Quantifying Adverse Drug Event Occurrence and Post-Adverse Drug Event Behaviors in Terms of Andersen Model of Health Care Utilization Constructs; Predisposing Characteristics, Enabling Resources, and Need Factors

by

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Abstract

Background: When patients experience a symptom, such as a possible ADE, they determine if they want to utilize formal health care services, self-care, or take no action at all. The Andersen Model of Healthcare Utilization addresses predictors that lead to the use of healthcare services or other personal health care decisions, and proposes that an individual's decision process is influenced by predisposing characteristics, enabling resources, and need factors. There is a gap in knowledge of what post-ADE behaviors older adults perform, and which predictors lead to those behaviors.

Objectives: The objectives of this study are to determine, using a nationally representative sample of Medicare/Medicaid enrollees, 1) the prevalence of ADEs in older adults, 2) of those who experienced an ADE, what post-ADE behaviors were performed, and 3) the relationship between enabling factors and post-ADE behaviors.

Results: This study shows that older adults are experiencing more ADEs than reported in previous literature. Need factors were all related to the occurrence of an ADE. Individuals performed a variety of post-ADE behaviors. Predisposing characteristics predicted cutting down or stopping medication on own, cutting down or stopping medication with physician authorization, and being hospitalized after experiencing an ADE. Need factors were related to cutting down or stopping medication with doctor's permission, visiting a doctor or emergency room, and being hospitalized. Finally, enabling resources were influential in talking to a doctor or visiting a doctor or emergency room after having an ADE. Predisposing characteristics were also related to performing a self-care post-ADE behavior.

Conclusion: Predisposing characteristics and need factors were significant in predicting ADE risk factors, while the addition of enabling resources help explain post-ADE behaviors.

Chapter 1

INTRODUCTION

Adverse drug events (ADEs) cause over 701,547 emergency room visits each year.[1] Of those 701,547 emergency room visits, 117,318 require further hospitalization for the experienced ADE.[1] Occurrence of ADEs rapidly increased 9.4% from 2010 to 2011.[2] Older Americans are twice as likely as their younger counterparts to visit an emergency room and seven times more likely to require hospitalization due to ADEs.[1] As individuals age, the risk of experiencing an ADE increases due to a larger number of prescription medications, frailty, memory issues, comorbidities, metabolic changes, and decreased drug clearance.[3-6]

When patients experience a symptom, such as a possible ADE, they determine if they want to utilize formal health care services, self-care, or take no action at all. Accordingly, the Andersen Model of Healthcare Utilization addresses predictors that lead to the use of healthcare services or other personal health care decisions, and proposes that an individual's decision process is influenced by predisposing characteristics, enabling resources, and need.[7] Identifying the factors that prevent or influence the use of health care services after experiencing an ADE can help identify concerns of patients who are avoiding health services and also failing to perform any post-ADE behavior, which will

ultimately improve patient health outcomes. Past literature that applies the Andersen Model to older adult health care utilization has not included post-ADE health behaviors.[8-18] Post-ADE behaviors include no behavior performed, discontinuation of medication on one's own, visiting doctor's office or emergency room, talking to a physician, and hospitalization. This will be the first study that will investigate which predictors lead to older adult post-ADE behaviors.

Predisposing characteristics are those characteristics that create a propensity for some individuals to seek and use health care services more than others. These characteristics include gender, age, ethnicity/race, marital status, and education. Need factors for care within the health care system or performing self-care behaviors are: functional status, perceived/self-report health status, and evaluated health status. Evaluated health status has been measured through a number of chronic conditions.[18] Although an individual may be more likely to use health care services according to their predisposing characteristics and need factors, resources need to be in place in order for the individual to seek care. Therefore, the enabling resources are those factors that allow health care services to be available to an individual for comsumption.[13] It has been shown that some older adults do not perform any post-ADE behaviors.[19] This may be due to a lack of enabling resources to perform formal or informal care to decrease symptoms.

Recently, enabling resources in older adult health decision research has included instrumental support, family structure, and living arrangement.[9,10,12] Instrumental support may be in the form of transportation, making financial contribution, helping with work obligations, or providing another form of direct relief or material aid.[20] One measure of instrumental support is if an older adult has transportation issues. Those older adults who

report having decreased transportation access reported using more formal health services.[12] This study will also include proximity of an older adult's children to add insight to the potential family availability for assistance, either in the form of informal care or assistance to seek formal care. Family structure is commonly measured by number of living children. It has been found that those who have more living children are more likely to have doctor visits, but no impact on hospital stays.[9] A third measure of enabling resources for older adults is living arrangement. Those older adults living alone are predicted to utilize more physicians visits than those who live with another person.[9,10] These measures of enabling resources are a recent addition to older adult health care decision making research and are appropriate in the application to post-ADE behavior research since some older adults who do not have any informal or formal care may not perform any needed post-ADE behaviors.

The 1995 Andersen Model is a decision-making model that clearly states that an individual may choose to seek professional health care or to perform other personal health choices.[7] However, past research focuses only on which services older adults use within the health care system.[8-18] These studies exclude other self-care behaviors that are performed outside of the health care system. This study of what behaviors are taken after older adults experience an adverse drug event will include those health care services utilized, self-care behaviors, and an individual taking no action at all.

In a time where there is a drastic increase in ADE prevalence, there is a **gap in knowledge** of what post-ADE behaviors older adults perform and which predictors lead to those behaviors.

This project consists of three studies that aim to examine post-ADE behaviors in more depth. The objectives of these three studies are:

1. Quantify the prevalence of self-reported ADEs in 2005 and 2007 and determine the predictors of experiencing no ADE in 2005 or 2007, experiencing at least one ADE in either 2005 or 2007, and those who experiencing an ADE in both 2005 and 2007.
2. Determine prevalence of different post-ADE behaviors, and quantify the relationship between predisposing characteristics, need factors, enabling resources and post-ADE behaviors performed in 2005 and 2007.
3. Determine the predictors to self-care and care-seeking post-ADE behaviors performed in 2005 and 2007.

LITERATURE REVIEW

This literature review consists of three sections. The first section reviews the literature on adverse drug events (ADEs). A summary of ADE risk factors, different methods to measure ADEs and the settings in which ADEs have been measured is presented. The second section is a literature review of studies that use the Andersen Model of Health Care Utilization among Older Adult in the United States. This second section ends with a summary of the predisposing characteristics, enabling resources, and need factors measures that have been used in this population. The chapter's final section presents a proposed framework to study post-ADE behaviors of older adults. The framework is tailored from the1995 version of the Andersen Model of Health Care Utilization with knowledge derived from the literature review of the predictors that influence older adult health service use.

This study involved two separate literature searches; ADEs and health care service utilization. Search terms for ADEs included: ADEs in older adults, ADE risk factors, ADE incidence, ADE prevalence, measures of ADEs, ADEs in hospitals, ADEs in nursing homes, ADEs in outpatient setting, and ADEs in community setting. The search terms for healthcare utilization included: Andersen Model of Health Care Utilization, older adult healthcare utilization, elderly adult healthcare utilization, enabling resources and healthcare utilization, caregiver healthcare decision-making, and older adult health care decision-making.

Section 1: Adverse Drug Events

At the outset, a broad overview of ADEs is presented, and this text is followed by an in-depth examination of each topic mentioned in the overview. These topics include ADE severity, risk factors of ADE, how ADEs are measured, where ADEs are measured and interventions studies to impact ADEs.

An adverse drug event (ADE) is defined as an injury due to medical treatment.[21-23] There are two harms of ADEs; intrinsic and extrinsic. An intrinsic harm is one that is a due to the pharmacological properties of the prescription medication, and this type of harm is also called an adverse drug reaction (ADR).[21] Extrinsic harm is created by the administration and use of the prescription.[21] This type of harm is also defined as medication error.[24] Therefore, an ADE includes ADRs and medication errors.

There have been two forms of medication errors that have been investigated as a cause of ADEs; patient errors and health care provider errors. Medication errors have been defined as inappropriate use of a drug that may or may not result in harm.[24-25] Field et al., studied patient medication error that resulted in an ADE. Medicare enrollees who received care at a large multispecialty group practice and experienced an ADE were enrolled in the study. It was shown that 31.8% of ADEs were caused by patients inaccurately administering their prescription medication, 41.9% caused by patients modifying their medication regimen, and 21.7% caused by patients not following clinical advice about their medication use.[26] In another study, McDonnell and Jacobs showed that 33% of adverse reactions were due to patient noncompliance.[27] Unintentional overdose has also been attributed to 66% of hospitalizations of older adults in America.[28]

Medication errors also occur by health care providers. It has been shown that 56% of ADEs that occurred in hospitalized adults were preventable.[29] Preventable ADEs have been identified within ordering, administration, transcription and dispensing procedures. Medication errors that lead to ADEs in hospitalized patients are most commonly caused by missed contraindication, inadequate clinical surveillance, and overdoses.[30]

The Adverse Event Reporting System, established by the Food and Drug Administration, indicated that 2.3 million ADE case reports have been made from 1969-2002.[31] From 1998-2005, reported serious ADEs increased 2.6-fold from 34,966 to 89,842.[32] Adverse drug events cause over 700,000 emergency room visits each year.[1] Of those 700,000 emergency room visits, 120,000 require further hospitalization for the experienced ADE.[1] The variation in ADE prevalence reported in past studies arises because of the different ways ADEs are measured and the different settings in which ADEs are measured.

With different measures and settings there have been different findings about which risk factors are associated with ADEs. The literature shows that antibiotics, anticoagulants, antidepressants, warfarin, and cardiovascular drugs are risk factors across settings for ADEs. Emergency department visits due to ADEs range from 3.6% to 21.0%.[33-36] The risk factors of ADEs leading to these emergency departments are greater number of prescription medications and being older.[35-36] The incidence of ADEs that lead to hospitalizations ranges from 9.6% to 37.5%[33,37-40] with greater number of prescription medications and patient non-compliance as risk factors for hospitalization.[40] For ADEs that occur during a patient's hospital stay, the incidence is 0.91% to 27.7%.[22,29-30,37,41-42] Risk factors for ADEs that occur while hospitalized include: number of newly prescribed

medications, total number of medications and decreased patient cognition.[42-43] Post-hospital discharge ADEs occur in 11.0% to 20.0% of patients.[43-45] Risk factors for these ADEs are being female, greater number of prescription medications and the interaction between number of medications and patient cognition.[43,45] Within nursing homes, there are 1.89 ADEs per 100-resident months and risk factors include being a new nursing home resident and taking 5 or more prescription medications.[46] Only three studies focused on ADEs that occur in the outpatient setting and found that 35% of outpatients experience an ADE.[47] Greater number of comorbidities, greater number of prescription medications, being female, and aged 80 years and older are risk factors for outpatient ADEs.[26,47-48]

ADE research has also focused on how to decrease potential ADEs by using computerized ADE alert systems and adding clinical pharmacist to health care teams within the institutional setting and pharmacist counseling in the outpatient setting. Results of these studies show that computerized ADE surveillance systems identify preventable ADEs better than health care provider voluntary reporting[49-50]but less effective than medical chart reviews.[51] Pharmacists have been placed on physician rounding teams on general medicine and intensive care units, and the presence of a pharmacist on these teams decreases preventable ADEs by 66% to 78%, repectively.[52-53]In addition, pharmacists have been shown to decrease potential ADEs for post-hospital discharge patients.[54]

ADE Severity

Throughout ADE research, classifications of the severity of the events have been made; however, these classifications remain inconsistent between studies. Besides fatal and life threatening, the classifications of ADE severity that vary are: serious, significant, and moderate. The underlying similarity of these severity classifications is that they all state that the patient who experiences an ADE utilizes some health care service. There are four categorizations of ADE severity. First, serious events have been defined as those adverse drug reactions which result in hospitalization, were fatal, life-threatening, or resulted in significant changes in the patient's treatment.[55] However, Bates et al. used three categories of ADE severity including life-threatening, serious, and significant.[29] A third study used three different severity levels to categorize ADEs.[27] Severe has been defined as potentially life-threatening, causes permanent damage, or requires intensive medical care.[27] Moderate ADEs are those that require change in drug therapy or specific treatment to prevent a further adverse outcome, symptoms are not resolved in 24 hours, prolonged stay of over 24 hours, or those ADEs that caused hospitalization admission to a non-intensive medical care unit.[27] Minor ADEs are those reactions which require no additional therapy or antidote, symptoms are resolved within 24 hours, and do not contribute to prolonging length of hospital stay.[27] Using this approach, it was found that 24% of ADEs were severe and 76% were classified as moderate.[27] Finally, a fourth measure of ADE severity can be found in a study conducted by Hardmeier et al.[30] This categorization of ADE severity is as follows: significant (ADEs that demand a dose change or termination of prescription medication, moderate (requires additional therapeutic changes), serious (prolong hospital stay, leading to permanent defects, life-

threatening complications), and lethal.[52]Although ADE severity classifications have not been consistent, they all focus on ADEs severe enough for health care utilization.

