third: Access to ongoing supply	6	3	0 – 3
Total deficiency score	20	13	0 – 13

After completing the medication list, the participants' medication bottles were kept displayed on the table in front of the participant. The lists of active medications and the labels on the containers were used as a reference for what was reported by the participant. Lexicomp Online was used as a reference to confirm the indication for any new or unfamiliar medications by the investigator. Moreover, the participants were encouraged to use their medication bottles any time to answer any question. The scored questions in the first section were asked for each medication that was brought to the visit by the patient, including scheduled and non-scheduled medications. In the second section, if more than one medication was taken, the participant was asked to count the required number of pills for only one medication, and open the bottle cap for different vial sizes or different packaging used by the participants. In the third section, the participant was asked to identify the existing refills for one or two medications and whether they could identify the name of the pharmacy, physician, or senior medical center from which they receive their medications.

Medication-Taking Behavior: The participants were asked questions related to their medication-taking behavior. First, the participants were asked whether they have medication adherence barriers. They were asked to report whether they had trouble reading the prescription labels, opening any medication bottles, refilling or getting the medication on time, or paying for their medications.

Medication nonadherence was assessed using the Self-Rating Scale Item (SRSI). It was chosen because it is a single item, self-reported medication adherence measure and it is easy to be administered in outpatient clinical settings. This single question is "thinking about the past four weeks, please rate your ability to take your medications as prescribed," using a five-point Likert scale (Excellent, Very Good, Good, Fair, Poor). This single item measure has been validated among HIV-infected patients, and has shown a significant positive correlation with other objective adherence measures. In the validation study, patients who rated their ability as excellent were considered adherent while all other responses were considered non-adherent. This measure has been validated using the medication event monitoring system (MEMS) with excellent responses representing a mean of about 80% adherence on MEMS.[8,9]

Receiving Assistance with Medications: The participants were asked whether they had someone reminding them to take their medication, setting up their medications in advance (i.e. setting up a pillbox), or ordering the refills for them on a regular basis. They were categorized into groups: receiving assistance and not receiving any assistance.

Pharmaceutical Aids/Services: Participants were asked whether they use any medication aids, such as a medication list or card, medication organizers (e.g. pill box) or reminders (e.g. calendar, phone application). Moreover, they were questioned about using any services that are provided by a pharmacy to help them to take or manage their medication, such as ordering specialized medication packaging (e.g. bubble packs or unit dose packaging, easy to open containers, large print label), or using medication synchronization, prescription home delivery or mail order services. Study participants were categorized into three groups: 1) not using any specialized services, 2) using one service, and 3) using two or more services.

Emergency Room Utilization: ER visits were assessed retrospectively over the past six months. Participants were asked whether they had been in the ER in the last six months, and if yes, how often. Moreover, the main reason for the ER visit was recorded (medical/health-related problems, fall-related problems, medication-related problems, or other). Participants were dichotomized into two groups: not reporting any ER visit, and reporting any ER visit.

Health Literacy: Health literacy was assessed using three brief screening questions. These questions have been validated to identify patients with limited and adequate health literacy skills. These questions are 1) how often do you have someone help you read hospital materials? 2) how often do you have problems learning about your medical condition because of difficulty reading hospital materials? and 3) how confident are you filling out forms by yourself?

Each question is scored on a five-point Likert scale. The scale for the first and second questions is Never, Occasionally, Sometimes, Often, and Always. While the scale for the third question is extremely, Quite a bit, Somewhat, A little bit, Not at all. The maximum total score is 15 and higher scores indicate lower health literacy. Based on prior studies, any participant reporting a three or greater (i.e. sometimes or somewhat and greater) on any question, was scored as having inadequate or low health literacy. [10,11] These three questions were suitable to be used in this study because they were brief and quick, it took less than three minutes, and easy scoring system.

Cognitive Status: Participants' cognitive status was assessed using the Mini-Cog tool.[12,13] The Mini-Cog is a quick, validated tool for screening for cognitive deficits in older adults in community settings. In addition, it has been used in the RHWP clinics to assess residents' cognitive function. It is commonly used by pharmacists as screening of dementia within assisted living, long-term care, and community settings.[12] It includes two components: a three-item recall and a clock-draw

task. During three-item recall, the investigator named three unrelated objects (e.g. village, kitchen, and baby) and asked the participant to recall them after completing the clock-draw task. For the clock-draw task, participants were asked to draw the face of a clock, then the hands of the clock pointing to 10 past 11:00. The maximum score for the Mini-cog is 5 points; one point for each word recalled correctly and two points for a normal clock drawing. A score of ≥ three represents participants with unimpaired cognitive function while a score of ≤ two represents participants with impaired cognitive function.[12,13, 14]

Functional Status: Functional status was assessed using the Katz Activities of Daily Living (ADL) Index. It is commonly used in research studies as well as one of the clinical assessments used in RHWP clinics. The ADL Index is a well-known tool used to evaluate participants' ability to perform daily living activities independently, including bathing, dressing, toileting, transferring, continence, and feeding. Participants responded Yes (independent) or No (dependent) for each one of the six functions. A score of 6-5 will be reported as full function, 4-3 as moderate impairment, and ≤ 2 as severe functional impairment.[15, 14] Moreover, participants were asked whether they use assistive devices or wear eyeglasses.

Depression Symptoms: The Geriatric Depression Scale-15 (GDS-15) was used to assess how the participants felt over the past week. It is a 15-item questionnaire that has been validated in community settings for screening for symptoms of depression. All questions are in Yes and No format. A score of 0 to 5 was recorded as normal (no indication of depression) while a score of > 5 indicated depression — which is consistent with previous literature.[14] It was selected because it is short and easy to be administered with easy scoring system as well as it is one of the assessment tools that used in RHWP clinics.

4.6 Ethical Consideration

In this study, participants were placed at greater than minimal risk due to the nature of data collected during the study interview. An expedited review was requested from the Institutional Review Board (IRB) at Virginia Commonwealth University (VCU). The IRB has approved the protocol of this study as an expedited study. Furthermore, all study materials including recruitment brochure and flyer, screening and full informed consent forms, and script for all study measures were reviewed and approved by the IRB. All participants signed the informed consent form that includes details about the study and clearly states that participation is voluntary. It also identifies the study investigator and the study PI. All interviews were conducted in the RHWP clinics in an assigned private area.

According to the study protocol that has been approved by the IRB, all completed interview and assessments forms were recorded by ID number, not the participants' names. The hard copy of the participants' data including consent forms, demographics, medical, and medications data was kept in closed boxes in a secure place with the study PI (Dr. Patricia Slattum) at the VCU office. All participants' data was entered into the Research Electronic Data Capture application (REDCap). It is a secure web application, used to build and manage surveys and databases for research, and applicable to store any type of data.[16] The findings for this study may be presented at meetings or published in papers, but participants' identifying information will not be disclosed. Identifiers were removed from the dataset built in this study, and de-identified data may be used for other research studies by this study team or another researcher.

4.7 Statistical Analyses

Descriptive statistics including mean and standard deviation, or frequency and percentage, where appropriate for all variables are described in the "Study Measures" section. All statistical analyses were performed using SAS statistical software (version 9.4, SAS Institute, Cary, NC) with a significance level of 0.05 and two-tailed tests.

Specific Aim One: Descriptive analysis was performed to determine the cognitive and functional deficiencies in MMC. The total MedMaIDE deficiency score represents the overall deficiency in MMC for each participant. The first and third areas represent cognitive deficiency while the second area assesses the functional deficiency in MMC. First, normality for the MedMaIDE sub-scores for each area and total deficiency score was checked. They were approximately normally distributed on the histograms. Therefore, the mean and ± standard deviation of MedMaIDE sub-scores and total score were reported.

Specific Aims Two: Linear regression analyses were conducted to identify variables that are associated with deficient/low MMC. The MedMaIDE total deficiency score was the outcome variable and used as continuous. The association between the total deficiency score and all study variables including demographics, comorbidities, medication-taking behavior, as well as geriatric assessments variables were tested. To compare the mean total deficiency score with continuous variables, Pearson' correlation was used. For categorical variables, two-sample T-test with dichotomous variables and one-way ANOVA with multi-level variables were used. Re-categorizing was performed for some variables to overcome small cell size and unequal variance issues. Race was re-categorized into white and nonwhite, marital status into never and ever married, living arrangement into living alone and with another, and health status into excellent/very good, good, and fair/poor. Moreover, the participants who rated their ability to take

their medications as prescribed as excellent were recorded as adherent while all other responses (very good, good, fair, and poor) were recorded as non-adherent. The Pearson's correlation coefficient (CC), mean and standard deviation (±SD) with p-value were reported. The mean difference and 95% confidence interval (CI) were reported for the significant associations.

Linear regression analyses were performed to identify the significant predictors that were associated with low MedMaIDE total deficiency score. First, all variables were tested using bivariate linear regression analyses (unadjusted models). These bivariate analyses have been conducted to check the linear regression model assumptions and build the final adjusted model. Linear regression assumptions are: 1) all observations are independent, 2) the outcome and the predictors have a linear relationship (linearity), 3) the residuals have a normal distribution (normality), and 4) equal variance for all observations (homoscedasticity). Violation of model assumptions was corrected with transformation or recategorization. Collinearity was checked for all predicted and outcome variables, and any variable with a high correlation coefficient of 0.8 was eliminated. Second, all predictor variables were used to build the multiple linear regression model (adjusted model). The adjusted models were created using backward selection technique with a p-to-stay value of 0.25 or less. The backward elimination was began with the least significant predictor, and the variables were removed one at the time.

Four separate models were created using the technique described. The first model tested the outcome with demographic characteristics and the second model included the comorbidities. The third one examined the medication-related variables including number of medications and daily doses that were taken, medication complexity, and medication-taking behavior. The last one included the variables for geriatric assessments such as health literacy, cognitive and functional status, fall, use of assistive devices, and depression symptoms. After completing the four models,

the significant variables were entered into one model. The parameter estimates, standard errors (±SE), and p-value were reported for both unadjusted and adjusted models.

Specific Aim Three: Linear regression analyses were conducted to determine the impact of receiving assistance with medication from someone and using pharmaceutical aids/services on MMC. The outcome variable was MedMaIDE total deficiency score while receiving assistance with medications and using medication aids/services were the main explanatory variables. The variable of receiving assistance with medications from someone was dichotomous (yes or no), while using pharmaceutical aids/services was three groups (using none, using one, using more than one).

The association between the total deficiency score and these two variables, were checked using two-sample t-test and one-way ANOVA. The bivariate models were performed to assess the linear relationship between these two variables and the MedMaIDE total deficiency score. A Multiple linear regression model was conducted using all the potential predictors from specific aim two. Using the same technique used in analyzing specific aim two, the model assumptions and collinearity were checked. Moreover, the backward selection model was used to build the final model. The main explanatory variables were kept in all final adjusted model regardless of their significance (p-value).

Specific Aim Four: The purpose of this analysis was to determine the association between MMC and ER utilization over the past six months. The dichotomous ER visits variable was the outcome variable while continuous MedMaIDE total deficiency score was the main explanatory variable. A descriptive table was created including all study variables, stratified by ER visit groups (not reporting any ER visit and reporting one or more ER visits). The difference between the two ER

visit groups was assessed using the Chi-square test or Fisher's exact test when the cell size is small (≤ 5) for the categorical variables. A two-sample T-test was used for continuous variables.

The association between ER utilization over the last six months (outcome) and MMC was examined using logistic regression analyses. Univariate logistic regression analysis was performed to determine the association between the ER visit groups and MedMaIDE deficiency scores, as well as other potential predictors for ER visits. The logistic regression assumptions were tested before conducting the adjusted logistic model. The logistic regression assumptions are: 1) the outcome is a binomial distribution, 2) the mean of the outcome is given by the logistic function which means continuous variables are equivalent, and all predictors are related to the log odds of the outcome, 3) the values of the outcome are statistically independent, and 4) there are no influential points. Collinearity was checked for all predictor and outcome variables, and any variable with a high correlation coefficient of ≥ 0.8 was eliminated. All potential predictors with modest association with ER visits (p-value ≤ 0.25) were included in the multiple logistic regression model. Thereafter, the adjusted model was created using backward selection technique with a p-to-stay value of 0.25 or less. The step-wise backward elimination began with the least significant predictor, and the variables were removed one at a time. The MedMaIDE total score was kept in the model regardless of its significance. The odds ratio for each level of categorical variables as well as for continuous variables with 95 % confidence interval (CI) and p-value were reported for both unadjusted and adjusted models. In addition, the final model fit was evaluated using Hosmer and Lemeshow Goodness-of-Fit test.