Risk Factors of Experiencing an ADE

Past ADE research indicates that risk factors of experiencing an ADE are: age, gender, number of comorbidities, number of prescription medications, taking certain medications, number of newly prescribed medications, physical functioning, cognitive ability, weight and being a new nursing home resident. The association of age and ADEs has been mixed in past research. In hospitalized patients, age has both been shown to be associated[56] and not associated[42] with ADEs. For ADEs that occur in older adults in the outpatient setting, age was not a risk factor for experiencing and ADE.[26]

Findings on the association of gender and ADEs are also mixed. It has been shown that being female is a risk factor for experiencing an ADE.[43,48,56] From 2.3 million ADE case studies reported from 1969-2002, 53% of adverse drug events were for females, 32% males, and 12% did not specify.[31] Being female in individuals who utilize home health services was associated with ADEs.[43] A study conducted of Medicare enrollees showed that being female was a risk factor of ADEs.[48] However, studies have also shown that there is no gender effect on hospitalizations admissions due to ADEs,[33] outpatient ADEs[26] or those patients who experience an ADE while in the hospital.[42]

Number of comorbidities as a risk factor for ADEs is mixed. In a 10-year cross-sectional study, comorbidities have been shown to be a risk factor of experiencing an ADE.[56] For nursing home residents, a score of 5 or more on the Charlson Cormorbidity Index was shown to be associated with increased risk of ADEs.[46] But in hospitalized

older adults, there was no association between a diagnoses of 4 or more comorbidities and ADEs.[42]

The evidence of number of prescription medications as a risk factor for ADEs is strong. The use of multiple medications increases the risk of experiencing an ADE.[26,35,38] For nursing home residents, the greater number of regularly scheduled medications is associated with an increased risk of an ADE.[46] Although the majority of studies show a greater number of prescriptions is associated with ADEs, one study of hospitalized older adults did not find an association between numbers of medication and ADEs.[42] Older patients often have changes of therapeutic treatment at the time of hospital admission or at hospital discharge.[57] It has been shown that a greater number of new medications prescribed at hospital discharge was associated with ADEs.[43] Number of new medications prescribed at time of hospital admission has also been shown to be a risk factor for an ADE.[41]

High-risk medications are those deemed by clinical experts that pose risk of harm and should generally be avoided in people aged 65 years or older.[58] This is because they are either ineffective or they have unnecessarily high risk and a safer alternative is currently available.[59] Although it has been shown that only 1.2% of hospitalizations due to ADEs are due to high-risk medications,[28] another study of hospitalized older adults suggests that high-risk medications should be closely monitored based on patient characteristics.[56]

Research has greatly focused on which prescription medications may be risk factors for ADEs. Medications commonly found in association with ADEs are: hypoglycemic medications,[26, 35, 59] diuretics,[26, 34,48] anticoagulants,[26,34-35,45,48]

cardiovascular drugs,[26,30,48,34] and antibiotics.[30,34,41,45,48]Other medications that have been associated with ADEs are: antithrombics,[30] hypnotics,[30] corticosteroids,[45,48] analgesics,[45] antipsychotics,[46] antidepressants,[46,48] digoxin,[36] hormones,[48] oral antiplatelet agents,[28] psychotropic drugs,[38] gastrointestinal drugs,[41] central nervous system drugs,[41]nonsteroidal anti-inflammatories,[30,34] and chemotherapeutic agents.[34]

Other risk factors that have not commonly been examined in ADE research are physical functioning, cognition, weight, and a new nursing home resident. Physical functioning before hospitalization was not associated with ADEs.[42] Decreased cognition has been shown to be associated with ADEs that occur in hospitalized older adults.[42] Within hospitalized patients, lower weight has been associated with ADEs.[56] Being a new resident at the nursing home was significantly related to ADEs.[46]

How ADEs Have Been Measured

Past ADE literature uses six methods to capture the occurrence of ADEs. The National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System (NEISS-CADES) and the Adverse Event Reporting System (AERS) are nationally-representative databases that focus on emergency department visits due to ADEs or reporting of ADEs by health care professionals, patients or drug manufacturers, respectively. Volunteer reporting by health care professionals, medical chart reviews, daily observation of patient by health care professionals and patient self-report have also been utilized to capture ADEs that occur either within the emergency department, hospital, nursing home, or outpatient settings.

The NEISS-CADES began in 2004 and is an ongoing, nationally representative probability sample of hospitals in the United States with a minimum of six beds and a 24-hour emergency department.[1] Trained coders at each hospital reviewed clinical records of every emergency department visit. The coders then identify physician-diagnosed adverse drug events and then report diagnosis, medication implicated in the ADE, and a narrative description of preceding circumstances. Data collection, quality assurance, management, and analyses are all conducted by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration human subject oversight bodies.[36]

One positive aspect of the NEISS-CADES is that is collects ADEs that were related to vaccines, prescriptions, over-the-counter medications, and supplements. However, the main limitation is how the NEISS-CADES defines an ADE case. It states that an ADE case needs to be an injury due to a use of a drug, must result in an emergency department visit, and the drug must have been used for therapeutic reasons (not drug abuse). Because of this definition, any adverse event an individual experienced that did not result in an emergency department visits is not determined as an actual ADE case. The NEISS-CADES has a bias towards acute onset ADEs that lead to an emergency department visit. Therefore, this measurement of ADEs should only be used to calculate the prevalence of ADEs in American emergency departments. This is because patients may decide to visit their doctor's office, talk to their pharmacist, self-care, or take no action at all after experiencing an ADE.

The Food and Drug Administration implemented the Adverse Event Reporting System (AERS) in 1969 to identify post-marketed drug safety problems and it is commonly used in ADE research.[31-32] ADE case reports are submitted by health care

professionals, consumers, and drug manufacturers to the reporting system.[31] From this system, drugs that are identified as having severe consequences are removed from the market. Now known as the FDA Adverse Event Reporting System (FAERS), this dataset takes the volunteer reporting to the FDA and codes the ADEs in terms of the Medical Dictionary for Regulatory Activities (MedDRA).[60] These codes allow for standardization of medical terminology in assist in sharing regulatory information domestically or internationally.[61] The purpose of the FAERS is to assist the FDA in post-market surveillance of medications. Therefore, the aim is to determine ADEs caused by particular *products*.

There are three limitations to the FAERS. First, like with all self-reports, there is no certainty that the reported ADE even happened or was due to a particular medication, as the FDA does not require a causal relationship between the prescription medication and the experienced ADE. Second, the FAERS does not include enough detail to properly evaluate the ADE event on a clinical or healthcare service utilization level, and it cannot be determined if the event lead to a particular behavior or use of healthcare services. Therefore, costs to patients and the healthcare system of the reported ADE cannot be determined. The final limitation is that the FDA states that the data found in FAERS cannot be used to determine incidence of ADEs in the U.S. population because there are many confounding factors that could impact whether an ADE is reported or not.[61]

Medical chart reviews have been used to capture ADEs using three methods. First, a daily chart review by a health care professional or trained nurse investigator can be used.[22] This method is used during longitudinal studies of patients who are hospitalized. Second, medical chart reviews can be performed at time intervals during a

longitudinal study.[46] Lastly, medical chart reviews are used in cross-sectional analyses either to capture all ADE event(s) and health care utilization due to the event(s)[29,33-34,37,40,45,48,54] or to confirm patient self-report of events.[22,44,45,54]

There are two limitations to using patient medical charts or electronic medical records (EMR) to determine ADE incidence. First, the record may not be of good quality either because of the system or because of accuracy in which healthcare professionals enter patient information into the system. The second issue with determining ADE prevalence with patient medical records is that record systems and electronic medical records vary between hospital networks. With these two limitations, generalizability of the findings to the national level may be difficult to accomplish.

When investigating the incidence of ADEs in already hospitalized patients, observation by healthcare professionals has been used to determine when an ADE occurs and what caused the event on a daily basis[30,42] or at time of emergency department visit.[35] Another method to capture ADEs that occurs in hospitalized patients is volunteer reporting by health care professionals.[22,29,41]

Healthcare professional reporting of clinically significant ADE has two limitations in measuring ADEs. First, this is a volunteer reporting in the healthcare setting. Not only is volunteer reporting inaccurate in measuring incidence, but there may be a culture of being error free within the healthcare profession. Therefore, health care professionals may be hesitant to report ADEs because these events may reveal medication errors or that the event was preventable. The second limitation is that this method only captures ADEs that occur while the patient is in the healthcare setting.

Because of these two limitations, these findings of ADE incidence cannot be soundly generalized outside of that particular hospital.

The least utilized method of capturing ADE incidence is patient self-report. A study by Chrischilles et al., self-reported ADEs were captured by asking subjects, "In the past 12 months, have you experienced an unwanted effect or side effect of a medication?" However, a patient report of an ADE occurrence is usually confirmed by medical chart review.[22,42,44, 54] Therefore, if a patient states that they experienced an ADE, but it did not lead to health care utilization, then their report of incidence is excluded generally from the analyses. Alternatively, patient self-report of ADEs have been confirmed by a pharmacist evaluation of reported negative effects with the patient's medication list.[47]

There are positive and negative aspects of self-reporting ADEs. First, the documentation of ADEs that occur in different settings may be captured. For example, those individuals who experience a mild ADE in the community setting and do not go to the emergency room may be captured. Alternatively, those individuals who had a severe ADE and were hospitalized would also report having an ADE. This, however, leads to a gap in knowing if the ADE is clinically significant to the individual's health outcomes. Patient self-reported ADEs may lead to a more accurate prevalence of ADEs in the United States. It captures those who had a mild or severe ADE and those who sought care within the healthcare or self-cared. Self-reported ADEs have the limitations of recall bias. Subjects may forget, fabricate, or exaggerate their ADE experience. Just like the FAERS, there is no proof that the subject had an ADE.

Where ADEs Have Been Measured

The six methods to measure the occurrence of ADE take place in six different settings: emergency department[33-36], hospitalization after emergency department visit,[28,40] ADEs that occur in already hospitalized patients,[22,29-30,41-42] general hospital admission,[37-38,62] post-hospital discharge,[44-45,54] nursing homes,[46] and the outpatient setting.[47-48] The incidence rates and risk factors of ADEs vary due to the measure of ADE and the setting in which the ADE occurs. In addition, ADE research has also focused on how to decrease potential ADEs in the hospital and during post-hospital discharge. ADE studies from each setting and studies focusing on methods to decrease potential ADEs are presented below, followed by a literature review summary.

Emergency Department. A study conducted by Budntiz et al. examined the 2004 and 2005 data from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System for individuals 65 years or older who utilized the emergency department or outpatient care due to an ADE.[36] From the list of medications that caused the visit, the authors determined if the medication was appropriate or not for older adults according to the Beer's criteria. Those medications which are always deemed inappropriate for older adults were only associated with 3.6% of visits. However, the authors found that 33.3% of visits were due to warfarin, insulin, and digoxin. The risk for an emergency room visit due to an ADE from these three medications was 35 times greater than for prescriptions that were deemed always inappropriate for older adults.[36]

In a 1-year prospective study of emergency department visits from single hospital, authors et al found that 4.3% of emergency visits were due to an ADE.[33] Of these ADEs,

19.1% of patients were then hospitalized following the emergency department visit. A trained nurse reviewed the medical charts and determined which events were potentially due to prescription drug use.[33]

A retrospective chart review study of all emergency department visits over a 1-year time period determined that 10.6% of all visits were due to an ADE.[34] Emergency department visits due to ADEs were associated with: chemotherapeutic agents, cardiovascular drugs, antibiotics, anticoagulants, diuretics, hypoglycemics, and nonsteroidal anti-inflammatories.[34]

Queneau et al. studied emergency department visits in 5 French hospitals and found through medical chart reviews that 17.0% of emergency department visits were the result of an ADE.[35] Those patients with a greater number of prescription medications were more likely to experience an ADE.