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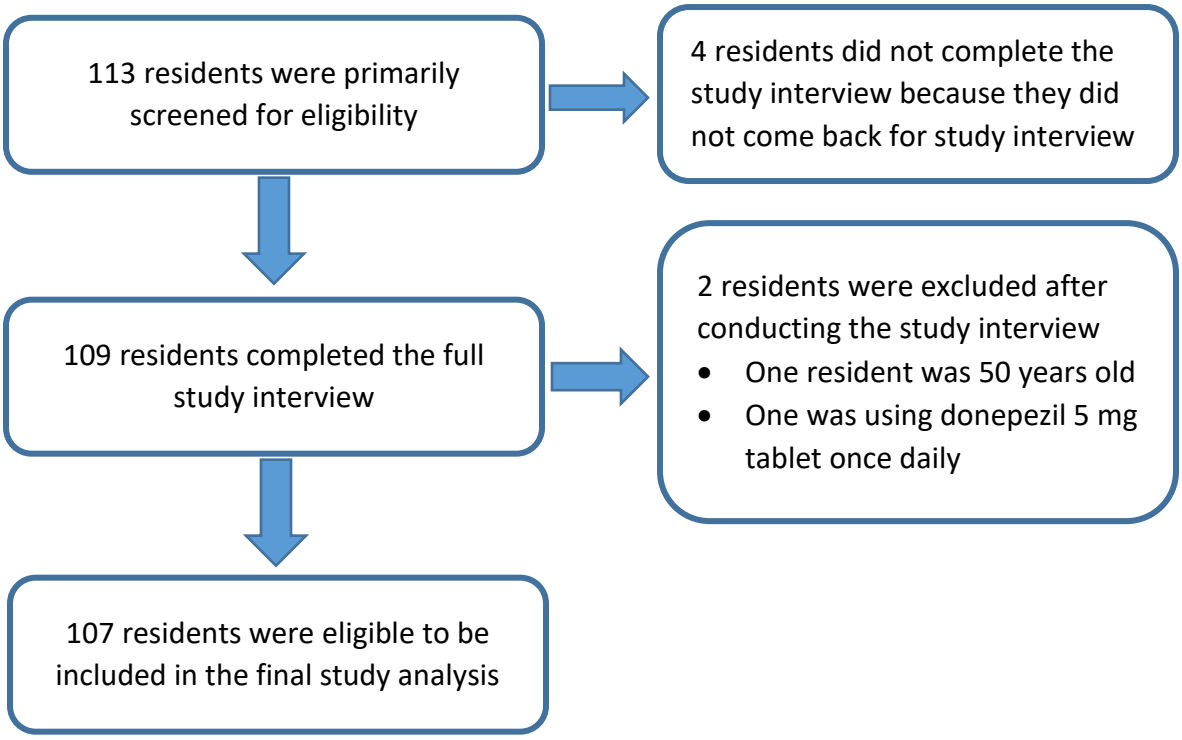
CHAPTER FIVE

RESULTS

5.1 Descriptive Results

It was initially planned to recruit 25% of the total enrollees belonging to RHWP which would have been about 87 residents. However, many more residents were screened within three months (July – August) than originally anticipated (113 residents). During this time period, 109 residents successfully completed the full study interview. The data of 107 participants were included in the final study analysis as described in Figure 5.1.

Figure 5.1 Process of Recruitment and Screening



In this study, the mean participant age was 68.54 years (±7.23) with a minimum age of 55 and a maximum of 89 years. Most of the participants were African-American (89%) who lived on their own independently (96%) in one of the five senior low-income housings. About 29% of participants did not complete high school or GED, 42% completed high school or the GED, and 31.78% had college education. There were 64 participants (59.81%) with dual eligible insurance coverage by Medicaid and Medicare. Moreover, 14 (13.08%) of participants were covered by Medicaid alone or other insurance, but not Medicare and 26 (24.30%) had Medicare alone or other insurance but not Medicaid. While only three participants (2.80%) were not eligible for either Medicaid or Medicare, they received medical care through a coordinated care program for uninsured people (Table 5.1).

The mean total functional comorbidities index was 4.92 (±2.85). Arthritis was the most common comorbidity (61.68%) reported by the participants followed by visual impairment such as cataracts, glaucoma, and macular degeneration (48.6%), obesity (44.86%) and upper gastrointestinal disease (42.99%). Table 5.2 summarizes the participants' medical history measured by FCI.

During the study interview, the participants brought on average 7.73 (±4.12) medications, the minimum was one prescription or OTC medication and a maximum of 21 medications. About 73% of them were using five or more prescription medications while 96.26% were using at least four OTC medications and 88.79% were taking at least one vitamin. The mean total doses that were taken by the participants was 8.13 (±5.11) per day. The mean score for MRCI was 13.95 (±8.64), with a maximum of 36.50 MRCI score.

Regarding medication adherence barriers, 47 participants (43.93%) reported having at least one difficulty with their medications such as trouble reading the prescription labels, opening the

medication bottles, refilling medication on time, or paying for medications. Only 20.56% (22 participants) of the study participants reported receiving assistance with these issues from someone such as family members, friends, RHWP, or primary care physician (PCP) office. However, 64.49% of participants reported not missing a dose of any of their medications in the last 7 days and about 42% rated their ability to take their medications during the past 4 weeks as excellent (Table 5.3). Using medication/drug organizers was the most common medication aid that was used by the study participants, in particular, 7-day pill box organizers. The second most popular was having medication lists/cards and the least popular was medication reminders either using calendar reminders or mobile applications. Thirty-two participants (29.91%) used prescription home delivery or mail order to fill their medications, while only 26 (24.30%) reported enrolling in medication synchronization services (Table 5.4).

The health literacy assessment showed that 46 participants (43%) had low or inadequate health literacy. The Mini-Cog total scores indicated that 33 (30.84%) participants had possible impaired cognitive function, while the total ADL scores indicated that 26 (24.30%) participants had moderate to low functional status. The fall rate was 11.21% over the last month. However, the majority of the participants used eyeglasses 87 (81.31%), either for reading or distance vision, and almost half (51.40%) were using some sort of assistive devices. About 25% of the participants had felt depressed over the last week (Table 5.5).

Table 5.1 Participants' Demographic Characteristics by MedMaIDE Score

Demographic Characteristics	Data summary, mean (±SD)	Pearson Correlation Coefficients	P-value
Age, years (range 55-89)	68.54 (7.23)	0.10	0.2917
	Data summary, N (%)	**Mean (±SD)**	**P-value**
Age			0.0774
55 - 64 years old	31 (28.97)	3.10 (2.23)	
65 - 74 years old	58 (54.21)	2.64 (1.85)	
75 years or older	18 (16.82)	3.83 (1.86)	
Sex			0.8821
Female	55 (51.40)	3.00 (2.20)	
Male	52 (48.60)	2.94 (1.78)	
Race			0.4877
White	15 (14.02)	3.00 (2.59)	
Black	89 (83.18)	2.92 (1.89)	
Other (1 Hispanic & 2 Native American)	3 (2.80)	4.33 (2.08)	
Marital Status			0.8530
Single (never married)	50 (46.73)	3.18 (2.23)	
Married	2 (1.87)	2.00 (0.00)	
Separated	7 (6.54)	2.71 (1.70)	
Divorced	31 (28.97)	2.81 (2.01)	
Widowed	17 (15.89)	2.88 (1.49)	
Educational Levels			0.0145*
Less than high school diploma	31 (28.97)	3.26 (1.69)	
High school /GED	42 (39.25)	3.48 (2.25)	
Some college	24 (22.43)	2.21 (1.77)	
College degree graduated	10 (9.35)	1.80 (1.32)	
Type of Insurance			0.6675
Medicaid only	14 (13.08)	2.57 (1.70)	
Medicare only	26 (24.30)	2.81 (1.83)	
Dual eligible	64 (59.81)	3.16 (2.16)	
Other	3 (2.80)	2.33 (0.58)	
Living Arrangement			0.4298
Alone	103 (96.26)	2.94 (1.99)	
With other	4 (3.74)	3.75 (2.06)	
Health Status			0.8753
Excellent/Very Good	31 (28.97)	3.00 (1.95)	
Good	37 (34.58)	3.08 (2.14)	
Fair/Poor	39 (36.45)	2.85 (1.94)	

** Significant P-value < 0.05*

Table 5.2 Participants' Medical History (Comorbidity) by MedMaIDE Score

Comorbidities	Data summary, mean (±SD)	Pearson Correlation Coefficients	P-value
Comorbidities (FCI) (range 0 – 14)	4.92 (2.85)	0.08	0.3882
Weight, pounds (range 100 -313)	187.81 (44.11)	-0.09	0.3504
Height, Inches (range 53 76)	66.37 (4.02)	-0.04	0.6919
BMI (range 16.74 -50.42)	30.17 (7.39)	-0.06	0.5277

Comorbidities	Data summary, N (%)	Mean (±SD)	P-value
Arthritis			0.7781
Yes	66 (61.68)	3.02 (2.03)	
No	41 (38.32)	2.90 (1.96)	
Visual impairment			0.1939
Yes	52 (48.60)	3.23 (2.06)	
No	55 (51.40)	2.73 (1.92)	
Obesity/ BMI > 30			0.4590
Yes	48 (44.86)	2.81 (2.06)	
No	59 (55.14)	3.10 (1.95)	
Upper gastrointestinal disease			0.6473
Yes	46 (42.99)	2.87 (2.17)	
No	61 (57.01)	3.05 (1.87)	
Depression			0.2282
Yes	41 (38.32)	3.27 (2.25)	
No	66 (61.68)	2.79 (1.82)	
Diabetes types I and II			0.9182
Yes	36 (33.64)	3.00 (1.88)	
No	71 (66.36)	2.96 (2.07)	
Anxiety or panic disorders			0.6097
Yes	35 (32.71)	3.11 (2.39)	
No	72 (67.29)	2.90 (1.79)	
Congestive heart failure			0.6090
Yes	34 (31.78)	3.12 (2.08)	
No	73 (68.22)	2.90 (1.97)	
Degenerative disc disease			0.2423
Yes	32 (29.91)	2.62 (2.06)	
No	75 (70.09)	3.12 (1.97)	
Asthma			0.1297
Yes	28 (26.17)	3.46 (2.38)	
No	79 (73.83)	2.80 (1.83)	
COPD or Emphysema			0.5901
Yes	24 (22.43)	3.17 (1.81)	
No	83 (77.57)	2.92 (2.05)	

Comorbidities	Data summary, N (%)	Mean (±SD)	P-value
Peripheral vascular disease			0.2577
Yes	23 (21.50)	3.39 (1.90)	
No	84 (78.50)	2.86 (2.02)	
Hearing impairment			0.1315
Yes	22 (20.56)	3.54 (2.26)	
No	85 (79.44)	2.82 (1.91)	
Stroke or TIA			0.0314*
Yes	21 (19.63)	3.81 (2.50)	
No	86 (80.37)	2.77 (1.81)	
Heart attack (MI)			0.7219
Yes	12 (11.21)	3.17 (1.40)	
No	95 (88.79)	2.95 (2.06)	
Osteoporosis			0.6718
Yes	5 (4.67)	2.60 (1.95)	
No	102 (95.33)	2.99 (2.01)	
Neurological disease			0.9888
Yes	1 (0.93)	3.00 (0.00)	
No	106 (99.07)	2.97 (2.01)	

** Significant P-value < 0.05*

Table 5.3 Medication-Taking Behavior by MedMaIDE Score

Variables	Data summary, mean (±SD)	Pearson Correlation Coefficients	P-value
Number of meds (range 1 – 21)	7.73 (4.12)	0.18	0.0707
Number of Rx (range 0 – 19)	6.92 (3.70)	0.15	0.1224
Number of OTC (range 0 -10)	0.82 (1.60)	0.10	0.3263
Number of vitamins, minerals & supplements (range 0 – 5)	0.64 (0.94)	0.08	0.4411
Number of daily doses (range 0 – 24)	8.13 (5.11)	0.088	0.3665
Medication Regimen Complexity (range 2 – 36.50)	13.95 (8.64)	0.11	0.2638
	Data summary, N (%)	**Mean (±SD)**	**P- value**
Polypharmacy			0.0610
4 or less meds	29 (27.10)	2.38 (1.84)	
5 or more meds	78 (72.90)	3.19 (2.02)	
Medication Adherence Barriers			
Trouble Reading Rx labels			0.0003*
Yes	22 (20.56)	4.32 (1.94)	
No	85 (79.44)	2.62 (1.87)	
Trouble Opening Rx bottles			0.0001*
Yes	13 (12.15)	4.92 (2.50)	
No	94 (87.85)	2.70 (1.77)	
Trouble Refiling meds on time			0.2884
Yes	11 (10.28)	2.36 (1.75)	
No	96 (89.72)	3.04 (2.02)	
Trouble Paying for meds			0.1728
Yes	18 (16.82)	2.56 (1.20)	
No	89 (83.18)	3.06 (2.12)	
Medication Non-adherence			
Missing a dose of any medication			0.9189
None	69 (64.49)	2.91 (1.93)	
One dose	17 (15.89)	3.06 (2.68)	
Two or more doses	21 (19.63)	3.10 (1.70)	
Ability to take meds as prescribed			0.0251*
Excellent (adherent)	45 (42.06)	2.47 (1.67)	
Not Excellent (Not adherent)	62 (57.94)	3.34 (2.14)	

** Significant P-value < 0.05*

Table 5.4 Receiving Assistance with Medications or Using Pharmaceutical Aid/Service by MedMaIDE

Variables	Data summary, N (%)	Mean (±SD)	P- value
Receiving assistance with medication form someone			
Reminder to take meds			0.0098*
Yes	6 (5.61)	5.00 (2.45)	
No	101 (94.39)	2.85 (1.68)	
Setting up meds in advance			0.6162
Yes	9 (8.41)	3.44 (2.92)	
No	98 (91.59)	2.93 (1.67)	
Ordering refills			0.2025
Yes	12 (11.21)	2.88 (1.67)	
No	95 (88.79)	3.67 (1.82)	
Receiving assistance with meds			0.1454
Yes	22 (20.56)	3.68 (2.64)	
No	85 (79.44)	2.79 (1.77)	
Medication aids are used			
Medication list/card			0.1010
Yes	45 (42.06)	2.60 (2.02)	
No	62 (57.94)	3.24 (1.96)	
Med/drug organizer			0.5172
Yes	47 (43.93)	2.83 (1.87)	
No	60 (56.07)	3.08 (2.10)	
Type of medication/drug organizer is used, (n=47)			
1-day pill box organizer (daily)	2 (4.26)		
7-day pill box organizer (weekly)	42 (89.36)		
14 –day pill box organizer	2 (4.26)		
Dose pill pouch	1 (2.13)		
Med/drug reminder			0.7258
Yes	7 (6.54)	2.71 (1.80)	0.7258
No	100 (93.46)	2.99 (2.02)	
Type of reminder is used, (n=7)			
Calendar	4 (57.14)		
Application on your phone	3 (42.86)		
Pharmacy services ordered or used			
Special packaging (bubble pack)			0.0277*
Yes	7 (6.54)	4.57 (2.44)	
No	100 (93.46)	2.86 (1.93)	
Easy to open caps (non-child resistant caps)			0.3825
Yes	10 (9.35)	3.50 (2.17)	
No	97 (90.65)	2.92 (1.98)	
Large print labels			0.3236

Yes	1 (0.93)	1.00 (0.00)	
No	106 (99.07)	2.99 (2.00)	
Medication synchronization			0.6760
Yes	26 (24.30)	3.12 (2.09)	
No	81 (75.70)	2.93 (1.98)	
Prescription home delivery (mail order)			0.3494
Yes	32 (29.91)	3.25 (1.85)	
No	75 (70.09)	2.85 (2.06)	
Using pharmaceutical aids or Services			0.2818
None	22 (20.56)	3.32 (1.96)	
One aid or service	35 (32.71)	2.54 (1.80)	
More than one	50 (46.73)	3.12 (2.13)	

** Significant P-value < 0.05*

Table 5.5 Geriatric Assessments by MedMaIDE Score

Geriatric Assessments	Data summary, N (%)	Mean (±SD)	P- value
Health literacy			0.0002*
High/adequate health literacy	61 (57.00)	2.33 (1.62)	
Low/inadequate health literacy	46 (43.00)	3.83 (2.14)	
Mini-cog: 3-item recall			0.9729
1 ≤ words	25 (23.36)	2.96 (1.88)	
2 ≥ words	82 (76.64)	2.98 (2.04)	
Mini-cog: Clock drawing test			0.6809
Normal	65 (60.75)	2.91 (1.97)	
Abnormal	42 (39.25)	3.07 (2.05)	
Cognitive status			0.4088
Possible impairment	33 (30.84)	3.21 (2.03)	
No impairment	74 (69.16)	2.87 (1.99)	
Functional status (ADL)			0.0339*
Highly independent	81 (75.70)	2.74 (1.85)	
Moderate/low independent	26 (24.30)	3.69 (2.29)	
Fall in the last month			0.0533
Yes	12 (11.21)	4.50 (2.71)	
No	95 (88.79	2.78 (1.82)	
Using assistive devices			0.0210*
Yes	55 (51.40)	3.40 (2.20)	
No	52 (48.60)	2.52 (1.66)	
Wearing eye-glasses			0.3503
Yes	87 (81.31)	2.89 (2.07)	
No	20 (18.69)	3.35 (1.63)	
Type of eyeglasses, (n=87)			
Distance vision only	5 (5.75)		
Reading only	41 (47.13)		
Both	41 (47.13)		
Depression status (GDS-15)			0.5984
Normal (≤ 5)	80 (74.77)	2.91 (1.93)	
Depression (≥ 5)	27 (25.23)	3.15 (2.21)	

** Significant P-value < 0.05*

5.2 Deficiencies in Medication Self-Management Capacity

On average approximately eight (±4.12) medications were brought by the participants for reviewing during the study interview. The study participants had about three (±2.00) total mean deficiency score as assessed by MedMaIDE. While some participants had no deficiencies, some of them recorded as many as 10 deficiencies in their MMC. On MedMaIDE, the first are assesses medication knowledge (i.e. recalling medication names, indications, and doses), the second area assesses medication-taking ability (i.e. opening medication vials, removing doses from packaging, filling a glass of water), and the third area determines patients' knowledge about ongoing supply of medications (i.e. identifying refills, having transportation to pharmacy). The mean deficiency sub-score for the first area was 2.17 (± 1.55). However, the mean sub-score for the second area was 0.22 (± 0.63) and the third area was 0.58 (± 0.71). Table 5.6 summarizes the MedMaID deficiencies scores. In addition, 69.16% of the participants were not able to name their medications, about 46% did not know the indication, and 38.32% of them could not state the correct dose or frequency for their medications. Furthermore, 41 participants (38.32%) were not able to identify the number of refills remaining on the prescription label (Table 5.7).

Table 5.6 MedMaIDE Deficiencies Scores

Deficiencies score	Mean (±SD)	Minimum – maximum
1st area sub-score	2.17 (1.55)	0 – 5
2nd area sub-score	0.22 (0.63)	0 – 4
3rd area sub-score	0.58 (0.71)	0 – 3
Total score	2.97 (2.00)	0 – 10

Table 5.7 Medication Management Skills Assessed by MedMaIDE

MedMaIDE items	N (%)
1st area: Deficiency in <u>what should be known</u> about medications	
1. Name all medications	74 (69.16)
2. State the time of the day for each medication	41 (38.32)
3. State how the medication should be taken	26 (24.30)
4. State why each medication is taken	50 (46.73)
5. Tell me the amount should be taken each time	41 (38.32)
2nd area: Deficiency in <u>how should medications be taken</u>	
1. Fill a glass of water	2 (1.87)
2. Remove top from the medication container	10 (9.35)
3. Count out the required number of pills into hand or cup	1 (0.93)
4. Demonstrate administration of each medication	3 (2.83)
5. Sip enough water to swallow medication	8 (7.48)
3rd area: Deficiency in <u>what should be known to get medication refills</u>	
1. Identify existing refills on a prescription	41 (38.32)
2. Identify who to contact to get a prescription refilled	8 (7.48)
3. Have resources to obtain the medications	13 (12.15)

5.3 Predictors for Low MMC

The association between MedMaIDE total deficiency score and the demographic characteristics were reported in Table 5.1. The mean MedMaIDE total deficiency score was significantly different across participants' educational level groups. The participants' with high school or less had a significantly higher mean of total deficiency score compared to those who had some college or graduated from college.

There was a positive linear relationship between the mean total of comorbidities and MedMaIDE scores, however, this relationship was not statistically significant. Moreover, none of the comorbidities were associated with MedMaIDE total deficiency scores except stroke or transient ischemic attack (Table 5.2). Participants' who did not report stroke had a significantly

lower mean of total deficiency scores compared with those who reported stroke with a significant mean difference of - 0.22 (95% CI: -1.44, - 0.99).

There were trends of a positive linear relationship between total deficiency score and number of medications, total daily doses taken, and medication regimen complexity (Table 5.3). Therefore, the deficiency in the ability to self-manage medication increases as the number of medications, daily doses, and medication regimen complexity increased. Moreover, the mean MedMaIDE total deficiency score was higher among those participants who reported using five or more medications than those who used four or fewer medications. However, this mean difference was not statistically significant [mean difference = - 0.81, (95% CI: -1.66, 0.04)].

There was a significant association between MedMaIDE total deficiency score and having trouble reading prescription labels and opening the medication bottles (Table 5.3). Participants who reported having trouble reading the labels and opening their medication bottles had significantly lower ability to manage their medications compared to other participants. The mean difference of total deficiency score was – 1.70 (95% CI: - 1.59, - 0.80) for those with trouble reading the labels and – 2.22 (95% CI: - 3.32, - 1.13) for those with trouble opening their medications bottles. Adherent participants who rated their ability to take their medications in the last four weeks as excellent had significantly lower total deficiency scores compared to others [mean difference = - 0.87; 95% CI (- 1.63, - 0.11)].

The mean MedMaIDE total deficiency score was not significantly different between those who received assistance with medications and those who did not (Table 5.4). However, the total deficiency score for those participants who had someone reminding them to take their on a regular basis was significantly higher than those who did not [mean difference = - 2.15; 95% CI (- 3.77, - 0.53); p-value = 0.010]. There was no significant association between MedMaIDE total deficiency

score and using pharmaceutical aids/services except ordering special packaging for medication (i.e. bubble pack). Participants who reported using bubble pack packaging had a significantly higher deficiency in their ability to manage their medications compared to others (mean difference = - 1.71; 95% CI: - 3.23, - 0.19).

Low or inadequate health literacy was significantly associated with higher MedMaIDE total deficiency score [mean difference = - 1.50; 95% CI (- 2.25, - 0.75); p-value = 0.0002]. Participants' cognitive function was not significantly associated with total deficiency score on MedMaIDE while there was a significant association with their functional status as measured by ADL. The participants who reported full ability to perform activities of daily living had significantly higher ability to self-manage their medications (mean difference = - 0.95; 95% CI: - 1.83, - 0.07). Furthermore, using assistive devices was significantly associated with a higher mean total deficiency score (mean difference = - 0.88; 95% CI: - 1.63, - 0.14). Participants who reported falls had a higher mean deficiency score compared with those who did not. However, this was not statistically significant (mean difference = - 1.72; 95% CI: - 3.47.63, - 0.03). Table 5.5 summarizes the association between MedMaIDE total deficiency score and Geriatric assessment variables.

In the bivariate analysis, the continuous variable of age was approximately normally distributed on the histogram and q-q plot for the residual. Therefore, the quadratic and categorical variables of age were tested, and no forms of age variables were significant. However, the categorical variable of age was included in the regression models because it showed a modest association with the outcome (p-value = 0.0719). The bivariate analyses showed that none of the demographic variables were significantly associated with the mean total deficiency score except educational level. The mean total deficiency score of MedMaIDE among the participants with an educational

level equal to high school or GED was on average 1.68 points higher than those with higher educational levels (Table 5.8). The adjusted model showed that only education level significantly predicted the participants' deficiency in medication management ability when adjusted for age and race. The mean total deficiency score on MedMaIDE was higher by an average of 1.84 points among the participants who had less than high school education and by 1.44 points among those with high school education when age and race were controlled (Table 5.8).

The bivariate analyses showed that the linear relationship between the number of comorbidities and total deficiency score was not significant. Moreover, only the participants who had had a previous stroke scored higher by an average of 1.04 points on MedMaIDE compared to those who did not. The adjusted model indicated that having asthma, stroke, and hearing impairment were significant predictors for the low ability to self-manage medications. The MedMaIDE total score increased by approximately one point on average among the participants with asthma, stroke, or hearing impairment (Table 5.9).

Table 5.10 summarizes the findings of unadjusted and adjusted models for MMC with medication-taking behavior variables. The unadjusted model suggested that the association between MedMaIDE total deficiency score and having trouble reading prescription labels or opening medication containers were significant. Participants who reported having difficulty reading the labels on the prescription bottles had a higher mean total deficiency score by an average of 1.70, compared to those who did not. Moreover, those who reported difficulties opening their medication vials or containers had a higher mean total deficiency score by an average of 2.22 compared to those who did not. Moreover, medication non-adherence, as assessed by asking the participants to rate their ability to take their medication as prescribed in the last four weeks, was significantly associated with medication management capacity. Those participants who were not

adherent had a significantly higher MedMaIDE total deficiency score by an average of 0.87 scores compared to adherent participants. The adjusted model for medication-taking behavior variables showed that reporting trouble reading prescription labels and opening medication bottles were significant predictors for poor medication self-management capacity. The total deficiency score increased by more than one point on average among the participants who reported difficulty reading the labels on the prescription bottles and opening the bottles.

In the bivariate analyses, health literacy, ADLs, fall, and using assistive devices were significantly associated with the mean total deficiency score of MedMaIDE (Table 5.11). The mean total deficiency score of MedMaIDE increased by 1.50 points among the participants who had low or inadequate health literacy compared to those who had high or adequate health literacy. Compared to those participants who were fully independent as assessed using ADLs, those with moderate or low ADL scores had a significantly higher deficiency in their ability to manage their medications by an average of 0.95 points. Participants who reported a fall in the last month or using an assistive device, had a total deficiency score on MedMaIDE that was significantly higher (by an average of 1.72 and 0.88 points, respectively) than others who did not. In the adjusted linear regression model, health literacy, ADLs, and fall were significant predictors for high MedMaIDE total deficiency scores. Reporting low health literacy or having a fall significantly increased participants' inability to manage their medication by more than one point on average. Having moderate or low ADL function significantly increased the total deficiency score by less than one point on MedMaIDE (0.83 points).