Hospital Admission. A cross-sectional study by Chan, Nicklason and Vial aimed to determine the incidence of hospital admissions due to ADEs in patients aged 75 years or more.[40] Within 24 hours of hospital admission, patients were interviewed about demographics, functional status of activities of daily living/instrumental activities of daily living, medication use, comorbidities, compliance, previous ADE, and cognitive ability (Mini Mental State Examination). Of these subjects, 30.4% of hospital admissions were a result of an ADE. Greater number of prescriptions was associated with ADE admission when compared to all other admissions. Non-compliance, omission or cessation of treatment accounted for 26% of ADE admissions. Cardiovascular prescriptions were associated with 48.4% of ADE admissions.[40]

Budnitz et al. conducted a study utilizing the 2007-2009 data from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System.[28] The authors aimed to estimate the rates of hospitalizations after an emergency department visit for Americans aged 65 or older. For this dataset, ADEs are determined by trained coders who go through the emergency department clinical records of 58 selected hospitals. It was found that two thirds of the hospitalizations after an emergency department visit were due to unintentional overdoses. ADEs caused by warfarin, insulin, oral antiplatelet agents, and oral hyperglycemic agents were implicated in 67% of hospitalizations. High-risk medications were not found to be associated with hospitalizations due to ADE.[28]

Doucet et al. studied the incidence of ADEs in a French hospital.[38] It was shown that 16.0% of hospitalization after an emergency department visit was the result of an ADE. Of these hospitalizations, 66.7% were associated with cardiovascular and psychotropic drugs.[38] ADEs were captured by medical chart review. Medical chart reviews have also shown that 20.5% of hospital admissions were due to an ADE.[37]

Hospitalized Patients. Hardmeier et al. followed inpatients to determine the incidence of ADEs while hospitalized.[30] ADEs were captured during the cohorts stay by daily documentation of drug exposure and adverse events. This study defined an ADE as events resulting in discomfort, drug withdrawal, dose reduction, and initiation of therapeutic measures. Among already hospitalized patients, 7.5% experienced an ADE. Medication errors which were associated with these ADEs were missing/inappropriate indication, missed contraindication, overdoses, and inadequate clinical surveillance.[30]

Medications which were most common among inpatient ADEs were antithrombotics, cardiovascular drugs, antibiotics, hypnotics, and non-steroidal anti-inflammatory.[30]

Another study conducted in two hospitals found that 27.7% of patients experience an ADE while they were hospitalized.[41] ADEs were captured by self-reports from health care professionals and patient self-report. Risk factors for ADEs were number of newly prescribed prescription medications and total number of prescription medications. In addition, taking a gastrointestinal drug, central nervous system drug, or an antibiotic was associated with experiencing an ADE.[41]

In 1995, Bates et al. examined the incidence of ADEs and potential ADEs during time of admission and hospital stay over a six-month time period in 11 medical and surgical units within two hospitals.[22] Self-report by nurses and pharmacists and daily chart reviews by nurse investigators captured ADEs that occurred at time of admission and medication errors that led to ADEs during the patient's hospital stay. The authors determined that 6.5 ADEs occurred per 100 admissions, excluding obstetrical admissions. This result extrapolates to 1900 ADEs per hospital per year. Of these ADEs, 12% were life-threatening, 30% serious, and 57% significant. Twenty-eight percent of these ADEs were deemed preventable. Errors that resulted in preventable ADEs were at stages of ordering, administration, transcription, and dispensing.[22]

Bates et al. published a prospective cohort study in 1993 that evaluated incidence of ADEs in hospitalized older adults in seven units in a tertiary care hospital.[29] ADEs were captured by three methods. First, self-report logs were placed in each unit and satellite pharmacy. Second, a trained research nurse collected the medical charts of each patient twice a day. Lastly, the nurse then reviewed these charts daily. It was shown that

out of 2,967 hospitalized patients, only 27 experienced an ADE and 34 potential ADEs were identified.[29]

A study by Gray et al. investigated incidence of ADEs in hospitalized older adults.[42] This prospective study identified ADEs through daily monitoring of inpatients aged 70 years or more. At time of admission, patients' demographics, cognition (Mini Mental State Examine), functional status prior to admission (ADL and IADL), and medication use were collected. At patient discharge, functional status, discharge diagnoses, and medication use during hospitalization was collected. From these data sources, it was determined that 14.6% of individuals aged 70 years or more experienced an ADE during their hospital stay. Of these ADEs, 54.2% were deemed preventable. Risk factors of experiencing an ADE during hospital stay were found to be decreased cognition and more new patient medications. Age, female, lower functional status prior to admission, more than four active diagnoses had no association with risk of experiencing and ADE.[42]

Post-Hospital Discharge. Another interest in ADE research is the incidence of ADEs after hospital discharge. In 2003, a prospective cohort study of 400 discharged patients was conducted to determine the incidence of ADEs within five weeks after discharge via phone interview.[44] If a subject answered "yes" to any of the selected symptoms during the telephone interview, they were asked to elaborate on the severity of the symptoms and any health care utilization since discharge. Along with hospital medical records, discharge summaries, emergency department clinical notes, and laboratory results, two physicians then determined if their stated symptoms were deemed

an ADE. The authors found that within five weeks after discharge, 12.5 % experience an ADE.[44]

Forster et al. published a study that focuses on post-hospital discharge ADEs in 2004.[45] This prospective cohort study of 400 patients discharged from a single hospital aimed to determine the incidence of ADEs within 20-24 days of discharge. ADE experience was collected via telephone interviews. Subjects were asked if there were any worsening of symptoms, physician visits, emergency department visits, or hospital readmission since discharge. If subjects responded 'Yes' to any of these items, they were asked to elaborate on severity of the symptoms. Combining the telephone interview results and hospital chart reviews, case summaries of each patient were created. Two physicians then evaluated the case summaries and deemed the patients' post-discharge experiences as an ADE or not.[45] It was shown that 11% of patients experienced an ADE after discharge. The medications associated with greater risk of experiencing an ADE were corticosteroids, anticoagulants, antibiotics, analgesics and cardiovascular agents. Risk of an ADE was also associated with greater number of prescription medications.[45]

A 1-month prospective cohort study of three home health agencies and the rates of ADEs after discharge was conducted from April 1994 to May 1996.[43] There were 256 participants aged 65 years or older who were receiving home nursing care after hospital discharge. An interview was held 5 days after discharge and another at 1-month follow-up and ADEs were captured through self-report. Twenty percent of subjects experienced an ADE. The logistic regression analysis found that being female and the interaction between number of medications and cognition were related to the experience of an ADE.[43]

Nursing Home. A 12-month prospective study of residents at 18 nursing homes showed that there were 1.89 ADEs per 100 resident-months.[5] ADEs were captured by medical chart reviews at 6-week intervals by three investigators (two nurses and one pharmacist). Risk factors of ADEs in a nursing home were found to be higher number of comorbidities, a new resident and taking 5 or more regular prescription medications.[11] Those residents taking nutrients and supplements were at lower risk of experiencing an ADE. In addition, the following medications were associated with a higher risk of ADE: anti-depressant, antipsychotics, and anti-infective medication.[5]

Outpatient. Field et al. conducted a 1-year case-control study of Medicare enrollees who obtain care by a multispecialty group practice.[48] ADEs were captured using medical chart abstractions at time of the event. This study is interested in those individuals that experience an ADE in the outpatient setting but sought out care from a physician. It was shown that females and those who are 80 years of age or older were at increased risk of experiencing an ADE. Patients taking anticoagulants, antidepressants, antibiotics, cardiovascular drugs, diuretics, hormones, and corticosteroids were also at increased risk. Those individuals who had more comorbidities, as determined by the Charlson Comorbidity Index, and a greater number of regular prescription medications were at higher risk of experiencing and ADE.[48]

Another study showed that 35% of older adults experienced an ADE in the outpatient setting over a 1-year time frame.[47] Patient self-report of an ADE experience was confirmed by a pharmacist evaluation of the medications the patients self-reported taking and the negative effects the patients described. Cardiovascular and central nervous system drugs were associated with 61.1% of ADEs.

Intervention Studies Investigating How to Decrease ADEs

Other than studying incidence and causes of ADEs in different settings, ADE research has also focused on how to decrease preventable ADEs. These approaches include computerized monitoring of potential ADEs through hospital medical chart systems or expanding the role of pharmacists in the inpatient and outpatient settings. It has been shown that adding a pharmacist on rounding teams on general medicine units decreases preventable ADEs by 78%.[53] Pharmacists added to physician rounds in the intensive care unit decreases potential ADEs by 66%.[52] This evidence shows a strong impact that pharmacist knowledge of medicines has the ability to significantly decrease preventable ADEs in the hospital setting.

In a randomized trial conducted by Schnipper et al. in 2006, pharmacist counseling at discharge, medication review, and telephone follow-up 3 to 5 days after hospital discharge was found to significantly lower the rate of preventable ADEs 30 days after discharge.[54] During the follow-up phone interviews, patients were asked about symptoms and potential ADEs. Case summaries were created for the treatment and control groups from phone follow-up discussions (treatment group only), medication lists at admission and discharge, hospital discharge summary, outpatient visit notes, discharge summaries from emergency department visits or hospital readmission, and laboratory tests results in the month since hospital discharge. Three physicians then evaluated these summaries for ADEs, then classified these ADEs as preventable or not. It was found that 11% of patients in the control group experienced a preventable ADE within a month of discharge while only 1% of the treatment group experienced a preventable ADE.[54]

Many hospitals use computerized surveillance of ADEs. These systems alert health care providers of previously known drug allergies generated during the drug order. It has been shown that these systems that alert drug allergies during the drug order identify significantly more ADEs than voluntary ADE reporting by health care providers method.[49] Due to continual monitoring of patients and potential ADEs and daily print outs of patients at risk, these computerized surveillance systems have been shown to reduce ADEs that are allergic or idiosyncratic in nature.[64] These ADEs occur at first time use of medication. Another computerized ADE detecting software, "Adverse Drug Event Trigger Tool," has been shown to increase ADE-detection approximately 50-fold over traditional health care professional reporting.[50] Although evidence is present for the effectiveness of computerized ADE surveillance, one study found that these computerized methods are less effective than medical chart reviews, but more effective than health care professional voluntary reporting.[51]

Critique

All of the literature reviewed has ADE measures that share a common assumption; severity after experiencing an ADE, the patient utilizes health care in some form. This assumption actually captures the severity of an ADE; not necessarily the occurrence of an ADE. These measures of ADEs therefore have a selection bias of ADEs that are severe enough for the patient to utilize health care services. The definition of ADE is an injury due to medical treatment.[21] This definition has no requirement that an individual must seek health care after experiencing an ADE. One study determined that not all individuals seek health care professional help after experiencing an ADE.[19] Two of

the three studies that used patient self-report to capture ADEs have a comparison with information gathered from a medical chart review to confirm if the patient had an ADE in clinical terms. These studies used self-reporting from patient or healthcare provider to trigger a check if ADE was documented in patient medical records. Then only those with an ADE documented in these patient records were included in the analyses. It has been shown that 29% of self-reported ADEs were not confirmed clinically. ADE research has looked at health care utilization as an indicator of an ADE. However, minor ADEs may lead an individual to stop taking their prescription medication without speaking to their physician. These non-health care service utilization behaviors may have a direct impact on patient adherence and health outcomes; however, they have never been studied.

Section 2: Andersen Model of Health Care Service Utilization

The Andersen Model of Health Service Utilization is a commonly used framework for researching healthcare utilization.[12] It was first developed by Andersen in 1968 and has continued to be revised into the most used version, the 1995 Andersen Model (Figure 1.1).[7] The Andersen Model has frequently been applied to older adult health service use.[12] The 1995 Andersen Model states that there are three major components: environment, population characteristics and health behavior. Studies applying the Andersen Model tend to measure population characteristics and health behavior. Population characteristics include predisposing characteristics, enabling resources and need. Health behavior includes the use of health services and personal health choices. Since this study is focused on an older adult population, the next section will provide a literature review of how the Andersen Model has been applied to older adult health care utilization. It will encompass description and reviews on the three dimensions of population characteristics and their impact on health behavior.

Predisposing Characteristics

Predisposing characteristics are comprised of three dimensions, including demographics, social structure, and health beliefs. An underlying assumption of this construct is that some individuals have the propensity to seek and use health care services more than others. Demographics are age, gender, marital status and family size.[13] Demographic information are measures of an individual's position within their life cycle. Social structure consists of employment, education, and ethnicity. Social structure measures are intended to capture the individual's location within the social structure and

therefore reflect the social behavioral norms to which the individual has been socialized.[13] The last dimension of predisposing characteristics is health beliefs. These are an individual's attitudes toward medical care in general and their attitudes toward their health condition. Findings of past literature of the Andersen Model being applied to older adult health behavior are presented below.

Age. The impact of age on health care service utilization is mixed. Older age has been shown to be associated with greater use of home care services, [12] increased use of physician visits, [15] hospital services,[15] more bed-disability days,[15] less likely to rely on informal health services, [13] less likely to rely on self-care.[13] Many studies have also found that age is not related to number of physician contacts, [10] physician visits, [12,15] emergency department visits, [15] ambulatory services [12] or hospital services,[12,15]

Gender. The directionality of the relationship between gender and health care service utilization are mixed across studies. It has been shown that women are less likely to take bed-disability days,[13] fewer hospitalizations,[13] and fewer physician visits.[8,13] However, another study found that females were significantly less likely to be hospitalized, but more likely to visit a physician and have more day-disability days.[9] Additional studies have found no significant impact of gender on hospital services,[11,12,15] physician contact,[10] doctor visit,[15] ambulatory care,[12] and emergency department visits.[15]

Marital Status. For health care utilization research of older adults, marital has no impact on different health care services across studies. Marital status has been shown to have no impact on doctor visits, [9,12] emergency department visits, [15] ambulatory service use, [12] or hospital stay.[9,12,15] In addition, being widowed also has no impact on health care utilization.[13] When grouped by race, older white individuals are more likely to be

married.[16] One study used being widowed as an indicator of marital status.[13] This was done because the article was more interested in how the living arrangement of the older adult impacted health service use. It was found that being widowed has no significant effects on any measure of health service utilization.[13]

Living Arrangement. There have been three living arrangement scenarios that have been used as a measure of predisposing characteristic; living alone, living with non-family and multigenerational family. A study conducted by Wolinsky and Johnson showed that living alone had no impact on health care utilization.[13] However, a study looking at older African American health care service use found that those African Americans who live alone are more likely to visit the physician than those African Americans who lived with a spouse or family.[8] However, another study shows that living alone has no impact on doctor visits, emergency department use or hospital services.[15] Living alone has also been shown to be significantly associated with having more physician contact.[10]

Those older adults in multigenerational family living arrangements used fewer home health care services.[13] When categorized by race, older African Americans are more likely to live with relatives than their white counterparts and older white adults are more likely to be living with their spouse.[16] Those older adults living with non-relatives are three times less likely to experience short-term hospital stays than those older adults living with their spouse.[16]

Kin Support/Non-Kin Support. Only one study looked into how the origin of support the older adult receives is related to use of health care. The presence of kin (family) support has been shown to be associated with greater physician visits.[13] It has

been shown that non-kin (friends, non-family) support significantly reduces bed-disability days, length of stay in hospitals, and likelihood of being admitted to a nursing home.[13]

Education. Level of education has been used as a measure of predisposing characteristics. The findings on the impact of education of health care service utilization are mixed. Those older adults that have a lower education were found to report the use of more home care services,[12] greater number of hospital days,[12] and doctor visits.[13] Contrarily, it has also been shown that higher education predicts more physician visits[8,9], but had no impact on hospitalizations and emergency department visits.[8] Additional studies have found that education does not predict hospital admission,[16] hospital stay,[9] or bed-disability days.[9]

Ethnicity/Race. The findings for impact on ethnicity and race on older adult health care utilization is mixed. Dunlop et al. conducted a two-year study of individuals aged 70 years or more to determine the impact of economic access in gender and ethnic disparities of health care services.[11] It was found that African American men had fewer physician visits, all minority men used fewer outpatient surgery, non-Hispanic white women used fewer hospital or outpatient services, and Hispanic women were less likely to use nursing home care.[11] Being non-White has been shown to predict more hospital stays.[15] Contrarily, it has also been found that no relationship exists between race and health care utilization.[13] In a study of 7,541 older Americans, African Americans are less likely to have a hospital admission than their White counterparts. [16] There is also evidence that ethnicity has no impact on hospital services, [11,12,15] physician visits, [12,15] emergency department use, [15] ambulatory care, [12] or bed-disability days.[9]

Health Belief. Surprisingly, few studies include health beliefs. Of those that measure this component of the Andersen Model, locus of control is commonly chosen. However, worry about health and illness beliefs have also been used. As presented above, the Dunlop et al. study found significant differences in health care service utilization between ethnicities and genders.[11] This study found that for those who had the same need level variations of utilization were found across gender and ethnicity lines. These differences in utilization were not explained by economic access. The authors state that cultural and attitudinal factors may be reasons behind these findings.[11] Worry, locus of control and illness beliefs were found in the literature to measure the health belief construct.

Health beliefs and worry about ones health has been shown to be a significant predictor of health behavior, including seeking care.[65] The authors hypothesized that those older adults who worry about their health are more likely to use health services.[13] Worry was measured by respondent whether their "overall health status for the past 12 months had caused them a great deal of worry, some worry, hardly any worry, or no worry at all."[13]

Those older adults who feel their have control over their health are less likely to die,[13] use fewer emergency department services,[8] fewer physician visits,[8] and fewer hospitalizations.[8] An increase of instrumental support among older African Americans has been shown to be associated with the use of more emergency department services.[8] Although there is evidence that locus of control has a positive association with health service use, one study determined that locus of control had no impact on doctor visits, emergency department visits, or hospital services.[15]

In a study of the very old in Germany, the Illness Concepts Scale was used to capture illness beliefs.[10] The Illness Concepts Scale measures ones perceived susceptibility, trust in physicians, belief in chance, trust in medications, expectation of side effects and self-confidence.[66] It was found that there was no significant relationship between illness beliefs and number of physician contacts.[10]

Enabling Resources

Although an individual may be more likely to use health care services according to their predisposing characteristics, resources are needed to be in place in order for the individual to seek care. Therefore, the enabling resources construct are those factors which allow health care services to be available to an individual for consumption. Family resources and community resources are the two dimensions of enabling resources.[7] Family resources refer to income, health insurance, and having a regular source of health care.[13] Community resources are measured by physician-to-population and hospital-bed-to-population ratios, geographic location and population density indices.[13] In the 1968 Andersen Model, it is stated that the enabling resources construct is the financial component of the model. However, the construct has evolved into resources that provide the "means" for an individual to consume care.[67] This construct now includes non-financial resources. In the past six years, this is to include instrumental/social/emotional support and others.

Family Income. It has been shown that income does not influence hospital admissions,[16] hospital services,[12,15] doctor visits,[15] or emergency department visits,[15] or ambulatory care services.[12] Another study found that older adults that have an annual

income of $7500-$14999 were more likely to have outpatient surgery than those older adults with an income of $15000 or more.[11]

Wealth. Wealth has recently been added to the list of enabling resources due to the inclusion of an individual's assets in the Health and Retirement Study, a nationally representative dataset. Only one study of older adult health care utilization has taken advantage of this measure to date. It was shown that those older adults with assets totaling $1,000-$49,000 predicts more nursing home service utilization than those who have assets totaling $50,000 or more.[11]

Insurance. Presence of insurance is commonly measured as an enabling resource.[8,11-13,15] Having Medicaid or private insurance has been shown to be associated with increased doctor office visits among older African Americans.[8] In studies of older adults in general, it has also been shown that having Medicaid increases doctor visits,[8,12-13] but has no impact on hospital admissions.[8,12] It was shown having private insurance as an older adult significantly predicted hosptializations,[8] and physician visits.[8,13] Contrarily, one study showed Medicaid and private insurance had no significant impact on volume of doctor visits.[17] However, it has been shown general health insurance (yes/no),[16] supplemental health insurance,[15] or other government insurance (ex. V.A. coverage)[12] do not impact hospital service use. Additionally, supplemental insurance had no influence on emergency department visits or doctor visits.[15] The findings for the impact Medicare has on health care utilization also vary. Medicare has been shown to impact doctor visits [8,11] and not influence doctor visits.[12] One study broke down Medicare coverage into Part A and Part B. The authors showed that Part A had no impact on physician visits but Part B

did.[17] There is common agreement among studies that Medicare coverage does not influence hospital admissions or days hospitalized.[8,12]

Education. Although education is commonly a measure of predisposing characteristics, it has been used as an enabling resource in a study. Predisposing characteristics are those factors that capture why some individuals are more drawn to seek care than others. Therefore, the assumption is, those that are more educated are more likely to use health care services. However, education is a measure of an enabling factor in this study because it is education in which could assist an older adult in the process of seeking out needed care. In this study, it was shown that having 12 years of education, or high school graduate, predicted more physician contact than those older adults who had fewer years of education.[11]

Regular Source of Care. The Andersen Model states that if an individual has a regular source of care, they have a higher accessibility to care and therefore, would more likely decide to seek care. Only three studies included regular source of care to study older adult health service use. In a study looking at emergency department utilization among elderly African Americans, it was shown that those without regular physician were more likely to utilize the emergency department.[8] Having a regular source of care has been shown to have a positive association on physician visits.[12,15] However, findings on the impact of having a regular source of care on hospital services is mixed.[12]

Number of Living Children. This measure was found in only one study. It has been found that those who have more living children are more likely to have doctor visits and bed-disability days, but no impact on hospital stays.[9]

Living Alone. As previously discussed, living arrangement, including living alone, is commonly included as a predisposing characteristics. In some studies it is considered an enabling resource because it has an impact on an older adult's accessibility and availability to health care. Those older adults living alone are predicted to utilize more physicians visits than those who live with another person.[9-10] It has been shown that an older person living alone does not predict hospital stay or bed-disability days.[9]

Instrumental Support. Instrumental support measures the direct support provided to an individual so he/she may seek medical care. Instrumental support may be in the form of transportation, making financial contribution, helping with work obligations, or providing another form of direct relief or material aid.[20] Those older adults who report having decreased transportation access reported using more ambulatory services, home care and had a greater number of hospital days.[12] It has also been shown that older African Americans who report higher instrumental support use more emergency department services and more doctor visits; however, there is no impact on hospitalization.[8] In a study of 1, 284 community-dwelling older adults, those who reported having more instrumental support from their informal networks, were more likely to report being hospitalized than those not receiving instrumental support.[18]

Need

Andersen states that need is comprised of perceived need and evaluative need. "Perceived need will better help to understand care-seeking and adherence to a medial regimen, while evaluated need will be more closely related to the kind and amount of treatment that will be provided after a patient has presented to a medical care provider.[7]

Perceived need includes how people view and experience their illness symptoms, functional state and overall general health.[7] Evaluative need is determined through professional assessments developed through objective measurements. Throughout the testing of the Andersen Model, it has been shown that need characteristics are the most important determinants to physician visits [17,69] and overall health care utilization. [7,12,15,68] Need characteristics may be measured by functional status, perceived/self-report health status, and evaluated health status.

Activities of Daily Living. Functional status is commonly measured with the Activities of Daily Living. [9,11-13,15-16] A literature review of the use of the Andersen Model to explain elderly healthcare utilization, found that physical functioning emerged as a significant indicator to service use.[69] It has also been shown that in older community-dwelling adults a decrease in physical functioning, measured by ADLs, was related to an increase in physician visits [8,9] ambulatory care use, [12] and hospitalizations.[8-9,12,16] In a study conducted by Wolinsky and Johnson 5,151 older adults were surveyed to model the Andersen Model with health care use. It was found that decreased physical functioning was significantly related to increased health care service utilization.[13] Lower ADLs have been shown to be significantly associated with days an individual is confined to their bed.[9,15] Although there are evidence that states ADLs are predictors of health care utilization, additional studies have found that ADLs do not influence doctor visits[12,15] or emergency department services.[15]

Instrumental Activities of Daily Living. Instrumental activities of daily living (IADLs) are those activities that require more planning, such as preparing a small meal or managing money. Decreased IADLs has been shown to be associated with days an older

adult is limited to their bed[15] and increased hospitalizations. [16] However, it has been shown that doctor visits, emergency department visits, and hospital services are not influenced by IADLs.[15]

Perceived/Self-Report Health Status. Older adults who reported a lower perceived health were more likely than others to have more physician visits[9,12-13,15] take more bed-disability days,[9,13] emergency department visits,[8] and hospital services.[9,12-13] In a nationally-representative study of older Americans, it was found that those who self-report having poorer health status were more likely to be admitted to the hospital.[16] One study demonstrated that perceived health status was not a predictor of emergency department visits or hospital service use.[15]

Evaluated Health Status. Many studies operationalize evaluated health status as a having a particular diagnosed health condition or total number of chronic conditions. The findings of evaluated health status vary across studies because studies use varied lists of chronic conditions for the participants to choose from.[8,18] Diagnosed chronic conditions of interest between studies vary greatly. In a study of older African Americans, heart and eye conditions have been shown to predict emergency department visits, diagnoses of cancer or a heart condition predicts hospitalizations, and doctor visits were predicted by the diagnoses of hypertension, arthritis, stroke, blood circulation problems and breathing problems.[8] A literature review of the chronically ill determined that depression and psychological distress were the strongest predictors of physician visits and hospitalizations.[80] One study had participants complete a checklist of different chronic conditions then included the summed number of self-reported chronic conditions into the

analyses.[18] It was found that those with more chronic conditions were more likely to use medical services but did not predict hospital services or home care.[18]

Summary

Overall, findings are mixed across all constructs and measures within each construct. In addition, measures selected to be in each study vary greatly across studies. What is apparent is that there are many predictors of older adult health care service use. It is clear that further investigation needs to be conducted for newly added measures, such as kin support, instrumental support and living arrangement (as an enabling resource).

It was also apparent that authors vary according to how they perceive living arrangement and education. Some view them as predisposing characteristics and others as an enabling resource. Predisposing characteristics are those factors that capture the underlying assumption that individuals have different propensities to seek use health care services than others. Therefore, when used as a predisposing characteristics, education and living arrangement are factors that add to an individual's propensity to seek care. For example, the more educated an individual is, the more likely they will seek care. Enabling resources are those factors that allow health care services to be available and accessible to an individual for comsumption.[13] Therefore, when education and living arrangement are used as an enabling resource, they are capturing the availability and accessibility of seeking care. For example, when an individual has a higher education, they have the skills to look up a physician and contact them. This use of education as a factor to increase accessibility of health care services aligns with the health literacy

approach to studying health care use.[70] Health literacy skills help an individual navigate the healthcare system, including filling out complex forms and locating providers and services.[71] It has been shown that those with higher education are more likely to have a higher health literacy and are more likely to seek care. In conclusion, a literature review of older adult health service utilization shows mixed findings among all constructs, differing measures applied to each study and varying approaches to the operationalization of constructs.

Section 3: Proposed Framework to Investigate Older Adult Post-ADE Behaviors

When patients experience a symptom such as a possible ADE, they employ a decision making process to determine if they want to utilize health care services or not. Therefore, the Andersen Model is appropriate to study post-ADE behaviors. However, the past literature of older adult health behaviors contains no research evaluating which behaviors and predictors of those behaviors are present after an older adult experiences an adverse drug behavior. ADEs are rapidly increasing, and it is important to determine what patients are doing and what factors predict different post-ADE behaviors.

The 1995 Andersen Model is a decision-making model that clearly states that an individual may choose to seek professional health care or to perform other personal health choices (Figure 1.1). However, past ADE research focuses only on which health care services older adults use. They exclude other self-care behaviors that are performed outside of the health care system. This study of what behaviors are taken after older adults experience an adverse drug event will include those health care services utilized, self-care behaviors, and an individual taking no action at all.

Proposed Framework to Investigate Post-ADE Behaviors

The Andersen model has been used to determine which characteristics of a patient are most likely to lead to health care utilization. However, this model has not been used to explain post-ADE behaviors. Past research has shown that some individuals utilize health care after experiencing an ADE. In addition, it has been shown that another group of individuals tend to self-treat or take no action at all after experiencing an ADE.[19] Therefore, a framework tailored from the 1995 Andersen Model of Health Care

Utilization is proposed to determine the relationships between a patient's need, predisposing characteristics, enabling resources and type of post-ADE behavior (Figure 1.2). The Health Belief Model, Common Sense Model, and Self-Deficit Theory provide evidence that post-ADE behaviors are a result of a decision-making process, while the Andersen Model provides a framework for how predisposing characteristics, enabling resources, and need impact post-ADE behavior performed.