The final adjusted model was built using all the significant variables from all the previous models (4 models). The significant predictors that were used to build the final model are participants' education level, having asthma, stroke, and/or hearing impairment, having trouble

reading prescriptions labels and opening prescription bottles, health literacy, ADLs, and falling. The final adjusted model showed that an education level of high school or less, difficulties reading prescription labels or opening the medication bottles, and low or inadequate health literacy were the significant predictors for high deficiency in the medication management capacity. The total deficiency score of MedMaIDE increased by more than one point on average among those participants who reported having high school education or less and reported difficulties reading the prescription labels or opening the medication bottles. The mean total deficincy score of participants with low health literacy increased by less than one point when compared with participants who had higher or adequate health literacy (Table 5.12).

Table 5.8 Unadjusted and Adjusted Linear Regression models of Total MedMaIDE Deficiency Score and Demographic Characteristics

	Unadjusted Model		Adjusted Model	
	Parameter Estimate (SE)	**P-Value**	**Parameter Estimate (SE)**	**P- Value**
Age		0.0774		0.1373
55 - 64 years old	-	-	-	-
65 - 74 years old	- 0.45 (0.43)	0.2970	- 0.46 (0.42)	0.2729
75 years or older	0.74 (0.58)	0.2093	0.56 (0.42)	0.3157
Sex				
Male	-	-		
Female	0.06 (0.38)	0.8821		
Race				
White	-		-	0.1437
None white	- 0.03 (0.55)	0.9530	-0.81 (0.56)	
Marital Status		0.3095		
Ever married	-	-		
Never married	0.39 (0.38)	0.3084		
Educational Level		0.0123*		0.0114*
College degree	-	-	-	-
Some College	0.41 (0.71)	0.5658	0.50 (0.71)	0.4841
High School/GED	1.68 (0.66)	0.0117*	1.84 (0.69)	0.0080*
Less than high School	1.46 (0.69)	0.0338*	1.44 (0.73)	0.0481*
Type of insurance		0.6555		
Other	-	-		
Medicaid	0.24 (1.26)	0.8496		
Medicare	0.47 (1.20)	0.6934		
Dual eligible	0.82 (1.17)	0.4802		
Living Arrangement		0.4243		
With Other	-	-		
Alone	- 0.81 (1.01)	0.4236		
Health Status		0.8719		
Excellent/Very good	-	-		
Good	0.08 (0.48)	0.8668		
Fair / Poor	- 0.15 (0.48)	0.7474		

* Significant P-value < 0.05

Table 5.9 Unadjusted and Adjusted Linear Regression Models of MeMaIDE Total Deficiency Score and Comorbidities

Comorbidities	Unadjusted Model		Adjusted Model	
	Parameter Estimate (SE)	P-value	Parameter Estimate (SE)	P- value
Arthritis	0.11 (0.40)	0.7755		
Asthma	0.67 (0.43)	0.1231	0.86 (0.42)	0.0412*
COPD or Emphysema	0.25 (0.46)	0.5854		
Congestive heart failure	0.21 (0.41)	0.6045		
Heart attack (MI)	0.22 (0.61)	0.7186		
Stroke or TIA	1.04 (0.47)	0.0277*	1.19 (0.46)	0.0101*
Peripheral vascular disease	0.53 (0.47)	0.2507	0.76 (0.45)	0.0919
Diabetes types I and II	0.04 (0.41)	0.9173	-0.50 (0.40)	0.2174
Upper gastrointestinal disease	-0.18 (0.39)	0.6433		
Depression	0.48 (0.39)	0.2211	0.57 (0.45)	0.2048
Anxiety or panic disorders	0.21 (0.41)	0.6052		
Visual impairment	0.50 (0.38)	0.1868		
Hearing impairment	0.72 (0.47)	0.1249	0.90 (0.45)	0.0464*
Degenerative disc disease	-0.49 (0.42)	0.2353	-0.57 (0.40)	0.1564
Obesity and/or BMI > 30	-0.29 (0.39)	0.4531	-0.44 (0.38)	0.2420
Number of comorbidities	0.10 (0.07)	0.2029		

Note: the reference for all comorbidities is "No vs. Yes", and for the number of comorbidities is "One-Comorbidity Increase).

** Significant P-value < 0.05*

Table 5.10 Unadjusted and Adjusted Linear Regression Models of MedMaIDE Total Score and Medication-Taking Behavior

Variable (reference)	Unadjusted Model		Adjusted Model	
	Parameter Estimate (SE)	P-value	Parameter Estimate (SE)	P-value
Medication History				
Number of meds (1-med increase)	0.09 (0.05)	0.0707	0.06 (0.04)	0.1550
Number of daily doses (1-dose increase)	0.03 (0.04)	0.3665		
Medication Regimen Complexity (1-score increase)	0.03 (0.02)	0.2638		
Medication Adherence Barriers: having trouble with				
Reading Rx labels (no-yes)	1.70 (0.45)	0.0001*	1.33 (0.42)	0.0017*
Opening Rx bottles (no-yes)	2.22 (0.55)	<.0001*	1.40 (0.56)	0.0118*
Refilling meds on time (no-yes)	- 0.68 (0.63)	0.2814	-0.85 (0.56)	0.1308
Paying for meds (no-yes)	- 0.50 (0.51)	0.3277		
Medication Non-adherence				
Missing a dose of any meds taken		0.9167		
None	-	-		
One dose	0.15 (0.54)	0.7864		
Two or more doses	0.18 (0.50)	0.7129		
Ability to take meds as prescribed				
Excellent (adherent)	-	-	-	
Not Excellent (Not adherent)	0.87 (0.38)	0.0218*	0.64 (0.36)	0.0711

* Significant P-value < 0.05

Table 5.11 Unadjusted and Adjusted Linear Regression Models of MedMaIDE Total Deficiency Score and Geriatric Assessments Variables

Variables	Unadjusted Model		Adjusted Model	
	Parameter Estimate (SE)	**P-value**	**Parameter Estimate (SE)**	**P-value**
Health literacy				
High/adequate health literacy	-	-	-	-
Low/inadequate health literacy	1.50 (0.32)	<.0001*	1.39 (0.35)	<.0001*
Cognitive Status (Mini-Cog)				
Possible impairment	-	-		
No impairment	-0.35 (0.41)	0.4025		
Functional status (ADL)				
Highly independent	-	-	-	-
Moderate/low independent	0.95 (0.44)	0.0300*	0.83 (0.40)	0.0365*
Fall in the last month (no-yes)	1.72 (0.59)	0.0033*	1.20 (0.55)	0.0289*
Using assistive devices (no-yes)	0.88 (0.37)	0.0188*		
Wearing eye-glasses (no-yes)	-0.46 (0.49)	0.3436	0.53 (0.43)	0.2246
Depression status (GDS-15)				
Normal (≤ 5)	-	-		
Depression (≥ 5)	0.24 (0.44)	0.5939		

** Significant P-value < 0.05*

Table 5.12 Final Adjusted model of MedMaIDE Total Deficiency Score and Significant Predictors

Variables	Adjusted model		Final adjusted model	
	Parameter Estimate (SE)	P-value	Parameter Estimate (SE)	P-value
Educational Level		0.0114*		0.0405*
College degree	-	-	-	-
Some College	0.50 (0.71)	0.4841	0.47 (0.60)	0.4326
High School/GED	1.84 (0.69)	0.0080*	1.32 (0.57)	0.0195*
Less than high School	1.44 (0.73)	0.0481*	1.24 (0.61)	0.0415*
Comorbidities				
Asthma (no-yes)	0.86 (0.42)	0.0412*		
Stroke or TIA (no-yes)	1.19 (0.46)	0.0101*		
Hearing impairment (no-yes)	0.90 (0.45)	0.0464		
Medication Adherence Barriers				
Trouble reading Rx labels (no-yes)	1.33 (0.42)	0.0017*	1.18 (0.41)	0.0036*
Trouble opening Rx bottles (no-yes)	1.40 (0.56)	0.0118*	1.43 (0.51)	0.0047*
Health Literacy				
High/adequate health literacy	-	-	-	-
Low/inadequate health literacy	1.39 (0.35)	<.0001*	0.90 (0.33)	0.0063*
Functional Status (ADL)				
Highly independent	-	-	-	-
Moderate/low independent	0.83 (0.40)	0.0365*	0.51 (0.37)	0.1733
Fall in the last month (no-yes)	1.20 (0.55)	0.0289*	0.80 (0.51)	0.1135

** Significant P-value < 0.05*

5.4 Impact of Using Pharmaceutical Aid/Service on MMC

Although there were only 22 (20.56%) participants receiving assistance with medication from someone, the majority of the participants (79.44%) used at least one pharmaceutical aid/service. There were 35 (32.71%) participants who used one aid/service, while 50 (46.73%) participants used more than one aid or pharmacy services. Drug organizers (pillbox) were the most common medication aid used by the participants (n=47, 43.93%) followed by medication lists or cards (n=45, 42.06%) and prescription home delivery/mail order (n=32, 29.91%). On the other hand, only 12 (11.21) participants had someone assist them with ordering their medications (Table 5.4).

Compared to the participants who did not receive assistance with medications, the mean MedMaIDE total deficiency score was not significantly different among those participant who received assistance with medication from someone. Likewise, the participants who use pharmaceutical aid/service had a total deficiency scores that was not significantly different than others (Table 5.4). However, mean total deficiency scores were significantly higher among the participants who had someone remind them to take their medications on a regular basis than those who did not (mean diff = -2.15, 95% CI: -3.77, -0.53). Furthermore, the participants who used special packaging, like bubble packaging had significantly higher mean total deficiency scores compared to others who did not use special packaging (mean diff = -1.71, 95% CI: -3.23, -0.19).

The unadjusted models indicated that the mean total deficiency score increased by on average 0.89 points when participants receiving assistance with medications from someone. MedMaIDE scores decreased by 0.77 points on average among the participant who used one pharmaceutical aid or service and by 0.22 in those who used more than one compared to those who did not use any (Table 5.13). However, none of these associations were statistically significant.

The adjusted model included the significant predictors from specific aim two (education level, trouble reading prescription labels, opening medication bottles, and health literacy). In addition, some other potential predictors such as the number of diseases, medications taken, and daily doses, medication complexity, and cognitive status were included. The adjusted model showed that when adjusting for receiving assistance with medication and using pharmaceutical aids/services, the participants with high total deficiency scores on MedMaIDE had not completed a college education, used more medications on a regular basis, reported difficulty reading the labels on their medication vials and opening their medication bottles, and had low health literacy. Moreover, using one pharmaceutical aids/services significantly decreased the mean total deficiency scores on MedMaIDE by an average of 0.93 points compared to those who did not use any (p-value = 0.0285). However, the overall reduction in the total deficiency score among those using pharmaceutical aids/services was not statistically significant in the adjusted models (Table 5.13). It seems like these might be correlated since individuals tend to start using pharmaceutical aids because they are having difficulty. The aids may not improve their medication capacity scores, but they may improve overall adherence.

Table 5.13 Unadjusted and Adjusted Linear Regression Models of MedMaIDE Total Deficiency Score and Using Pharmaceutical Aid/Service

Variables	Unadjusted Model		Adjusted Model	
	Parameter Estimate (SE)	P-value	Parameter Estimate (SE)	P-value
Receiving assistance with meds				
No	-	-	-	-
Yes	0.89 (0.47)	0.0560	0.24 (0.38)	0.5334
Using pharmaceutical aid/service				0.0853
Using none	-	-	-	-
Using one	-0.77 (0.53)	0.1468	-0.93 (0.42)	0.0285*
Using more than	-0.20 (0.50)	0.6933	-0.76 (0.43)	0.0764
Educational Level		0.0114		0.0325*
College degree	-	-	-	-
Some College	0.50 (0.71)	0.4841	0.27 (0.58)	0.6421
High School/GED	1.84 (0.69)	0.0080	1.25 (0.55)	0.0236*
Less than high School	1.44 (0.73)	0.0481	0.99 (0.60)	0.0979
Asthma (no-yes)	0.86 (0.42)	0.0412		
Stroke or TIA (no-yes)	1.19 (0.46)	0.0101		
Hearing impairment (no-yes)	0.90 (0.45)	0.0464	0.46 (0.37)	0.2180
Number of comorbidities (1-comorbidity increase)	0.10 (0.07)	0.2029	-0.09 (0.06)	0.1372
Number of meds taken (1-med increase)	0.09 (0.05)	0.0707	0.11 (0.04)	0.0127*
Number of daily doses (1-dose increase)	0.03 (0.04)	0.3665		
MRC (1-point increase)	0.03 (0.02)	0.2638		
Trouble reading Rx labels (no-yes)	1.33 (0.42)	0.0017	1.11 (0.39)	0.0047*
Trouble opening Rx bottles (no-yes)	1.40 (0.56)	0.0118	1.16 (0.50)	0.0198*
Health Literacy				
High/adequate health literacy	-	-	-	-
Low/inadequate health literacy	1.39 (0.35)	<.0001	0.97 (0.33)	0.0029*
Cognitive status (Mini-Cog)				
Possible impairment	-	-		
No impairment	-0.35 (0.41)	0.4025		
Functional status (ADLs)				
Highly independent	-	-	-	-
Moderate/low independent	0.83 (0.40)	0.0365	0.63 (0.37)	0.0902
Fall in the last month (no-yes)	1.20 (0.55)	0.0289	0.92 (0.49)	0.0632

** Significant P-value < 0.05*

5.5 Association Between MMC and ER Utilization

The rate of the Emergency Room (ER) visits over the last six months was 21.5% (n=23), however, this might be not sufficient size to test the association between MMC and ER visits. Among those ER visits, 17 participants (73.91%) reported only one ER visits while six participants (26.09%) reported more than one ER visits within six months. The most common reasons for those ER visits were uncontrolled symptoms (15 visits, 65.22%) such as abdominal pain, headache, and shortness of breath. Only five visits (21.73%) were due to medication-related problems such as running out of medications and adverse drug reactions. While three (13.05%) of them were due to other reasons such as a car accident, a suicidal attempt, and falling.