Post-ADE behaviors are the result of a decision-making process. ADE symptoms are experienced before an individual's acknowledgment of what is causing those symptoms. It has been shown that those who are experiencing an ADE do not always believe that those symptoms are caused by a medication.[72] Some individuals believe that ADE symptoms of a stomach ache may be due to food poisoning.[72] Alternatively, some older adults may attribute ADE symptoms to issues with aging. Therefore, the acknowledgment of the origin of the experienced symptoms may impact the post-ADE behavior performed.

An individual can experience a mild, significant, or severe ADE. Utilization of different self-care and care-seeking post-ADE behaviors are influenced by patient factors and family factors. The post-ADE behavior performed depends on many factors. The Andersen Model of Health Care Utilization provides the skeleton of the proposed framework while the Health Belief Model, Common Sense Model, and Self-Care Deficit Theory explain additional factors that apply to post-ADE behaviors. Combining these models and theories provide the factors that predict post-ADE behavior and the post-ADE behavior performed. Overall, these predicting factors include patient factors (predisposing characteristics -- health beliefs, medication beliefs, illness representation,

socio-demographic characteristics; need factors -- clinical characteristics, ability to self-care) and family factors (enabling resources).

Patient Factors

The Andersen Model constructs include predisposing characteristics, enabling resources and need. Predisposing characteristics and need factors are patient-related factors while enabling resources cover family factors. Predisposing characteristics are those existing aspects that make some individuals to have the propensity to seek and use health care services than others. Demographics are deemed predisposing characteristics. Need characteristics may be measured by functional status, perceived/self-report health status, and evaluated health status. Although an individual may be more likely to use health care services according to their predisposing characteristics, resources are needed to be in place in order for the individual to seek care. Therefore, the enabling resources constructs are those factors that allow health care services to be available to an individual for consumption. Examples of enabling resources are family structure, family availability, transportation, family income, wealth and insurance coverage. Although the Andersen Model has been shown to be strong at modeling older adult healthcare utilization, the Health Belief Model, Common Sense Model, and the Self-Care Deficit Theory add additional explanation to post-ADE behaviors.

Patient health beliefs and medication beliefs have been shown to contribute to an individual's reporting of ADE symptoms and health care utilization.[73-74] An individual's health beliefs consist of perceived severity, perceived susceptibility, benefits of performing health behavior, and the barriers to performing a health behavior. The Health

Belief Model states that patients evaluate the possibility of performing a health behavior by considering these four beliefs. In the context of an ADE, perceived severity is one determinant to self-care or seeks care. If an older adult acknowledges that there is a negative symptom but feels that it is only a mild symptom, they may perform self-care behaviors, like stop taking the prescription without consulting a doctor. However, if an older adult perceives an ADE symptom as severe then they may opt to go to the emergency room. Perceived barriers to seeking care or self-care are also important when an individual experiences an ADE. For example, even if an individual perceives the ADE's symptom as mild, and would desire to perform self-care behaviors, but is not able to, then that individual may take no action at all or seek out health care services to perform care for them.

The Common Sense Model focuses on illness representations and coping behaviors. Therefore, this model would assist in determining the relationship between patient beliefs and the post-ADE behaviors they preform. The underlying assumption of this model is that individuals are goal directed.[75] When an individual faces a health threat he/she will face the obstacle of decreasing that health threat. The model also states that an individual must first identify a health threat and then identify the threat as an illness in order to employ a coping strategy. Coping strategies include seeking care from a health care professional, expressing emotion, or denial. A health threat is acknowledged when an individual's health status has changed. In order for an individual to then identify the threat as an illness they employ the evaluation of 5 illness representation beliefs: 1) Identity -- what is the illness? 2) Cause – what caused the illness? 3) Timeline – how long

will the illness last? 4) Consequences – how will the illness affect me? 5) Cure/Controllability – can this illness be controlled or cured? [76]

Medication beliefs have been shown to influence coping responses individuals perform in response to health threats.[77-78] In addition, medication beliefs have been shown to be related to patient reporting of ADEs.[73,79] There are medication-specific and general medication beliefs. Medication-specific beliefs focus on a particular medication. For example, if an individual has heard that their friend has experienced a severe ADE resulting from a particular medication, then he/she may have more negative beliefs about that particular prescription. It is possible to have positive general medication beliefs but negative medication-specific beliefs. In addition there are necessity and concern medication beliefs. Necessity beliefs are an individual's beliefs on how much they need their medication in order to maintain their level of health. It has been shown that past experiences influence necessity beleifs.[80] For example, if an individual experienced an ADE in the past, but had a high necessity belief for that medication, they may maintain taking that prescription even with the risk of experiencing another ADE. Concern beliefs are patients' anxieties about the harmful effects of a specific prescription medication.[79] It has been shown that those individuals that have strong concern beliefs were more likely to report the symptoms of an ADE.[73] These individuals may pay more attention to potential unwanted reactions due to their concern about the medications they are taking. Therefore, they are more likely to report ADE symptoms.

It has been shown that socio-demographic factors and clinical characteristics of individuals are related to medication beliefs. Males are more likely to have negative general medication beliefs than females.[81] Older adults are found to have more positive

medication beliefs than younger individuals.[82] Ethnicity has also been shown to influence medication beliefs. Asians are more likely to have negative medication beliefs when compared to those from a European decent.[81] Level of education has also been shown to be a factor.[81-82] Being diagnosed with a chronic condition and taking a prescription medication is related to stronger necessity beliefs.[83-84] Lastly, individual who practice alternative self-care behaviors, such as taking herbal remedies, have more negative medication beliefs.[81-82]

Family Factors

According to the self-care deficit theory, if an individual was not able to care for himself or herself then a caregiver or nurse would step in to provide assistance where patient's capabilities fall short.[85] For example, if an older adult experienced ADE symptoms that made him/her have diarrhea, and the older adult was not able to use the toilet on their own, then a family member would have to assist in the process. If there are no family members around to help care for the older adult, or if the family members were not able to perform this type of care, then the older adult may seek care within the health care system. The family's ability to care for their older parent acts an enabling resource. The Andersen Model of Health Care Utilization states that enabling resources are those factors that allows health care services to be available to an individual for comsumption.[13]

Applying constructs from the Health Belief Model, Common Sense Model, Self-Deficit Model, and the Andersen Model of Health Care Utilization to post-ADE behavior, it is apparent that post-ADE behaviors are a decision-making process and not an impulse

behavior. This study will test the Andersen Model constructs from this overall post-ADE behavior model.

This study will measure only Andersen Model variables of the proposed theoretical framework due to three reasons. First, while the Health Belief Model, Common Sense Model, and Self-Deficit Theory provide evidence that post-ADE behaviors are a result of a decision-making process, the Andersen Model is more comprehensive in that all three general constructs are included, namely patient factors, family factors, and outcome. The second reason to test the Andersen Model portion of the proposed framework was because the Health and Retirement Study (HRS) and the Prescription Drug Study (PDS) were developed to determine the changes in labor force participation and the healthcare utilization as individuals age. Therefore, it is natural that the HRS and PDS include variables found in the three Andersen Model constructs; predisposing characteristics, need factors, and enabling resources. The final reason why the Andersen Model portion of the overall proposed framework was selected was because the Andersen Model of Health Service Utilization is a commonly accepted framework for researching healthcare decision-making. Therefore, it was determined that testing Andersen Model constructs of the proposed framework would be appropriate for the initial investigation into ADE risk factors and ADE post-ADE behaviors, in the Medicare/Medicaid population, that would begin to close the gaps from previous ADE research (Figure 1.3).

Outcome Measures. As the 1995 version of the Andersen Model illustrates, individuals may decide to seek care provided within the health care system or employ other health care choices. There are three categories of post-ADE behavior: 1) no action

taken, 2) use of care within the health care system and 3) self-care. Use of care within the health care system includes talking to a doctor, visiting a physician or emergency room, and hospital admission. Self-care post-ADE behavior may include treating on own or cutting down/stopping their prescription drug on own without a physician's advice.

Predisposing Characteristics. These measures will include: age, gender, ethnicity, race, education, geographic region, urban/rural status, marital status, health beliefs, medication beliefs, and illness representation.

Enabling Resources. The enabling resources included in this framework include family structure, family availability, living arrangement, insurance status, wealth, instrumental support (nursing home/paid caregiver), and transportation availability.

Need. Following historical measures of the need construct, this study will include physical functioning, cognition, number of prescriptions, number of high-risk medications, and number of chronic health conditions to the analyses.

ADE behaviors that occur within the health care system in commonly investigated. This is due to the ease of collecting ADE occurrence data within the health care systems. This study will provide initial insight into other post-ADE behaviors that occur outside the health care system. These include taking no action at all and discontinuing the prescription medication without physician consultation.

In addition, the major gap in older adult health behavior is that enabling resources have not be explored to the depth that would provide significant understanding to why individuals use certain types of health care services. In the 1968 Andersen Model, it is stated that the enabling resources construct is the financial component of the model. However, the construct has evolved into resources that provide the "means" for an

individual to consume care.[67] This construct now includes non-financial resources. In the past six years, this is to include instrumental/social/emotional support and others. However, these non-financial enabling resources have not been explored for post-ADE behaviors. This study will include family structure, family availability and transportation as enabling resources

Summary

Overall, literature has shown mixed results in ADE risk factors, primarily due to different measures of ADEs and where ADEs were captured. There have been six different measures of ADEs researched in six different settings. With a bias in ADE research leading to capturing ADEs in the healthcare setting and post-ADE behaviors that lead to seeking health care services, there exists a gap in ADE research in what post-ADE behaviors may be performed outside of the healthcare system and what factors predict these types of behaviors. The objective of this study is to determine the prevalence of self-reported ADEs, and determine if the Andersen Model constructs predict different types of post-ADE behaviors.

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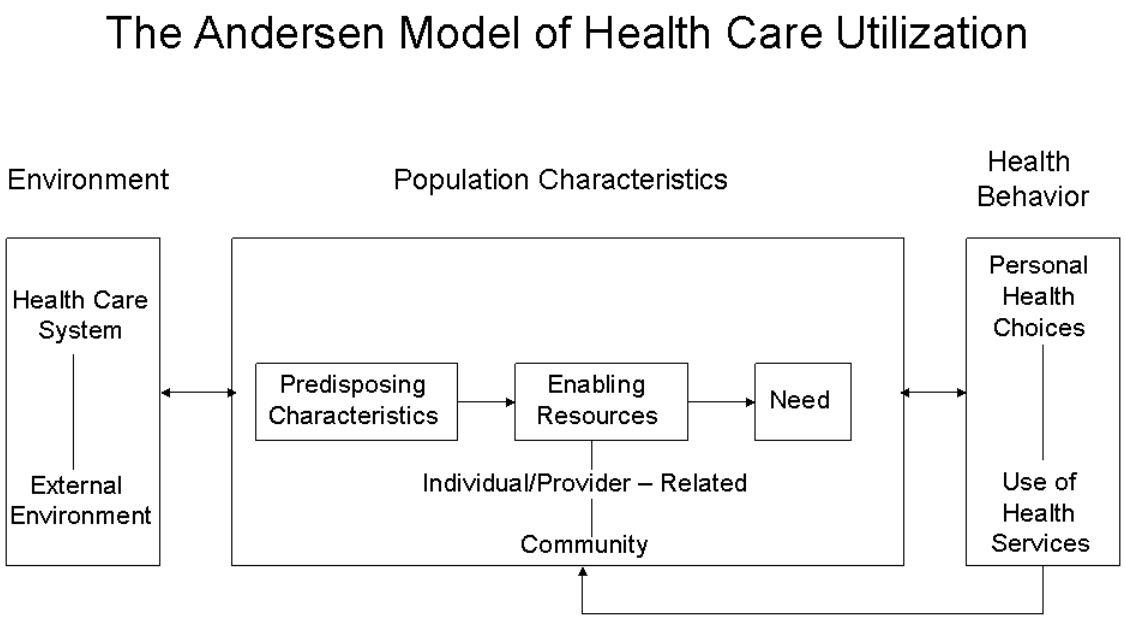
FIGURE 1.1: THE 1995 ANDERSEN MODEL OF HEALTH CARE UTILIZATION



RM Andersen. Revisiting the behavioral model and access to medical care: does it matter? *J Health Social Behavior* 1995;36:1-10.