There was no significant difference in demographic characteristics between ER visit groups except in age and educational level. Reported ER visits were significantly higher among the participants aged 65 years and older with college or some college education compared with younger participants with less education levels (Table 5.14). Moreover, having at least one ER visit was significantly higher among the participants who reported having congestive heart failure, depression, and anxiety than those who did not. In addition, there was a significant difference in the mean total number of comorbidities among ER visit groups (Table 5.15). The mean difference in the total number of comorbidities was 1.55 higher among participants with ER visits compared to the no ER visit groups (95% CI: -2.85, -0.25).

The MedMaIDE total deficiency score was lower among the participants who reported ER visits compared to those who did not. The mean difference in the MedMaIDE total deficiency score was 0.91 (95%CI: 1.97, 0.46, p-value = 0.0536). The sample size might be not sufficient to examine this association between MMC and ER visits. Furthermore, ER visit groups had a higher mean number of medications, daily doses taken, as well as medication complexity compared to the participants in the no ER visits group (Table 5.16). However, none of these differences were

statistically significant. There was no significant difference between the two ER visit groups in medication-taking behavior variables. Furthermore, geriatric assessments including health literacy, cognitive and functional status, history of fall, using assistive devices, wearing eyeglasses, and depression status, were not significantly different among the participants in either ER visit group (Table 5.17).

The unadjusted logistic regression model indicated that there was no significant association between medication self-management capacity and ER visits. However, as the total deficiency score of MedMaIDE increased, the odds of visiting the ER decreased. Moreover, the odds of reporting ER visits within six months increased among the younger participants who were 55 – 64 years old as well as the participants with college or some college education. Compared to the participants aged 65 years and older, the odds of reporting ER visits was 2.93 times higher among the participants aged 55- 64 years. Compared to the participants with high school (or less education), those with college education (or some college) were 3.07 times more likely to have ER visits. For every one comorbidity increase, the odds of reporting ER visits increased by 1.20 times (95% CI: 1.02, 1.41).

The final adjusted model included the potential variables: age, educational level, health status, total number of comorbidities, medication and daily doses taken, medication regimen complexity, cognitive and functional status, and having depression symptoms. There was no significant association between the MedMaIDE total deficiency scores and ER visits, even when controlling for participants' age, educational level, and comorbidities. This adjusted model suggested that for every one-score increase in the total deficiency score, the odds of ER visits increased by 1.23 times. However, increasing number of comorbidities was the only significant predictor for reporting ER visits when adjusting for participants' age educational level, functional

status, and medication self-management capacity (Table 5.18). The final model fit was evaluated using the Hosmer and Lemeshow Goodness-of-Fit Test, which indicated that the model had adequate fit to the data, and did not deviate significantly from the data (Chi-square = 3.54, P-value = 0.8961).

Table 5.14 Participants' Demographic Characteristics by ER Visits

Demographic Characteristics	ER Visits in the last 6 months		
	None N= 84 (78.50) Mean (SD)	At least one N= 23 (21.50) Mean (SD)	P-value
Age	69.24 (7.47)	66 (5.74)	0.0566
	N (Col %)	**N (Col %)**	**P-value**
Age			0.0245*
55 - 64 years old	20 (23.81)	11 (47.83)	
65 years or older	64 (76.19)	12 (52.17)	
Sex			0.3052
Male	43 (51.19)	9 (39.13)	
Female	41 (48.81)	14 (60.87)	
Race			0.3065
White	10 (11.90)	5 (21.74)	
None white	74 (88.10)	18 (78.26)	
Marital Status			0.7243
Ever married	44 (52.38)	13 (56.52)	
Never married	40 (47.62)	10 (43.48)	
Educational Level			0.0013*
College degree	3 (3.57)	7 (30.43)	
Some College	19 (22.62)	5 (21.74)	
High School/GED	38 (45.24)	4 (17.39)	
Less than High School	24 (28.57)	7 (30.43)	
Educational Level			0.0177*
College degree/some	22 (26.19)	12 (52.17)	
High school or less	62 (73.81)	11 (47.83)	
Type of insurance			0.2531
Medicaid	11 (13.10)	3 (13.04)	
Medicare	22 (26.19)	4 (17.39)	
Dual eligible	50 (59.52)	14 (60.87)	
Other	1 (1.19)	2 (8.70)	
Living Arrangement			1.0000
Alone	81 (96.43)	22 (95.65)	
With Other	3 (3.57)	1 (4.35)	
Health Status			0.4198
Excellent/Very good	25 (29.76)	6 (26.09)	
Good	31 (36.90)	6 (26.09)	
Fair / Poor	28 (33.33)	11 (47.83)	
Health Status			0.2007
Excellent/Very good/Good	56 (66.67)	12 (52.17)	
Fair / Poor	28 (33.33)	11 (47.83)	

* Significant P-value < 0.05

Table 5.15 Participants' Comorbidities by ER Visits

Comorbidities	ER Visits in the last 6 months		
	None N= 84 (78.50) N (Col %)	At least one N= 23 (21.50) N (Col %)	P-value
Arthritis	49 (58.33)	17 (73.91)	0.1733
Osteoporosis	2 (2.38)	3 (13.04)	0.0654
Asthma	23 (27.38)	5 (21.74)	0.5855
COPD, ARDS, or Emphysema	16 (19.05)	8 (34.78)	0.1089
Congestive heart failure	22 (26.19)	12 (52.17)	0.0177*
Heart attack	8 (9.52)	4 (17.39)	0.2828
Stroke or TIA	15 (17.86)	6 (26.09)	0.3786
Peripheral vascular disease	19 (22.62)	4 (17.39)	0.7765
Diabetes types I and II	28 (33.33)	8 (34.78)	0.8963
Upper gastrointestinal disease	37 (44.05)	9 (39.13)	0.6730
Depression	28 (33.33)	13 (56.52)	0.0427*
Anxiety or panic disorders	22 (26.19)	13 (56.52)	0.0060*
Visual impairment	39 (46.43)	13 (56.52)	0.3908
Hearing impairment	19 (22.62)	3 (13.04)	0.3942
Degenerative disc disease	22 (26.19)	10 (43.48)	0.1086
Obesity and/or (BMI) > 30	36 (42.86)	12 (52.17)	0.4260
	Mean (SD)	**Mean (SD)**	**P-value**
Number of comorbidities	4.58 (2.64)	6.13 (3.28)	0.0201*

* Significant P-value < 0.05

Table 5.16 Medication-Related Variables by ER Visits

	ER Visits in the last 6 months		
	None N= 84 (78.50) Mean (SD)	**At least one N= 23 (21.50) Mean (SD)**	**P-value**
MedMaIDE total deficiency score	3.17 (2.08)	2.26 (1.48)	0.0536
Number of meds	7.40 (3.97)	8.91 (4.54)	0.1207
Number of daily doses	7.80 (5.16)	9.35 (4.84)	0.1988
Medication Regimen Complexity	13.23 (8.37)	16.59 (9.29)	0.0991
	N (Col %)	**N (Col %)**	**P-value**
Receiving meds assistance from someone			0.8746
Yes	17 (20.24)	5 (21.74)	
No	67 (79.76)	18 (78.26)	
Using Pharmaceutical aids/services			0.5270
Using none	18 (21.43)	4 (17.39)	
Using one	27 (32.14)	8 (34.78)	
Using more than one	39 (46.43)	11 (47.83)	
Medication Adherence Barriers			0.3683
Yes	35 (41.67)	12 (52.17)	
No	49 (58.33)	11 (47.83)	
Reading Rx labels	16 (19.05)	6 (26.09)	0.4592
Opening Rx bottles	13 (15.48)	0	0.0662
Refilling meds on time	6 (7.14)	5 (21.74)	0.0559
Paying for meds	12 (14.29)	6 (26.09)	0.1801
Medication Non-adherence			
Missing a dose of any meds taken last week			0.2983
None	53 (63.10)	16 (69.57)	
One dose	12 (14.29)	5 (21.74)	
Two or more doses	19 (22.62)	2 (8.70)	
Ability to take meds as prescribed			0.5270
Excellent (adherent)	34 (40.48)	11 (47.83)	
Not Excellent (Not adherent)	50 (59.52)	12 (52.17)	

* Significant P-value < 0.05

Table 5.17 Geriatric Assessments Variables by ER visits

	ER Visits in the last 6 months		
	None N= 84 (78.50) N (Col %)	**At least one N= 23 (21.50) N (Col %)**	P-value
Health Literacy			0.5970
High/adequate	49 (58.33)	12 (52.17)	
Low/inadequate	35 (41.67)	11 (47.83)	
Cognitive Function			0.1338
Possible impairment	29 (34.52)	4 (17.39)	
No impairment	55 (65.48)	19 (82.61)	
Functional Status			0.1822
Highly independent	61 (72.62)	20 (86.96)	
Moderate/Low independent	23 (27.38)	3 (13.04)	
Using Assistive device	46 (54.76)	9 (39.13)	0.1839
Fall	9 (10.71)	3 (13.04)	0.7182
Wearing eyeglasses	68 (80.95)	19 (82.61)	1.0000
Having depression symptoms			0.2341
Normal (no depression)	65 (77.38)	15 (65.22)	
Depression symptoms	19 (22.62)	8 (34.78)	

* Significant P-value < 0.05

Table 5.18 Unadjusted and Adjusted Logistic Regression Models for ER Visits and Potential Predictors

	Unadjusted Model		Adjusted Model	
	OR (95 % CI)	**P-Value**	**OR (95 % CI)**	**P-Value**
MedMaIDE total deficiency score (1-point increase)	0.77 (0.58, 1.01)	0.0573	0.81 (0.60, 1.10)	0.1809
Age				
65 years or older	-	-	-	-
55 - 64 years old	2.93 (1.12, 7.66)	0.0280*	2.89 (0.96, 8.66)	0.0583
Educational Level				
High school or less	-	-	-	-
College degree/some	3.07 (1.19, 7.96)	0.0207*	2.59 (0.88, 7.62)	0.0837
Health Status		0.2041		
Excellent/very good/good	-			
Fair/Poor	1.83 (0.72, 4.67)			
Number of comorbidities (1-comorbidity increase)	1.20 (1.02, 1.41)	0.0253*	1.25 (1.03, 1.52)	0.0219*
Number of meds (1-med increase)	1.09 (0.98, 1.22)	0.1241		
Number of daily doses (1-dose increase)	1.06 (0.97, 1.15)	0.2008		
MRC (1-point increase)	1.04 (0.99, 1.10)	0.1025		
Health Literacy				
High/adequate	-	-		
Low/inadequate	1.28 (0.51, 3.24)	0.5975		
Cognitive Function				
Possible impairment	-	-		
No impairment	2.50 (0.78, 8.06)	0.1235		
Functional Status				
Moderate/Low indep.	-	-	-	-
Highly independent	2.51 (0.68, 9.27)	0.1662	3.66 (0.81,16.58)	0.0926
Fall				
No	-	-		
Yes	1.25 (0.31, 5.05)	0.7541		
Having depression symptoms				
Normal (no depression)	-	-		
Depression symptoms	1.82 (0.67, 4.95)	0.2380		

* Significant P-value < 0.05H

CHAPTER SIX

DISCUSSION AND CONCLUSION

6.1 Discussion

To the best of our knowledge, this is the first study examining the relationship between MMC and a wide range of variables among older adults living in the subsidized housing community. This study adds several findings to the existing literature. First, a resident aged 55 years or older and living in subsidized housing uses on average approximately eight medications that are associated with about five medical conditions. Second, many low-income older adults have limited ability to manage their own medications, in particular, they have a lack of knowledge about their medications. Third, among members of this group, low educational level, low health literacy, and reporting difficulties reading medication labels or opening medication bottles are significant risk factors for medication mismanagement. Four, assessing older adults' ability to manage their own medication using a standardized tool like MedMaIDE helps to identify those at risk for medication mismanagement and is useful for individualizing interventions based on their needs and specific deficiencies.

The study sample was recruited from five subsidized housing communities, and they represent the common characteristics of the residents of HUD buildings. The study sample was more likely to live on their own independently with multiple chronic conditions, and were more likely to have limited educational level and health literacy, and reported fair or poor health status.