FIGURE 1.2: PROPOSED FRAMWORK

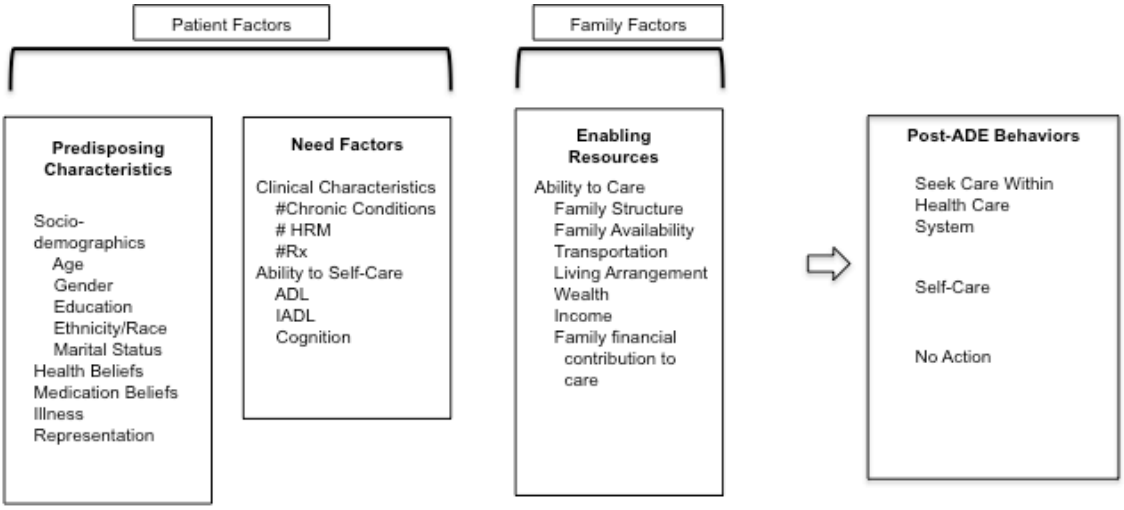
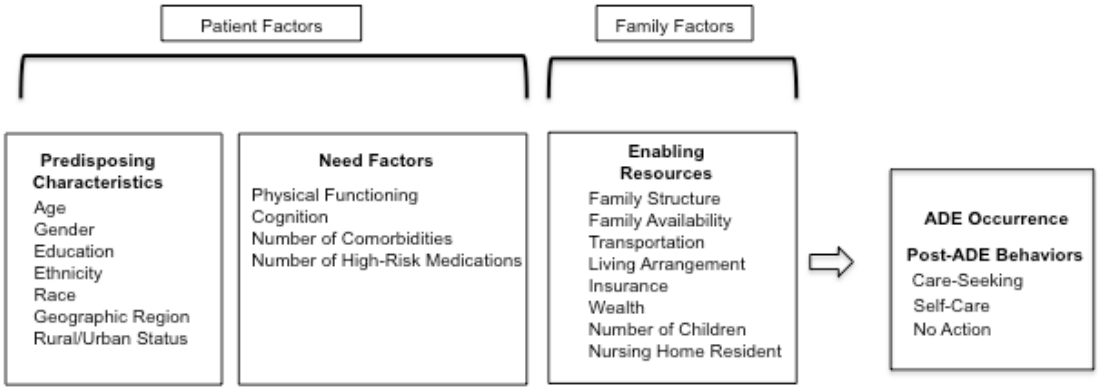


FIGURE 1.3: PARTIAL FRAMEWORK TESTED IN THREE STUDIES



Chapter 2

QUANTIFYING THE RELATIONSHIP BETWEEN PREDISPOSING CHARACTERISTICS, ENABLING RESOURCES, NEED FACTORS, AND THE OCCURRENCE OF AN ADVERSE DRUG EVENT

Introduction

An adverse drug event (ADE) is defined as an injury due to medical treatment.[1] There are two harms to ADEs; intrinsic and extrinsic. An intrinsic harm is one that is a due to the pharmacological properties of the prescription medication, and this type of harm is also called an adverse drug reaction (ADR).[1] Extrinsic harm is created by the administration and use of the prescription.[1] This type of harm is also defined as medication error. Adverse drug events (ADEs) cause over 701,547 emergency room visits each year.[1] Of those 701,547 emergency room visits, 117,318 require further hospitalization for the experienced ADE.[1] Occurrence of ADEs rapidly increased 9.4% from 2010 to 2011.[2] About one in three older persons taking at least five medications will experience an adverse drug event each year.[3] Older Americans are twice as likely as their younger counterparts to visit an emergency room and seven times more likely to require hospitalization due to ADEs.[1] To decrease cost to the health care system and increase quality of care, it is important to determine the risk factors for an ADE specific to older

Americans. Past research reveals mixed findings for ADE risk factors due to varying populations of interest and methodologies utilized.

It has been shown that risk factors of experiencing an ADE among older adults are: age, gender, number of comorbidities, number of prescription medications, taking high-risk medications, physical functioning, and cognitive ability. Except for number of prescription medications, all risk factors have conflicting evidence on experiencing an ADE. This is primarily due to varying subject population and/or health care settings in the previous studies. For example, the association of age and ADEs has been mixed. In hospitalized patients age has both been shown to be associated[4] and not associated[5] with ADEs. For ADEs that occur in older adults in the outpatient setting, age was not a risk factor.[6]

Findings about the association of gender and ADEs are also mixed, and some studies show that being female is a risk factor for experiencing an ADE.[4, 7, 8] From 2.3 million ADE case studies reported from 1969-2002, 53% of adverse drug events were for females, 32% males, and 12% were not specified.[9] Being female in home health settings was associated with ADEs.[7] A study conducted of Medicare enrollees showed that being female was a risk factor of ADEs.[8] However, studies have also shown that there is no gender effect on hospitalization admissions due to ADEs,[10] outpatient ADEs,[6] or those patients who experience an ADE while in the hospital.[5]

Number of comorbidities as a risk factor for ADEs is mixed. In a 10-year cross-sectional study, comorbidities have been shown to be a risk factor of experiencing an ADE.[4] For nursing home residents, a score of 5 or more on the Charlson Cormorbidity Index was shown to be associated with increased risk of ADEs.[11] However, in

hospitalized older adults there was no association between a diagnoses of 4 or more comorbidities and ADEs.[5]

The evidence of number of prescription medications as a risk factor for ADEs is strong. The use of multiple medications increases the risk of experiencing an ADE.[6, 12, 13] For nursing home residents the greater number of regularly scheduled medications is associated with an increased risk of an ADE.[11] Although the majority of studies show a greater number of prescriptions is associated with ADEs, one study of hospitalized older adults did not find an association between medications and ADEs.[5] Older patients often change therapeutic treatment at time of hospital admission or at hospital discharge, and a greater number of new medications prescribed at hospital discharge was associated with ADEs.[7] The number of new medications prescribed at time of hospital admission has also been shown to be a risk factor for an ADE.[14]

High-risk medications are those deemed by clinical experts that pose risk of harm and should generally be avoided in people aged 65 years or older because they are either ineffective or they have unnecessarily high risk and safer alternative is currently available.[15] Although it has been shown that only 1.2% of hospitalizations due to ADEs are due to high-risk medications,[16] another study of hospitalized older adults suggests that high-risk medications should be closely monitored based on patient characteristics.[4]

Other risk factors that have not been commonly examined in ADE research are physical functioning and cognition. Physical functioning before hospitalization was not associated with ADEs.[5] Decreased cognition has been shown to be associated with ADEs that occur in hospitalized older adults.[5]

Overall, risk factors for experiencing an ADE may include: age, gender, number of comorbidities, number of prescription medications, taking high-risk medications, physical functioning, and cognitive ability. Clinical characteristics have been researched in past ADE research. There exists a gap in literature of other characteristics, such as enabling resources, which may influence ADE occurrence. Literature exists on how health beliefs, insurance status, and social support impact healthcare utilization, but not on how these characteristics may influence the occurrence of ADEs. With an aging population, taking multiple medications, and potentially experiencing more than one ADE overtime, it is important to determine what ADE risk factors, other than clinical factors, exist for older adults to improve quality of patient care and policy.

This study will use constructs from the Andersen Behavioral Model to capture a comprehensive illustration of what personal characteristics are predictors of number of ADEs experienced. The Andersen model has been used to determine which characteristics of a patient are most likely to lead to health care utilization. However, this model has not been used to explain post-ADE behaviors. Past research has shown that some individuals utilize health care after experiencing an ADE. It has also been shown that another group of individuals tend to self-treat or take no action at all after experiencing an ADE.[17] Therefore, a framework tailored from the 1995 Andersen Model of Health Care Utilization is proposed to determine the relationships between a patient's need, predisposing characteristics, enabling resources and type of post-ADE behavior. This model provides a framework that includes past ADE risk factors explored, such as demographics and clinical factors. Therefore, since past literature is mixed on risk factors in older Americans, this will provide a platform for further investigation. In

addition, this model also includes personal, social, and environmental factors that may play a major role in experiencing an ADE, but not previously investigated.

The Andersen Model includes predisposing characteristics, needs factors, and enabling resources. Predisposing characteristics are those characteristics that create a propensity for some individuals to seek and use healthcare services more than others.[18] For example, those who are older are on average sicker, and more likely to use more healthcare services than their younger counterparts. Need factors are those characteristics that influence the use of healthcare services.[19] For example, those who have more comorbidities are more likely to need more healthcare services than those who are healthier. Although an individual may be more likely to use health care services according to their predisposing characteristics and need factors, resources need to be in place in order for the individual to seek care. Therefore, the enabling resources are those factors that allow health care services to be available to an individual for consumption.[20] An example of an enabling resource is instrumental support. Those who have decreased cognition but have more instrumental support may not experience ADEs as often as those who have better cognition but no instrumental support. This may be because they have those that have instrumental support have another person taking on health maintenance behaviors for them, such as organizing medication.

The objectives of this study were to (1) quantify the prevalence of self-reported ADEs among a nationally representative sample of older adults, and (2) determine the relationship between Andersen Model variables and experiencing no ADE, one ADE in either 2005 or 2007, and one ADE in both 2005 and 2007.

Research Methods

Design

This study used a cross-sectional analyses of data from the 2005 Prescription Drug Study (PDS), 2007 PDS, 2004 Health and Retirement Study (HRS), 2006 HRS, RAND Income and Wealth Imputation File, HRS Tracker File, and the HRS Cross-Wave Region and Mobility File.

Data Sources

Health and Retirement Study. The University of Michigan Health and Retirement Study (HRS) is a longitudinal panel study that surveys a representative sample of more than 26,000 Americans over the age of 50 every two years. Since 1992, the study has collected information about income, work, assets, pension plans, health insurance, disability, physical health and functioning, cognitive functioning, and health care expenditures. The HRS (Health and Retirement Study) is sponsored by the National Institute on Aging (grant number NIA U01AG009740) and is conducted by the University of Michigan. The HRS sampling methods can be found in Appendix A. This study will focus on the 2004 and 2006 panels of the HRS. The data collection period for the 2004 interview was March 2004 through February 2005, and the 2006 HRS panel data collection period was March 2006 through February 2007.

Prescription Drug Study. The HRS 2005 Prescription Drug Study is the first wave of a two-wave mail survey designed to track changes in prescription drug utilization over Medicare Part D implementation. The baseline wave was administered in

2005, and a second survey was done in 2007. These two surveys were intended to capture prescription drug use, coverage, and satisfaction prior to the implementation of Medicare Part D, and changes in these variables after its implementation. The 2005 and 2007 waves of the HRS Prescription Drug Study were funded by the National Institute on Aging through a competing supplement to the Health and Retirement Study and through supplemental funding provided by the Centers for Medicare & Medicaid Services (CMS). Descriptions of the PDS sampling methods and the creation of weights may be found in Appendix A.

HRS Tracker File. The HRS Tracker file was developed to assist in using HRS data across waves. There is one record for each subject that contains basic demographic information, interview status, and if, when and how an interview was conducted in each wave.[21]

RAND Income and Wealth Imputation File. The RAND Income and Wealth Imputation Files contain the component and ownership variables that were used in RAND HRS income and wealth summary measures.[22]

HRS Cross-Wave Region and Mobility File. This file matches the HRS Tracker file Household Identifier (HHID) and Person Number (PN) and contains one record for each subject. This file includes: (1) cross-wave geographic information, (2) child Zip Codes, (3) region in which the respondent was born, (4) region where the respondent lived at age 10, (5) for each wave, the region where the respondent was reached for an interview, (6) the HRS Urban-Rural Code, an urban/suburban/ex-urban flag derived from the Beale Rural-Urban Continuum Code, (7) distance-moved variables for each pair of

interview years, and (8) information on geographic information processing techniques for each wave.

Study Population

The inclusion criteria consisted of subjects who (1) completed the 2005 PDS and 2007 PDS and (2) completed both the 2004 HRS and 2006 HRS. The PDS sample included HRS respondents born in 1942 or earlier (65th birthday in 2007) or already covered by Medicare or Medicaid at some time between 2002 and 2004.

Measures of Interest

Predisposing Characteristics

Predisposing characteristics included: age, gender, highest degree attained, ethnicity, race, urban/rural status, and geographic region. Age, gender, education, ethnicity and race are from the HRS Tracker File. Urban/rural status and geographic region are from the Cross-Wave Region and Mobility File.

Demographics. The interviewer documented the subject's gender and was coded as a dummy variable with females being the reference group. Level of education attained had the following response options: No degree, GED, High School Diploma, Two-year college, 4-year College, Master degree, Professional Degree, and Degree unknown/some college. Dummy variables were created for: 1) less than high school, 2) high school diploma, and 3) 4-year college degree. Less than high school was deemed the reference group. Race response options included: White/Caucasian, Black/African American, and Other. Dummy variables were created for: 1) White/Caucasian, 2) Black/African

American, 3) other. Ethnicity grouped into one dummy variable for Hispanic and Non-Hispanic. Non-Hispanic was deemed the reference group.

Rural-Urban Status. Beale Codes (also known as Rural-Urban Continuum Codes) were developed by the United States Department of Agriculture (USDA) and categorize populations into 12 groups by size (Appendix B). The HRS groups the 12 Beale Codes into 3 categories; urban, suburban, and ex-urban. Dummy variables were created with these three categories and urban were deemed the reference group.

Geographic Region. HRS codes geographic regions into 13 groups (Appendix B). In the United States For this study, HRS geographic codes were then further categorized into Northeast, Midwest, South, and West. Dummy variables were created for these four geographic regions with Northeast as the reference group.

Need Factors

Need factors included: physical functioning (activities of daily living and instrumental activities of daily living), number of comorbidities, cognition, number of regular prescriptions, and number of high risk medications. Physical functioning and number of comorbidities were from the 2004 HRS and 2006 HRS. Number of regular prescriptions and number of high-risk medications were from the 2005 PDS and 2007 PDS. Cognition was from the HRS total cognition imputation file.

Activities of Daily Living (ADLs). All subjects were given an initial evaluation of mobility to determine skip patterns during the interview. Further details of this and how skip patterns were handled for ADLs can be found in Appendix B. The six ADL items were as follows: because of your health do you have any difficulty with dressing,

including putting on (1) shoes and socks? (2) Bathing or showering? (3) Using the toilet, including getting up and down? (4) Eating, such as cutting up your food? (5) Walking across a room? or (6) Getting in or out of bed? Response options included: Yes, No, Can't do, Don't do, Don't know, Refuse to answer. Shinar et al. validated the activities of daily living measure for phone interviews.[23] To be conservative, all responses other than 'No' were coded as 1. 'No' was coded as 0. For all subjects a summed ADL score was created. Subjects could have a final summed score of 0 to 6 (no difficulty to difficulty with all ADLs), and this variable was kept as continuous during analyses.

Instrumental Activities of Daily Living (IADLs). The five IADL items were as follows: because of a health, do you have any difficulty (1) Preparing a hot meal? (2) Using a map to figure out how to get around in a strange place? (3) Shopping for groceries? (4) Making phone calls? or (5) Taking medications? Response options included: Yes, No, Don't Know, Refuse to Answer, and all responses, other than 'No', were coded as 1. For all subjects, a summed IADL score was created, and subjects had a final summed score of 0 to 6 (no difficulty to difficulty with all IADLs). This was kept as a continuous variable during analyses.

Cognition. The HRS measures cognition in terms of episodic memory, mental status, and vocabulary among self-respondents. Overall cognition was captured by using the Telephone Interview for Cognitive Status (TICS). TICS is a version of the Mini Mental State Examination [24] and has been adapted for telephone administration.[25] Cognition was a summed score of the subjects ranging from 0-35. A TICS cutoff score of <25 best distinguished between demented and non-demented patients. The TICS sensitivity (1.00) and specificity (0.83) are excellent and comparable to the sensitivity

(0.83) and specificity (0.87) of the MMSE, with dementia defined as a score <24.[26] Subjects' final total cognition score was kept as a continuous variable.

Number of Comorbidities . Subjects were asked if they have been diagnosed with 10 common chronic conditions among older adults including diabetes, lung disease, heart disease (heart attack, coronary heart disease, angina, congestive heart failure, or other heart problems), mental health condition (emotional, nervous, or psychiatric problems), arthritis, hypertension, cancer (excluding minor skin cancer), memory-related condition, stroke, and glaucoma. A summed count was calculated to determine how many chronic conditions a subject had, and the score ranged from 0-10.

Number of Regular Prescriptions. Subjects were asked to report how many of their prescription drugs they took on a regular basis, and this was kept as a continuous variable during analyses.

Number of High Risk Medications. In the PDS subjects are asked to list all prescriptions that they take. From these self-reported medication names, a count of the number of high risk medications for each individual was done using the National Committee of Quality Assurance list of high risk medications in the elderly (Appendix C) This list of high-risk medications was selected over others because it is commonly used by the Healthcare Effectiveness Data and Information Set (HEDIS). [27] Those who did not take any prescriptions within the past month or the past year were counted as taking zero high-risk medications.

Enabling Resources

Enabling resources included: wealth, family structure, family availability, ability to drive, family living arrangement, having at least one private or supplemental insurance plan in addition to Medicare, and being a nursing home resident. All these variables, except for wealth, were from the 2004 HRS and 2006 HRS. The total wealth variable is from the RAND Income and Wealth Imputation File.

Wealth. The RAND imputed wealth variable used in this study was the net value of total wealth (including second home) minus all debt. Assets are added from primary residence, second home, other real estate, transportation, business, IRA retirement account, stocks, CDs, bonds, and any other reported assets in savings. From these assets, debts from primary mortgage, second home mortgage, other homes loans and debts were subtracted, and this result was left at as continuous variable during analyses.

Family Structure. Subjects were asked, "What is the total number of children or step-children you have?", and number of children was a continuous variable. Those who previously reported having no children in their first wave of interviews were intentionally skipped in later waves and were recoded as having zero children.

Family Availability. Family availability was determined by asking two questions. Subjects were asked if they have a child that lives within 10 miles, or 2 blocks. Subjects were coded as 0 if they had no child within 2 blocks or 10 miles. Subjects were coded as 1 if they had a child that lived within 10 miles, and coded 2 if they had a child that lived within 2 blocks. Those who reported having no children were intentionally skipped and coded as 0 since they have no children living within 10 miles or 2 blocks.

Ability to Drive. Subjects were asked, "Are you able to drive?" and the response options included: Yes, No, Don't Know, Refuse to Answer. Subjects were coded as 0 if they were not able to drive and 1 if they could drive. If a subject was under the age of 65, they were intentionally skipped in this section, as HRS assumes that those who are under 65 are able to drive, and these respondents were coded as having no difficulty driving.

Living arrangement. Living arrangement was determined by asking two questions. First, "Do you live with your spouse/partner?" and "What is the number of children in your household?" A summed living arrangement score of 0 indicates living with no family. A score of 1 indicates living with one family member. A score of 2 indicates living with both spouse and one child.

Private and/or Supplemental Insurance in Addition to Medicare. The subjects were asked, "Now, we'd like to ask about all the other types of health insurance plans you might have, such as insurance through an employer or a business, coverage for retirees, or health insurance you buy for yourself, including any (Medigap or) other supplemental coverage. Do NOT include long-term care insurance, or anything that you have just told me about. How many other such plans do you have?" This variable was categorized into having at least one additional private or supplemental insurance plan. Those who stated that they did not have any additional private or supplemental insurance on top of Medicare were the reference group during analyses.

Nursing Home Resident. The interviewer can document this if he/she is able to determine if subject is living in nursing home. If not, the subject is asked, "Are you living in a nursing home or other health care facility?" A dummy variable was created

and those who are not living in a nursing home were deemed the reference group during analyses.

Outcome Measures

Outcome variables included: the occurrence of an ADE in the past year from the 2005 PDS and 2007 PDS. Subjects were asked, "In the past year, have you had any side effects, unwanted reactions, or other health problems from medications you were taking?" yes/no? Subjects were coded as 0 if they did not experience an ADE and 1 if they did experience an ADE.

Statistical Analyses

This study utilized the weighted data provided by the Health and Retirement Study, from the Institute for Social Research, at the University of Michigan. Weights were provided for both 2005 and 2007 PDS data.

Overall Statistics. Frequencies and descriptive statistics were performed for all predisposing characteristics, need factors, and enabling resources. Weighted frequencies were performed to determine the prevalence of ADEs in 2005 and 2007. Frequencies were calculated to determine how many people experienced no ADE, one ADE in either 2005 *or* 2007, and two ADEs, one in 2005 *and* one in 2007. Spearman and Pearson correlations were performed between all independent and dependent variables to determine associations.

Logistic Regression. To determine if the occurrence of an ADE was explained by predisposing characteristics, enabling resources, and need factors, two binary logistic regressions were performed. The predisposing characteristics, enabling resources and need factors were taken either from the year before or the year of the experienced ADE. For example, the 2004 HRS contains these predictors while the 2005 PDS collected ADE occurrence. The full regression models were completed. Variables with high standard of error are found in these full models, due to additional multicollinearity. Multicollinearity, determined by VIF values above 5, will be handled. The model will then be re-run. A reduced model was then conducted consisting of age, gender, race (Caucasian/African American), and ethnicity (Hispanic/Non-Hispanic), and the variables with significant coefficients in the full model.

The model below shows prediction of the occurrence of one ADE. The occurrence of two ADEs was also predicted.

Occurrence of one ADE (0=No, 1=Yes) = β_1Age + β_2Gender + β_3Hispanic + β_4Race1 + β_5Race2 + β_6 Education1 + β_7 Education2 + β_8 + Nursing Home Resident + β_9Cognition+ β_{10} #Comorbidities + β_{11}Private/Supplemental Insurance+ β_{12} #Rx + β_{13} #HRM + β_{14}Wealth+ β_{15}ADL + β_{16} IADL+ β_{17}#Children+ β_{18} Able to Drive + β_{19} Family Availability1 + β_{20}Family Availability2 + β_{21} Family Living Arrangement1 + β_{22}Family Living Arrangement2 + β_{23}Urban/Rural1 + β_{24}Urban/Rural2 + β_{25}Region1 + β_{26}Region2 + β_{27}Region3

Differences between those who experienced no ADE, one ADE, and those who experienced two ADEs. Chi-square and t-tests were performed on all predisposing

characteristics, enabling resources, and need factor variables to determine potential differences between (1) those that experienced no ADEs in either 2005 or 2007, (2) those who experienced one ADE in 2005 or 2007, and (3) those who experienced an ADE in both 2005 and 2007.

A multinomial logistic regression was conducted to determine if predisposing characteristics, enabling resources, and need factors determined the occurrence of ADEs. Multinomial logistic regression compares multiple groups through a combination of binary logistic regressions. Multinomial logistic regression provides a set of coefficients for each of the comparisons. The resulting equations can be used to compute the probability that a subject is a member of each of the three groups. When separate logistic regressions are performed between groups, standard errors are slightly larger than the standard errors in a multinomial logistic regression. The multinomial logistic regression used experienced no ADE as the reference group. The model was:

ADE Occurrence (0=experienced no ADE in either year, 1=experienced one ADE in either 2005 or 2007, 2= experienced an ADE in both 2005 and 2007) = β_1Age + β_2Gender + β_3Hispanic + β_4Race1 + β_5Race2 + β_6 Education1 + β_7 Education2 + β_8 + Nursing Home Resident + β_9Cognition+ β_{10} #Comorbidities + β_{11}Private/Supplemental Insurance+ β_{12} #Rx + β_{13} #HRM + β_{14}Wealth+ β_{15}ADL + β_{16} IADL+ β_{17}#Children+ β_{18} Able to Drive + β_{19} Family Availability1 + β_{20}Family Availability2 + β_{21} Family Living Arrangement1 + β_{22}Family Living Arrangement2 + β_{23}Urban/Rural1 + β_{24}Urban/Rural2 + β_{25}Region1 + β_{26}Region2 + β_{27}Region3

Results

There were 3536 individuals that completed both 2005 and 2007 PDS. The majority were female, White, non-Hispanic, had a high school diploma, and were, on average, 71 years of age (Table 2.1). In addition, the majority of the individuals were from the South and not from a suburban area (Table 2.1). These Americans mostly live in an urban area (44.5%) or a rural area (33.2%). Clinically, subjects had on average 2 comorbidities, were taking 4 prescription medications, and did not take a high-risk medication (Table 2.2). Functionally, adults sampled had no difficulty in performing ADLs or IADLs (Table 2.2). Very few lived in a nursing home or with both a spouse and a child (Table 2.3). About half the sample had no children within 10 miles of their home, and the other half did have at least one child living within 10 miles (Table 2.3). On average, older adults had 3.5 children (Table 2.3).

Of the 3536 subjects, 506 (14.3%) had an ADE in 2005, and 465 (13.2%) had an ADE in 2007. Overall, 18.5% of subjects had one ADE in either year, and 4.5% had an ADE in both 2005 and 2007. Having more education was related to self-reporting having more ADEs (Table 2.4). In addition, males were more likely to report having no ADEs (Table 2.4).

Variables were grouped into two timeframes, 2004-2005 and 2006-2007. Correlations were run between all Andersen Model contracts within each of these timeframes to determine any correlations, and there were no significant correlations between Andersen Model constructs over 0.49 (Table 2.5).

In terms of predicting an ADE in *either* year, there were differences in model and regression coefficient significance when regressions were run with and without the weights. Therefore, regressions were run without weights while controlling for age, gender, being African American/Black, and being Hispanic. This regression will be taking variables from 2006 and 2007. No multicollinearity was found between 2006/2007 variables when testing variables' VIF. The full and reduced logistic regression models predicting experiencing one ADE were statistically significant (Table 2.6). The reduced model shows that those who were female and had a greater number of comorbidities were more likely to experience one ADE in either year than those who did not have an ADE in either year (Table 2.6).

Independent t-tests and a multinomial logistic regression were then performed to determine differences between the three groups (no ADE, ADE in either year, and an ADE in both years). It was found that those with more comorbidities, more difficulty in performing ADLs, and more regular prescription medications were more likely to report having an ADE in either year than reporting having no ADE (Table 2.7). T-tests comparing one ADE in both years versus no ADE, those who were older, had more comorbidities, more regular prescription medications, worse cognition in 2004, and more difficulty performing ADLs were more likely to report having one ADE in both 2005 and 2007 than reporting having no ADE in either year (Table 2.7). Lastly, the t-tests comparing ADEs in both years versus one ADE in either year, only having more prescription medications in 2007 was statistically different between those who reported having one ADE in either year and those who reported having an ADE in both 2005 and 2007 (Table 2.7).