The results of this cross-sectional study showed that older adults who live in low-income housing communities had an average of about three deficiencies in their medication management capacity as assessed using MedMaIDE. Among 107 participants age 55 years or older, 98 (91.59%) of them had one or more deficiencies in medication management and 81 (75.70%) had two or more deficiencies in medication management. These findings are higher than what a previous study

found using the same assessment tool (Orwig D., et al.).[1] The participants of that study were 50 community-dwelling older adults with an average age of 78.18 (±7.21) and about 9.38 (±3.74) years of education, and their annual income ranged from $9,000 to 12,000.[1] In that study, the mean total deficiency score was approximately two (±1.96), and 70% had one or more deficiencies in medication management on MedMaIDE.[1] Specifically, the sub-score for the first area was 2.17 (±1.55) in our study, which is almost double what was found in the previous study [1.46 (±1.54)]. These high overall scores might be due to relying on the written directions on the labels to compare to what the participants reported when assessing their knowledge about medications.[1] As a result, one point (unable) was given for any discrepancies that occurred between what was reported by the participant and what was written on the labels during the assessment of MMC. Nevertheless, credits were given for any appropriate answer reported by the participants when the indication was not specified on the labels and the medication had multiple indications. This may increase the sub-score for the first area as well as the overall score. Furthermore, the most difficult skill was naming the medications followed by stating the indication, timing, frequency, and identifying existing refills. These findings are consistent with the previous study. However, the participants in that study were older than this study (78.18 vs. 68.54 years). The sample in both studies was highly independent, cognitively intact, and used a high number of prescription medications on average (approximately ≥ 7 medications on average). Unfortunately, we cannot compare our findings with the other studies using MedMaIDE to assess the deficiencies in medication management because the participants were caregivers.[2,3]

The analysis of this study shows that low educational level, reporting difficulties reading the medication labels or opening the medication bottles, and low or inadequate health literacy are strong independent predictors for low medication self-management capacity among low-income

older adults. These predictors remained significant even after adjusting for all other significant predictors in one model.

We found a robust association between participants' ability to self-manage their medications and educational level. Participants with less than or equal to high school education had a significantly higher deficiency in their ability to manage medications compared to those with a college education or more. While numerous studies describe the association between educational level and medication management, the findings are inconsistent.[4–8] One of the previous studies showed that the odds of being unable to identify all medications increased 3 times among patients with less than 12 years of schooling.[4,5] The negative association was seen in the studies that included a well-educated sample.[4] In contrast, about 68.22% of our sample had less than or equal to high school education which can be used as an indicator of living in low socioeconomic status (SES). Therefore, our findings may support evidence that has found that low socioeconomic status is a risk factor for medication mismanagement.[7,8] Also, it is consistent with the idea that education level is a social determinant of health.[9]

Consistent with the literature, our findings showed that low/inadequate health literacy was significantly related to low MMC. An observational study found that patients with inadequate health literacy were 18 times more likely to be unable to identify all of their medications compared to patients with adequate health literacy.[4] Furthermore, other studies have shown that patients with low health literacy are unable to understand medication instruction easily.[10,11] In a published survey for Medicare managed care enrollees, 47.5% of respondents with inadequate health literacy were unable to identify the appropriate timing of the dose that was written on the labels, and 54.3% inadequate-literacy respondents struggled to explain how to take a medication on an empty stomach.[11] These findings in combination with our study findings indicate that low health literacy

may impact an individual's cognitive ability to manage medications. Consequently, health care providers, in particular pharmacists, should consider the patients' level of education, health literacy, and SES when providing education about medication use.

In this study, the association between the deficiency in medication management capacity and self-reported medication adherence was statistically significant only in the bivariate analysis. Reporting trouble reading labels and opening medication bottles was significantly related to the deficiency in MMC in both bivariate and multivariate analysis. We found that the participants who reported trouble reading labels or opening medication bottles had a higher total deficiency score by more than one point on average compared to others who did not report these medication-related difficulties. In the literature, there has been a conflict regarding the correlation between MMC and both objectively measured and self-reported medication adherence[1,8,12,13] The validation study of MedMaIDE showed that as the deficiency in medication management increases, the medication adherence (based on 30-day pill count) decreases.[1] Other studies concluded that patients' capacity to manage meditations does not significantly impact their adherence status. The developers (Murry et al.) of the medication assessment instrument (MAI), one of the MMC assessment tools, reported a significant association between medication adherence and two skills of medication management among community-dwelling older adults.[12] These two skills were inability/difficulty to open a flip top lid and read a medication label.[12] Even though it is not entirely clear why this relationship exists, it could be due to the low educational level, visual impairment, having arthritis or any other factors. This finding indicates that the pharmacist should check older adult patients' ability to read the details on the label and remove the cap on the medication vials before leaving the pharmacy. Thereafter, further investigation should be done to identify the appropriate intervention. Older adult patients who live alone are at risk for medication errors when they cannot read the directions

on the label or cannot open child-resistant caps. In addition, they may lack assistance with medication at home which may put them at higher risk of medication errors. Therefore, the directions on the label of all medications, not just newly prescribed medication, should be reviewed with elderly patients before leaving the physicians office and/or pharmacy. In addition, the information about the availability of non-child resistant caps and other medication packaging should be provided to older adult patients.

The findings of this study suggested that the association between MMC and the number of comorbidities did not exist. This is consistent with what has been reported in existing literature.[5,7] However, we found that specific comorbidities like asthma, stroke and hearing impairment are positive predictors for deficiency in medication management when adjusting for other comorbidities and number of comorbidities. In general, stroke may contribute to cognitive and physical impairments, and arthritis contributes to dexterity issues among older adult patients. In addition, patients with asthma and stroke are typically prescribed complicated and multiple medication regimens.[14] However, our findings indicated that there was a non-significant relationship between limited medication management capacity and taking a high number of medications and daily doses taken, and complicated medication regimens. These findings are consistent with what has been reported previously.[5,7,8,15] Therefore, the limited MMC among patients with asthma and stroke might not be related to using multiple and complex medication regimens. Furthermore, a cross-sectional study observed that using hearing aids does not impact older adults' ability to take oral medication.[7] Another study showed that lacking the knowledge and skills to manage heart failure medications are related to negative health outcomes.[16]

On the bivariate analyses, we observed that limited ability to perform basic ADLs, using assistive devices, and a history of falling are positive predictors for deficiency in medication

management capacity. However, this was not the case in the multivariate analysis. The MedMaIDE validation study found that self-reported ADLs and IADLs were not significantly related to the sample's ability to manage their medication, similar to what has been reported in other studies.[1,5] However, a one year follow up study confirmed a significant relation between MMC and both self-reported ADLs and IADLs after six months.[15]

Unlike other studies, this study failed to observe the significant relationship between MMC and participants' cognitive function.[1,4,5,7,8,15] This inconsistent finding with other studies might be due to two reasons. First, the Mini-Cog was used in this study to assess cognitive function, while most of the previous studies used the Mini-Mental State Examination (MMSE). Second, the sample in this study was relatively cognitively intact. The participants who had Alzheimer's disease, dementia, or were taking any medications for memory (such as cholinesterase inhibitors and memantine) were excluded. Moreover, a cross-sectional study concluded that the Mini-Cog is a significant screening tool for determining patients' ability to organize a pillbox. The findings of that study showed a weak correlation between MMSE and ability to organize the pillbox.[17] Another study concluded that impaired concentration and poor visual and verbal memory were predictive of poor medication planning ability, while limited motor dexterity and strength was an indicator of inability to open the child-resistant cap and cutting pills.[18]

Even though the MMSE covers more aspects of cognitive function ─ including orientation, word registration, attention and calculation, recall, and language ─ it fails to detect people with deficiency in executive cognitive function (ECF). Moreover, individual's age, educational level, literacy, SES, and language affect MMSE scores.[19,20] Consequently, older adults who have a low educational level or SES, and limited communication skills may score poorly on the MMSE even when they are cognitively intact.[20,21] On the other hand, the clock drawing test component of the

Mini-Cog assessment is specifically designed to assess ECF. Additionally, scoring on the Mini-Cog is not related to age, educational level, or language.[19,20] Since managing a medication regimen appropriately requires coordination of simple tasks, like identifying the medication, opening and removing the medication from packaging and recalling the dosing time and frequency, it mainly depends on an individual's ECF.[21] Therefore, Mini-Cog might be the appropriate screening tool to identify people with the required cognitive function to self-manage their medication independently.

Consistent with the literature, older adults' cognitive and functional ability to manage their medication was not influenced by depression symptoms as measured by the GDS.[5,7,15] In addition, we did not observe a difference in medication management among the participants who were diagnosed with depression or anxiety.

When the residents had someone reminding them to take medication on regular basis, more deficiency in medication management was observed than those who did not have assistance (MedMaIDE total score: 5.00 (±2.45) vs. 2.85 (±1.68), p-value = 0.0098). In addition, using bubble pack packaging was related to a higher deficiency in medication management (4.57 (±2.44) vs. 2.86 (±1.93), p-value = 0.0277). A study reported patients who were using blister pack and receiving reminders from someone to take medications were more likely to have limited ability to recall medication instructions.[22] When individuals have trouble with medication management are often offered specialized packaging like bubble pack as a way to help them. Using specialized packaging may not necessarily improve their knowledge about medications but it helps keeping them on schedule. However, the packages may or may not be easier to open depending on the packaging system. In this case, maybe the poor capacity is the cause of getting packaging.

Therefore, it helps to improve adherence, but not necessarily by increasing their capacity to manage medications especially concerning knowledge of their medications.

As expected, the findings of this study suggest that using pillbox organization increased older adults' ability to manage their medication. Even though pillbox (43.93%) was the most common medication aid used by the participants, the relationship between MMC and using a medication organizer aid was not statistically significant. This might be explained by participant difficulty organizing or refilling the pillbox, an item that was not captured using MeMaIDE. Even though MedMaIDE was designed to assess patients' ability to manage different dosage forms, it does not asses their ability to organize or fill the pillbox. A cross-sectional study concluded that patients' cognitive ability to comprehend prescriptions impacts their ability to correctly organize and fill the pillbox. This study proposed a new tool (Medi-Cog) as a screening for determining pillbox organization ability and identifying patients at risk for medication mismanagement.[17]

In our study, limited MMC was observed when the participants reported assistance with medications from someone (i.e. reminding them to take medication, setting up the pillbox, or ordering there refills). While, high MMC was observed among the participants who used medication aids (i.e. drug list/card, organizer, or reminder) or pharmacy services (i.e. special packaging, non-child-resistant cap, prescription home delivery, or mail order). However, these observations were not statistically significant even when adjusted for other significant predictors for self-managing of medications. In the adjusted model, taking a high number of medications turned out to be as a positive predictor for deficiency in medication management along with low educational level, reporting difficulties reading labels and opening bottles, and limited health literacy when adjusted for receiving assistance with medication and using medication aids or pharmacy services. However, the literature suggests that using medication aids and medication

synchronization programs can improve medication adherence.[23,24] Indeed, using at least one pharmaceutical aids/services might correlate with low MMC since individuals tend to start receiving help or using pharmaceutical aids because they are having difficulty. The aids and assistance with medication may not improve their medication capacity scores, but they may improve overall adherence.

This study shed light on the issue of emergency room utilization among the study sample. Since 2012, when RHWP clinics were implemented, the overall rates of ER visits have decreased.[25] Despite this fact, there were 23 (21.50%) participants who reported ER visits within six months before the study interview. The findings suggest that age, educational level, and number of comorbidities are significantly associated with ER visits among the study sample. Although the association between ER visits and deficiency in medication management was not significant, we observed that the deficiency in medication management capacity was higher among the participants who reported ER visits compared to those who did not. In addition, an ordinal logistic regression model was conducted as a sensitivity analysis to examine whether the deficiency in MMC increased the number of ER visits. The ER visits were categorized into three groups: 1) no ER visits [84 (78.50%)], 2) one ER visit [17 (15.89%)], and 3) more than one ER visits [6 (5.61%)]. The finding of this ordinal logistic analysis showed that the association between MMC and number of ER visits was not statistically significant [OR = 0.782 (95% CI: 0.598, 1.023), P-value = 0.0723]. This finding is not different than that of the logistic regression analysis (ER visit vs. no ER visit), which also found no significant difference. This may be because there is no true association between medication management capacity and ER visits or that there was insufficient sample size to detect a true difference (Type II error)

In contrast, a one-year follow-up study reported that the change in MMC between baseline and six months was significantly related to an increased number of ER visits.[15] Another 6-month follow up study concluded that having limited medication knowledge was significantly associated with more ER visits among patients 50 years and older with congestive heart failure.[16]

In our study, ER visits were assessed retrospectively, which might not be as accurate as other studies that followed patients prospectively. The nature of self-reported data coupled with the recall period of six months might be factors that affected the accuracy of the reported number. Even though six months seems like a reasonable period for an average healthy person to recall, it was clear to the study investigator how difficult it was for some of the participants to recall the information. A study that looked at the accuracy of self-reported data of health services utilization among older adults who were 65 years concluded that the health services use were under-reported by those older adults.[26] The finding of that study found that 28.1% of older adults who were 65 years and older failed to report ER visits over 12 months when compared with electronic record data.[26] Another justification for our findings is that the vast majority of the participants were receiving care from RHWP clinics. Typically, the RHWP team provide a follow-up visit at home or at clinic for those participants who reported ER visits. During this follow-up visit, the interprofessional team works with residents to identify any care coordination needs, whether they are medication or health-related needs. Thereafter, the team works with the resident to fulfill his/her needs, such as providing medication reconciliation, education/counseling about medications or health conditions, disease monitoring, or accessing prescription medications or healthcare services.[25] As a result, those participants with ER visits might be scored low on MedMaIDE which indicates having a high ability to manage their medications independently.

6.2 Study Limitations

To the best of our knowledge, this is the first study examining the relationship between MMC and a wide range of variables among older adults living in the subsidized housing community. This study has several limitations. First, the study sample size was relatively small, which may lead to a type II error. Therefore, this study has low power to detect the significant relationship between MMC and some variables. This study intended to study a minority population of older adults who live in the low-income housing community, and 107 participants have successfully completed the study. We were fortunate to have complete data without any missing variables, which increases the study power, despite the small sample size. Further, four separate models were conducted to identify the significant predictors of limited MMC to address the sample size issue.

Using a non-probability (non-random) sampling strategy may lead to limited generalizability and selection bias due to homogeneity among the sample characteristics. Therefore, the findings cannot be generalized to all community-dwelling older adults. The eligible age was 55 years or older which may not represent the common chronological age classification for older adults in developed countries like the U.S. The sample was recruited from five subsidized housing locations in downtown Richmond VA, which serve a predominately vulnerable older adult population who lives with a high burden of chronic diseases coupled with economic challenges and limited access to health resources. By setting this age criterion, we considered the biological/physiological age which is influenced by various factors such as lifestyle, chronic diseases, genetics, alcohol consumption, SES, and living location.[27] The participants' average age was about 68 years, and most were African American (83%) with high school or less education, and living with about five medical conditions. Surprisingly, there was an almost equal proportion

of male and female participants (48.60 vs. 51.40%, respectively), which may be considered a strength for this study. The characteristics of this study' sample were similar to the characteristics of participants in RHWP clinics. Despite our limitations, research in this minority high-risk community is needed and may inform future intervention to improve medication self-management and increase independence. In addition, most of our findings were consistent with previous studies of MMC performed in different settings.

Another study limitation is that the nature of the study data might introduce some biases to the findings. Self-reported data may be subject to social desirability and recall bias. Furthermore, there might be a selection bias due to using a self-selected sample. This sample included mostly people with a greater interest in taking medication safely and as prescribed, which might not represent the attitudes or behaviors of the general demographic. During the assessment of MMC, we relied on the participants to display and report all medications they were using on regular basis and on the written directions on the labels of these medications to determine their ability to manage medications. Unfortunately, we do not have access to the residents' medical record or pharmacy records, so we may over or underestimate the sample's MMC. However, we were able to assess older adults' medication knowledge for both prescription and OTC medications. We observed a high deficiency in medication management among the study sample. This was somewhat surprising because most of the participants were receiving care coordination services from the RHWP clinics. In addition, participants' medical history was assessed using the functional comorbidity index which includes only 18 self-reported medical conditions. Thus, we missed many chronic conditions/disease that participants might have had that were not included in an index designed to predict functional impairment.

In this study, MedMaIDE was chosen over a wide number of validated tools that were designed to assess MMC for several reasons. One of these reasons is that it evaluates older adults' cognitive and functional abilities to administer/take different dosage forms, not only oral medications. However, it does not assess the ability to organize or fill medication organizers such as pillboxes, which is one of the study limitations. Pillboxes are the most common medication organization tool used by about 10 million older adults.[17] Therefore, further study is needed to investigate the older adult's ability to use a pillbox correctly using an appropriate assessment tool. Additionally, MedMaIDE might be subject to floor or ceiling effects which occurs when most of the participants are scored near the minimum or maximum score.[28] However, the total deficiency score on MedMaID was normally distributed with a minimum score of 0 and maximum score of 10. Moreover, MedMaIDE is a performance-based tool using the patient's own medication. Most of the residents were very collaborative and they brought all medications for review, while a few of them forgot or decided to bring only some of them. Refrigerated medications (heat sensitive) like insulin and controlled medications were the most often forgotten or not brought medications for review.

There was a potential for interviewer bias and measurement bias. However, these types of bias cannot be completely excluded. All the interviews were conducted and the data were collected by one interviewer, which may control the interviewer bias and minimize the variance in the data. The interview procedure and the assessment order was specified in the study protocol, and all the study assessments were selected based on validity and reliability data.

The last limitation is that the study findings may be influenced by other potential combinations of mediators or moderators that should be controlled. For example, we assume all study participants have low socioeconomic status since the participants met certain celling income

criteria for residing in subsidized housing. Whereas financial/income information may determine the optimal socioeconomic level, this information is sensitive and not easily obtained as well as may be difficult to interpret. As a result, the study findings might be interpreted differently by controlling those potential mediators or moderators.

6.3 Future Direction

A number of observational studies have been done in this area of medication self-management, however, most of them were limited to small sample sizes, and had generalizability limitations. Future research should be directed toward prospective and interventional studies for a larger sample size with a more diverse population. The stronger study design would be randomized prospective cohort study. It would be worthwhile to use a random sampling strategy with a comparison (control) group to overcome the issues of limited generalizability and selection bias. We could randomly select a cohort sample of older adults from nationally representative registry data such as HUDs or Medicare data.

By following up the participants prospectively, we could understand how the cognitive and functional ability to appropriately manage medications changes over time. It would be important to study how age-related changes in cognitive and functional status affect the ability to manage medication independently over time. The power of our study was insufficient to determine the relationship between MMC and ER visits. The prospective study design will be more appropriate to examine the relationship between patients' ability to manage medications and clinical outcomes such as hospitalization, ER visits, and institutionalization. Furthermore, we could study the association between MMC and medication outcomes such as medication errors, and medication adherence. It would be interesting to determine the patients' ability to manage medications using two different standardized assessment tools, one of them using the patients' own medications and

the another using simulated mediations. In addition, a future study could identify the required skills and the potential predictors for limited ability to manage pillbox.

This study found that people with low MMC were more likely to start using medication aids or pharmaceutical services which might improve overall adherence but not necessarily improve the ability to manage medications. It would be worthwhile to look at the causal relationship in future studies where MMC would be compared before and after intervention with pharmaceutical services or RHWP clinic visits. By conducting this experimental design we could test the hypothesis of whether or not implementing medication interventions would improve a patient's ability to take medications as prescribed. As a result, the role of using a different types of medication intervention would be studied including the use of pillbox otherwise specialized packaging, prescription home delivery, medication regimen simplification and medication counseling. Also, the effectiveness of implementing medication intervention as identified after MMC assessments would be determined. Future research in RHWP should examine whether medication self-management capacity could predict who might not be able to remain living independently safely or who might need additional support to remain independent. This line of research would strengthen the evidence on the utility of using a standardized validated tool to assess MMC in outpatient settings. The effect of potential mediators and moderators should be considered and controlled in the future study.

Clinical Implications

The findings of this study would be used to improve the effectiveness of clinical assessments that used in RHWP clinics to identify residents' health deficits and determine their needs. Medication management is a basic self-care activity, and inclusion of MMC assessment in comprehensive geriatric assessments is recommended to promote safe use of medications among

older adults living independently in low-income senior housing. In this study, the association between low MMC and low educational level and health literacy was statistically significant. Therefore, screening for health literacy might be a useful clinical assessment to identify those older adult residents who should get MMC assessment. The findings showed that the three health literacy questions that were used could be a good screening tool. Additionally, questioning the participants at RHWP about whether or not they have difficulty opening and reading prescription medications can be used to determine those who need a full MMC assessment. Assessing MMC using a standardized and validated tool helps to detect the cognitive and functional limitation in medication management and target intervention based on needs.

6.4 Conclusion

Many older adult residents of low-income housing communities have deficient capacity to manage their medications independently. Insufficient medication knowledge is more prevalent among low-income older adults. Low educational level and health literacy and reporting difficulty reading the prescription labels and opening the medication bottles are contributing factors to mediation mismanagement. This present study adds to the growing body of evidence suggesting that assessing older adults' ability to manage their own medications using a performance-based tool such as MedMaIDE may help to identify those individuals with limited medication management capacity and lead to individualized intervention thereafter. Healthcare providers, in particular pharmacists, should consider assessing older adults' capacity for self-managing medication to identify key targets for interventions, which will promote healthy aging in-place and independence by enhancing the safe use of medications. There is a need for additional research studying the change in MMC over a long period of time among a larger sample. It would also be

useful to study intervention strategies that may improve medication management skills such as specialized packaging, pillbox organization, improved labeling, and counseling.

6.5 References

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Appendix 1

Screening for Eligibility Form

Screening for Eligibility Sheet

Study Title: Understanding Medication Self-Management Capacity Among Independent Older Adults

Participant ID number: _____

#	Eligibility Criteria	Answers
1	Are you 55 years or older?	Yes / No
2	Are you able to read and converse in English?	Yes / No
3	Do you live independently?	Yes / No
4	Are you taking at least one prescription or over-the-counter medication?	Yes / No
5	Does someone (e.g. family member, caregiver, or friend) help you take or administer your own medications on a regular basis?	Yes / No
6	Have you ever been told by a doctor or health professional that you have Alzheimer's disease?	Yes / No
7	Have you ever been told by a doctor or health professional that you have dementia or memory problem?	Yes / No
8	Are you taking any medication for your memory? For example: cholinesterase inhibitors including donepezil (Aricept ®), rivastigmine (Exelon®), galantamine (Razadyne®, Razadyne ER®); Memantine (Namenda®, Namenda Titration Pak®, Namenda XR®, or Namenda XR Titration Pack®); or combination of Memantine and Donepezil (Namzaric®).	Yes / No
9	Do you have any problem to bring your medications that you use every day (on a regular basis) including, prescription and over-the-counter, vitamins/minerals for review?	Yes / No

Residents who meet the following criteria are eligible to participate in this study:

1- aged 55 years or older
2- able to read and converse in English
3- living independently and not relying on another person to administer medications (i.e. family members, friends, or caregivers)
4- currently taking at least one prescription or over-the-counter (OTC) medication
5- not have Alzheimer's disease or dementia diagnosis
6- not taking cholinesterase inhibitors or memantine (i.e. inferred diagnosis of dementia)

Eligible: Yes / No

If the residents did not meet all the eligibility criteria as written above, discard this form.

If the resident met all eligibility criteria as written above, ask him/her the following:

1- Participant Name: _____
2- Phone number to make a reminder phone call (optional): _____
3- Schedule a time for study interview based on his/her preference

   Date: _____

   Time: _____
4- Give him/her a medication bag and ask him/her to bring all current medication containers with you in the study interview including prescription and over-the-counter medications, and vitamins/minerals.

Appendix 2

Study Flyer and Brochure

Medication Self-Management Capacity Interview

Are you interested participating in our research?

- **Are you aged 55 years or older ?**
- **Are you able to read and converse in English?**
- **Do you take at last one medication ?**
- **Do you live independently and do not rely on another person to take your medication?**

If YES, you may be eligible to participate!

All participants will receive a compensation!

Participants will spend no longer than 60 minutes of being interviewed at the RHWP clinic in the building about their medication use

Please Contact:

Amal Badawoud, VCU School of Pharmacy

Phone Number: (804) 428-0583 **Email:** badawoudam@vcu.edu

- VCU is conducting a study about medication self-management capacity in your community
- You are invited to participate in this study
- Your participation is voluntary
- Your information will remain confidential

Medication Self-Management Capacity Interview

Dr. Patricia Slattum & Amal Badawoud

VCU School of Pharmacy
410 N. 12th Street
BOX 980533
Richmond, VA 23298-0533

Phone: (804) 428-0583
E-mail:
badawoudam@vcu.edu

Do you take one or more mediations?

Do manage your mediations independently?

Seeking volunteers 55 and older !

Study Interview

- During this study interview, you will be asked questions regarding your medical history and medication-taking behavior.
- Your capacity to manage your own medication will be assessed.

Your Participation

Interview:

- You will be interviewed in-person for this study.
- The interview will take about **60** minutes.
- The interview will be scheduled at a time convenient for you.

You are eligible if you are:

- aged **55** years or older
- able to read and converse in **English**
- taking **at least one** medication
- not relying on someone to take your medications
- Not taking any medication

The study is approved by the Virginia Commonwealth University Institutional Review Board

For more information or to schedule an appointment to participate, please contact:

Amal Badawoud
Phone: (804) 428-0583
E-mail:
badawoudam@vcu.edu

VCU School of Pharmacy
410 N. 12th Street
BOX 980533
Richmond, VA 23298-0533

Appendix 3

In Person and Telephone Screening Consent Form

Version # 2 Date: 04/03/2018
VCU IRB Protocol Number: HM20012770

In-Person Screening Interview Consent

Study Title: Understanding Medication Self-Management Capacity Among Independent Older Adults

Greetings,

Thank you for your interest to find out more about our research study.

My name is Amal Badawoud, and I am a doctoral candidate at Virginia Commonwealth University (VCU), and under the supervision of Dr. Patricia Slattum, Director of the Geriatric Pharmacotherapy Program at School of Pharmacy, VCU.

The purpose of our research study is to understand more about medication self-management capacity among independent older adults. Specifically, we will study if there is a relationship between your ability to self-manage your medications and your medical conditions, medications, cognitive and functional status, and emergency room use over the past six months.

If you decide to be in this research study, you will be asked to bring all medications including prescription medications, over-the-counter medication, and vitamins/minerals for review and complete study assessments during a scheduled study interview.

Do you have any questions or concerns? Now that you have a basic understanding of the study, do you think you might be interested in participating?

If No: Thank you very much for your time

If the participant is interested in participating, complete the Screening Consent Form

Purpose and Procedures: To see if you are eligible to be in this research study, I would like to ask you some questions about your age, medication history, whether you are living independently, able to manage your medication with no assistance, and having Alzheimer's disease, dementia or memory problem. This screening interview will take approximately five minutes or less.

You have the option to complete this screening process over the phone instead of completing this interview in-person. If you would like to complete it over phone, just let me know. You can call me at (603) 264-5359, Monday to Friday from 8:00 am to 5:00 pm.

Voluntary Participation: Your participation is voluntary. You may choose to not participate in this screening interview, stop the interview at any time, or skip any questions with no penalty or loss of benefits to which you are otherwise entitled.

Risks and Benefits: The screening questions might make you feel uncomfortable. There is also a small risk that someone outside the study could see and misuse information about you. You will not benefit from taking this survey.

Confidentiality Protections: Information that you give me will be kept as confidential as possible by storing it in secure databases accessible only to the following people: study personnel, authorized people at VCU or VCUHS who oversee research, and authorized officials of the Department of Health and Human Services.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

HIPAA Authorization:

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

To conduct of this research we may use your history and physical exam, information about mental health, and medication history.

By agreeing to be in this study, you authorize VCU and VCU Health to use and/or share your health information for this research. The health information just described may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research: the Principal Investigator and Research Staff, Health Care Providers at VCU and VCU Health, Institutional Review Boards, Government/Health Agencies, and Others as Required by Law. Once

your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Questions about the Study: If you have any questions, concerns, or complaints about your participation in this research, please contact Dr. Patricia Slattum at her office phone: (804) 828-6355. If you want to talk to someone separate from the research team, please contact the VCU Office of Research at 804-827-2157.

Do you have any questions about this study?

CONSENT

Do you consent to participate in this screening interview?

_____ YES – CONDUCT INTERVIEW

Participant name (Printed): _____ Date: _____

Name of Person Conducting Informed Consent (Printed): _____

Signature of Person Conducting the Informed Consent: _____

Principal Investigator signature (Dr. Patricia Slattum) _____

_____ NO – Thank you for your time.

Consent Script for Telephone Screening Interview

Study Title: Understanding Medication Self-Management Capacity Among Independent Older Adults

Greetings,

Thank you for calling to find out more about our research study (or I am returning your call to provide more information about our research study).

My name is Amal Badawoud, and I am a doctoral candidate at Virginia Commonwealth University (VCU), and under the supervision of Dr. Patricia Slattum, Director of the Geriatric Pharmacotherapy Program at School of Pharmacy, VCU.

The purpose of our research study is to understand more about medication self-management capacity among independent older adults. Specifically, we will study if there is a relationship between your ability to self-manage your medications and your medical conditions, medications, cognitive and functional status, and emergency room use over the past six months.

If you decide to be in this research study, you will be asked to bring all medications including prescription medication, over-the-counter medication, and vitamins/minerals for review and complete study assessments during the scheduled study interview.

Do you have any questions or concerns? Now that you have a basic understanding of the study, do you think you might be interested in participating?

If No: Thank you very much for your time

If the participant is interested in participating, complete the Screening Consent Form

Telephone Screening Interview Consent

Purpose and Procedures: To see if you are eligible to be in this research study, I would like to ask you some questions about your age, medication history, whether you are living independently, able to manage your medication with no assistance, and having Alzheimer's disease, dementia or memory problem. This screening interview will take approximately five minutes or less.

You have the option to complete this screening process in-person instead of completing this interview over the phone. If you would like to complete it in-person, just let me know. I will be available in the community area at your resident building during Richmond Health and Wellness Program (RHWP) clinic hours. You can come and I will be happy to complete this process in-person with you.

[redacted]ding name	Clinic day	Clinic hours
[redacted]	Monday	8:30 am to 12:00 pm
[redacted]	Monday	1:30 pm to 4:30 pm
[redacted]	Wednesday	8:30 am to 12:00 pm
[redacted]	Wednesday	1:30 pm to 4:30 pm
[redacted]e	Thursday	8:30 am to 4:30 pm

Voluntary Participation: Your participation is voluntary. You may choose to not participate in this screening interview, stop the interview at any time, or skip any questions with no penalty or loss of benefits to which you are otherwise entitled.

Risks and Benefits: The screening questions might make you feel uncomfortable. There is also a small risk that someone outside the study could see and misuse information about you. You will not benefit from taking this survey.

Confidentiality Protections: Information that you give me will be kept as confidential as possible by storing it in secure databases accessible only to the following people: study personnel, authorized people at VCU or VCUHS who oversee research, and authorized officials of the Department of Health and Human Services.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

HIPAA Authorization:

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

To conduct of this research we may use your history and physical exam, information about mental health, and medication history.

By agreeing to be in this study, you authorize VCU and VCU Health to use and/or share your health information for this research. The health information just described may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research: the Principal Investigator and Research Staff, Health Care Providers at VCU and VCU Health, Institutional Review Boards, Government/Health Agencies, and Others as Required by Law. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Questions about the Study: If you have any questions, concerns, or complaints about your participation in this research, please contact Dr. Patricia Slattum at her office phone: (804) 828-6355. If you want to talk to someone separate from the research team, please contact the VCU Office of Research at 804-827-2157.

Do you have any questions about this study?

CONSENT

Do you consent to participate in this screening interview?

_____ YES – CONDUCT INTERVIEW

Participant name (Printed): _____ Date: _____

Name of Person Conducting Informed Consent (Printed): _____

Signature of Person Conducting the Informed Consent: _____

Principal Investigator signature (Dr. Patricia Slattum) _____ _____

_____ NO – Thank you for your time.

Appendix 4

Script for the Phone Call/Message Reminder

Version # 1 Date: 04/09/2018
VCU IRB Protocol Number: HM20012770

Script for the Phone Call/Message Reminder

Study Title: Understanding Medication Self-Management Capacity (MMC) Among Independent Older Adults at Richmond Health and Wellness Program (RHWP)

When the participant picks up the call:

Hello, I am Amal Badawoud, from Virginia Commonwealth University School of Pharmacy.

May I please speak to (participant name)?

I am just calling to remind you that you agreed to participate in a research study with us, which is about understanding medication self-management capacity among independent older adults, you have scheduled study interview tomorrow at [time]. The interview is located in your residence community area [specific room location]. Can you still make it tomorrow?

(If Yes or positive response) Please, do not forget to bring with you the medication bag with all your current medication containers/vials that you are using on a regular bases.

(After positive response) Great. See you tomorrow.

(Or after negative response) Okay, that is too bad. Do you want to reschedule the study interview?

(If yes) I have openings on [day] at [time]. Could you make it then? (Try until you have an agreed-upon time and day).

(If no) Thank you for your time. Good-bye.

If reach a voice-mail, leave message:

This message is for Mrs/Ms. _____. My name is Amal Badawoud from Virginia Commonwealth University, School of Pharmacy. I am just calling to remind you that you agreed to participate in a research study with us, which is about understanding medication self-management capacity among independent older adults, you have a scheduled study interview tomorrow at [time]. The interview is located in your residence community area [specific room location]. Please, do not forget to bring with you the medication bag with all your current medication containers/vials that you are use on a regular bases. If you need to reschedule the study interview or you have any questions, please give me a call at (603) 264-5359.

Thank you. See you tomorrow.

Appendix 5

Research Subject Information and Consent Form

Research Subject Information and Consent Form

Study Title: Understanding Medication Self-Management Capacity Among Independent Older Adults

VCU IRB Number: HM20012770

Greetings,

You are invited to participate in this study about medication self-management capacity. This study is conducted by Virginia Commonwealth University (VCU). It is being conducted by Amal Badawoud, Doctoral candidate at VCU, and under the supervision of Dr. Patricia Slattum, Director of the Geriatric Pharmacotherapy Program, at School of Pharmacy, VCU.

Please ask the study staff to explain any information that is not clear or you do not fully understand in this consent form. You may take an unsigned copy of this consent form to think about before making your decision.

Purpose of the Study

The purpose of this research study is to understand how adults aged 55 years or older manage/take their own medications independently. We will examine if there is a relationship between ability to self-manage of medication and number of medical conditions, number of medications and doses that are taken on a regular basis, cognitive and function status, and emergency room utilization over the past six months. You are asked to participate in this research study because you are aged 55 years or older, able to read and converse in English, living independently and not relying on someone (family members, friends, or caregivers) to take or administer your medication, and taking at least one prescription or over the counter medication.

Description of the Study and Your Involvement

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and agree to bring all medications including prescription medication, over-the-counter medication, and vitamins/minerals for reviewing and complete all the study assessments during the study interview.

During the interview at first, you will be asked questions regarding your demographic characteristics, including age, sex, marital status, race, educational level, and type of insurance, as well as health conditions that you have. After that, the research staff will record your medication names and doses from the label on the containers. After completing this, the research staff will assess your ability to manage and take your own medications and ask you some questions regarding your medication-taking behaviors and using drug organizer/reminder or ordering special packaging or services from your pharmacy. Then, you will be asked to report any emergency room visits over the past six months. Following this, your health literacy, cognitive and functional status, and how you felt over the past week will be assessed. The study interview will take 60 minutes or less to be completed.

No personal information about you will be revealed to staff or residents at your building residence during or after the study.

Risks and Discomforts

The study interview will be conducted in a private area within your residence building. All study assessments will be done by research staff (Amal Badawoud) and under the supervision of the principal investigator of this research study Dr. Patricia Slattum. The interview will last within 60 minutes. If you feel you want a break between different assessments, please ask the interviewer to stop for few minutes. If you feel exhausted or discomfort or distress from answering any questions in the interview, you can stop and ask for a break or withdraw at any time during the interview. You may also choose not to answer particular questions in the interview.

The assessments you will complete may show that you have limited capacity to manage your medications or limited medication knowledge. We will let you know after completing the interview and encourage you to request a medication management session from healthcare

providers in Richmond Health and Wellness Program (RHWP) clinic at your residence building, or your pharmacist.

All information collected about your demographic characteristics, medical history, medications, and cognitive and functional status will be confidential. It will not be disclosed to staff or residents of your residence community.

We will minimize any risk of transmitting your personal identifying information to persons not involved in the study by keeping all signed consent forms in a secure place at VCU that only the principal investigators have access to. All interview and assessments forms will be stored de-identified in a secure place at VCU and only the study personnel who are directly involved with the research and other authorized personnel who monitor research at VCU will have access to them.

Benefits to You and Others

There is no direct benefit to you for participating in this research study. However, your participation will help researchers learn more about cognitive and physical function deficiencies in medication self-management capacity among older adults. The findings of this study would potentially be helpful to inform healthcare researchers and policymakers to promote safe use of medications for better health outcomes and independent living as well. In general, we do not have any plans to provide you with individual research results. If any of the assessments in the interview indicate that you have a previously unknown condition, we will refer you to your health care providers at RHWP.

Costs

There are no costs for participating in this study other than the time you will spend to complete the study interview.

Payment for Participation

You will receive $15 and a complete updated medication list as compensation for your participation in this study. You will need to complete a research participant form that will ask you to provide your social security number, name, and address in order to receive the monetary

compensation for your participation. Federal law requires completing this form. The information in this form will be kept confidential and will only be used in order to process payment.

Confidentiality

All information collected during the study interview about your age, sex, race, marital status, educational level, insurance, and medical and medication history in addition to the results of all other assessments will be kept confidential. All this information is being collected for research purposes.

All completed interview and assessments forms will be recorded by ID number, not your name, and stored in a secure cabinet at a VCU office. All data will be entered into a secured computerized database and stored in password protected files at a VCU office. Access to all data will be limited to study personal who have received the required training on maintaining confidentiality of individuals participating in research.

Information collected for the study and the consent form signed by you may be looked at or copied for research or legal purpose by Virginia Commonwealth University. The findings for this study may be presented at meetings or published in papers, but your identifying information will not ever be used in these meetings or papers.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary. It is your choice to participate in this study. The alternative is not to participate in this study. Refusal to participate will involve no penalty or loss of benefits. If you choose to participate, you may stop at any time during the interview without any penalty or loss of benefit. You may also choose not to answer particular questions that are asked in the interview.

How will your health information be used and searched during the study?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research: history and physical exam, information about mental health, and medication history

Who will use or share protected health information about you?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research: Principal Investigator and Research Staff, Health Care Providers at VCU and VCU Health, Institutional Review Boards, Government/Health Agencies, and Other as Required by Law.

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use your protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you

revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

Questions

If you have any questions, complains, or concerns about your participation in this study, please contact:

Dr. Patricia Slattum, Pharm D, Ph.D.
Director of Geriatric Pharmacotherapy Program
Department of Pharmacotherapy and Outcomes Sciences
School of Pharmacy
Virginia Commonwealth University
Address: 410 North 12th Street, Smith Building, Room 656A
Richmond, VA 23298-0533
Office phone: (804) 828-6355
Cell phone: (804) 519-8838
Email: pwslattu@vcu.edu

For other questions about your rights as a participant in this study, please contact:

Office of Research, Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Phone: (804) 827- 2157

Consent

I have been given chance to read this consent form. I understand the information about this study. All questions and concerns that I have about the study have been clearly answered and addressed. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

Participant name (Printed)

Participant signature

Date

Name of Person Conducting Informed Consent (Printed)

Date

Principal Investigator signature (Dr. Patricia Slattum)

Date

Thank you for your participation in this study