In predicting an ADE in *both* years, although no multicollinearity between 2006/2007 variables was detected with VIF, some variables were found to be multicollinear during the analyses due to an unreasonably high coefficient standard error. Having a child live within 2 blocks, and being a nursing home resident were excluded due to mutlicollinearity found in unreasonably high standard errors in running the full model predicting experiencing an ADE in both 2005 and 2007. The full and reduced models, excluding these two variables, were statistically significant in predicting experiencing an ADE in both years (Table 2.8). The reduced model showed that having a higher number of regular prescription medications, more comorbidities, being younger, and being White/Caucasian predicted experiencing an ADE in both years (Table 2.8).

For the multinomial logistic regression the same two variables were excluded due to multicollinearity: being a nursing home resident and living with both spouse and a child. The full and reduced multinomial logistic regression to compare the three groups of individuals (no ADEs, 1ADE in either year, 1ADEs in both years) with having no ADEs as the reference group was statistically significant (Table 2.9). The reduced model showed that those who have one ADE in either year have, on average, more comorbidities and were more likely to be male than those who have no ADEs. This model also illustrates that those that have one ADE in both years were more likely to be younger, have more comorbidities, more regular prescription medications, and more likely to be White than those that have no ADEs (Table 2.9).

Discussion

Past literature has shown that approximately 700,000 adverse drug events result in injury or death each year in the United States.[28] Since this number is calculated using the Adverse Event Reporting System (FAERS) established by the Food and Drug Administration, it takes into account all ages and only those adverse drug events that were voluntarily reported by patients and healthcare professionals. When applying weights to those who completed both the 2005 PDA and 2007 PDS, 6,034,077 older adults had an ADE in 2005 and 5,839,490 in 2007. These estimates are about 850% more than the 700,000 emergency room visits estimated in past literature. This *drastic* difference exists due to the type of methodology used to capture occurrence of ADEs. The HRS captures self-reported ADEs that may vary in severity, while the FAERS captures only those severe ADEs. Overall, it is apparent that individuals are self-reporting having more ADEs than reported with previous methods, such as surveillance systems in hospitals or at the national level. This is important, because if more older adults are self-reporting experiencing ADEs more than previously captured within the healthcare system, then this implies that not all seeking care within the healthcare system. This needs to be investigated further in order to improve patient care for older adults.

Predisposing Characteristics

Because past literature supports that need factors are risk factors for ADEs, it was hypothesized that need factors would contribute to ADE experience. However, the findings indicate that some predisposing characteristics were related to ADE occurrence. First, These results show that being younger was related to having two ADEs from 2005-

2007. Past literature on ADE risk factors have mixed results on age impacting ADE occurrence.[29-30] For this study, there is one strong potential explanation for the finding that younger individuals have more ADEs. Those who were Medicare eligible were sampled for the Prescription Drug Study, and in this dataset there were 543 adults aged 36 to 64 years of age. This indicates that those individuals who are younger than 65 years of age and Medicare eligible are those who have disabilities, permanent kidney failure or Lou Gerig's disease. It is then expected that these individuals, although younger than the rest of the sample, would have more ADEs. This study identified the differences in ADE occurrence between disabled and non-disabled adults for ADE. It is clear that further investigation needs to be conducted into how practitioners and policy makers can assist in increasing quality patient care for disabled adults. These improvements may then lead to a decrease ADE occurrence for disabled adults and a decrease in cost to the healthcare system caused by this subpopulation.

Interestingly, gender, education, and race were found to be predictors of ADEs. Chi-square tests showed that females were more likely to report having one ADE in either year than no ADEs and reporting having an ADE in both years. The multinomial logistic regression uncovered that being male was only statistically different between having no ADE and having an ADE in either year (Figure 2.1). Women may be more likely or willing to report experiencing an ADE, but when controlling for all individual characteristics, only being male was a predictor of having one ADE in either year. In addition, more education predicted reporting more ADEs. These findings may be due to the fact that this study is collecting self-reported ADE experiences. For example, women may report less severe ADEs, while men may only report severe ADEs, or White people

may be more willing to report experiencing an ADE. Those who are more educated may be more likely to recognize an ADE, as opposed to physical symptoms due to the aging process. There may be differences in gender or race groups that lead to different reporting patterns or cognitive recognition of what an ADE is. Further investigation into how individual characteristics relate to self-reporting ADEs, and severity of the ADE experienced will provide a more comprehensive picture of ADEs in older adults.

Need Factors

Unlike previous ADE literature, this study presents prospective ADE risk factors for adults. From following individuals over two years, it is clear that not only are need factors related to ADE occurrence, but different need factors predict the frequency of experiencing an ADE. It was hypothesized that those who have more need factors would be more likely to experience ADEs. Although some need factors were shown to be risk factors in experiencing an ADE, not all the hypothesized need factors were significant. The following need factors were not predictors of older adults having an ADE: difficulty performing IADLs, cognition, and number of high-risk medications. This may be due to the fact that the majority of respondents did not have difficulties in IADLs, were not demented, and very few were taking a high-risk medication.

Literature has stated that having more comorbidities is related to experiencing an ADEs.[29] This study confirmed past findings and further demonstrated that the more comorbidities, the more likely the individual will have more ADEs over time (Figure 2.1). The use of multiple medications has also been shown to increase the risk of experiencing an ADE.[31-33]. When applying a prospective analyses, it was shown that not

only were these need factors indicators of experiencing an ADE, but these need factors are predictors of having more ADEs than those adults who reported having no ADE over two years.

Enabling Resources

Past literature did not investigate the relationship between enabling resources and ADEs. Although this is the first study to determine any relationship, it was found that enabling resources did not have a significant impact on the occurrence of ADEs. In addition, living in a nursing home and living with spouse and child were excluded due to high standard errors in the multinomial logistic regression, due to the fact that very few subjects had these living arrangements. It is possible that those who live with family or in a nursing home, although have more need factors, have increased instrumental support from caregivers. With a larger sample size, detection of correlation and multicollinearity between need factors and enabling resources may be detected.

Policy Implications

Implementing simple additions to the documentation of patient information in medication therapy management (MTM) services may improve patient care and decrease cost to the healthcare system. MTM services were implemented to optimize therapeutic outcomes for individual patients.[34] Currently, the Center for Medicare and Medicaid Services (CMS) general eligibility criteria for MTM services to be covered by Medicare Part D programs include: 1) having at least three chronic conditions, 2) between 2-8

prescription drugs, 3) and a total of $3144 total drug expenditure.[35] The PDS sampled those who were Medicare enrollees. This study illustrated that having more number of prescriptions and comorbidities predicted having more ADEs over time. Therefore, it would be beneficial to add an ADE risk factor component into the MTM service framework. This component could include a checklist of major ADE risk factors and frequency of experienced ADEs over the past four years. The pharmacist could then determine the overall risk of experiencing an ADE for the patient, communicate this risk level to their primary physician, and provide appropriate counseling to: 1) assist patients in identifying an ADE specific to their prescription medications, and 2) to encourage post-ADE behaviors that do not threaten health outcomes (such as stopping medication without physician's permission). This simple addition to the MTM service would improve patient care by counseling patients and alerting practitioners of high-risk ADE patients.

Limitations

There were two major limitations that are present in this study. First, the number of comorbidities was limited to the 10 common chronic conditions that are present in older adults. Subjects may have comorbidities that are not represented in the data. Therefore, there may be a limitation of underrepresentation of comorbidities. Second, this is a self-reported survey. All variables were self-reported except for gender, age, geographic region, and rural/urban status. Although this limitation exists, this threat is decreased since interviewers are trained to collect the most accurate data, during the

HRS, in a manner that decreases imprecise answers due to memory or social desirability. However, the PDS was a mail survey. There exists a concern for recall bias for the item measuring experiencing an ADE within the past year. In addition, questionnaire completeness is of concern. Approximately 10% of subjects did not complete the section of the survey where they were instructed to list their current prescription medications. Therefore, there may be an underrepresentation of the number of high-risk medications subjects were taking. This may have led to the lack of significant relationship between ADE occurrence and number of high-risk medications.

Generalizability

The Prescription Drug Study sample was drawn from the 2004 Health and Retirement Study. The Health and Retirement Study longitudinal panels study that surveys a representative sample of more than 26,000 Americans every two years. The PDS weights could not be applied due to two reasons. First, weights almost always increase the standard errors of the estimates. This introduces instability into the data. Second, very large or small weights also introduce instabilities into the data. For example, there were subjects who had zero weights and a few subjects who had large weights. Since weights primarily adjust means and proportions, weights may adversely affect inferential data. After running the analyses with and without the weights, it was clear that the PDS weights could not be applied due to the instabilities in the data. The technique of using self-weighted data, but controlling for the variables used to create the weights is commonly accepted. The variables used to create the PDS weights were: age,

sex, race/ethnicity, education, coupleness, self-rated health, number of physical limitations, type of drug coverage, and level of out-of-pocket spending on drugs. Although PDS weights couldn't be utilized, age, gender, race, and ethnicity were controlled in analyses. Type of drug coverage was not controlled for because everyone in the PDS sample had Medicare and/or Medicaid. However, having any additional supplemental or private insurance was measured and included in all full regression models. In addition, all full regression models included ADLs, IADLs, and level of education to control for physical limitations. Although the self-weighted analyses attempted to control for all variables that make up the PDS weights, the HRS and PDS sampling methodologies were strong, and the findings may cautiously be generalized.

Conclusion

This study shows that older adults are experiencing more ADEs than reported with previous methods, including surveillance systems at the hospital or national level. Number of comorbidities, number of prescription medications, difficulty performing ADLs, decreased cognition, and being male were all related to the occurrence of an ADE in older adults. It is apparent that need factors play a significant role in the occurrence of ADEs in older adults.

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TABLE 2.1: OVERALL SAMPLE DEMOGRAPHICS (n=3536)

	2004 n(%)	**2006 n (%)**
Gender		
Male	1490 (42.1)	
Female	2046 (57.9)	
Race/Ethnicity		
White/Caucasian	2968 (83.9)	
Black/African American	484 (13.7)	
Other	84 (2.4)	
Hispanic		
Yes	354 (10.0)	
No	3182 (90.0)	
Missing	0	
Education Level Attained		
No Degree	944 (26.7)	
GED/High School Diploma	1997 (56.5)	
At Least a Four-year Degree	595 (16.8)	
Geographic Region 2006		
Northeast: New England	135 (3.8)	133 (3.8)
Northeast: Middle Atlantic	408 (11.5)	399 (11.3)
Midwest: East North Central	554 (5.7)	540 (15.3)
Midwest: West North Central	311 (8.8)	315 (8.9)
West: Mountain	117 (5.0)	177 (5.0)
West: Pacific	439 (12.4)	436 (12.3)
South: South Atlantic	861 (24.3)	855 (24.2)
South: West South Central	406 (11.5)	406 (11.5)
South: East South Central	223 (6.3)	219 (6.2)
Missing/Don't Know	22 (0.6)	56 (1.6)
Urban/Rural 2006		
Urban	1573 (44.5)	1537 (43.5)
Suburban	780 (22.1)	774 (21.9)
Ex-Urban	1173 (33.2)	1171 (33.1)
No match in rural-urban code	10 (0.3)	11 (0.3)
Missing	0	43 (1.2)
	Mean (SD)	**Mean (SD)**
Age	71.29 (8.23)	73.29 (8.23)

TABLE 2.2: NEED FACTORS OF SAMPLE (n=3536)

	2004 Mean (SD)	**2006 Mean (SD)**
Summed Score ADL	0.35 (.97)	0.41 (1.04)
Summed Score IADL	0.67 (1.13)	0.75 (1.3)
Number of Comorbidities	2.38(1.45)	2.24 (1.42)
Total Cognition Score	22.06 (4.88)	21.71 (5.31)
	2005 Mean (SD)	**2007 Mean (SD)**
Number of Regular Prescriptions	4.32 (3.43)	4.66(3.66)
Number of HRM	0.16 (0.45)	0.15 (0.43)

TABLE 2.3: ENABLING RESOURCES IN 2004 AND 2006 (n=3536)

	2004 n(%)	**2006 n(%)**
Living in Nursing Home	41 (1.4)	51 (1.5)
Missing	0	43 (1.2)
Able to Drive a Car		
Yes	3067 (86.7)	2947 (83.3)
No	469 (13.3)	589 (16.7)
Missing/Refuse to Answer	0	0
Living Arrangement		
Lives with no family	1010 (28.6)	1091 (30.9)
Lives with spouse or child	2207 (62.4)	2049 (57.9)
Lives with spouse and child	319 (9.0)	283 (8.0)
Missing	0	113 (3.2)
Any Private/Supplemental Insurance in addition to Medicare		
Yes	2148 (60.7)	1594 (45.1)
No	1388 (39.3)	1899 (53.7)
Missing	0	43 (1.2)
Family Availability		
No children within 10 miles	1573 (44.5)	1662 (47.0)
At least one child within 10 miles	1722 (48.7)	1685 (47.7)
At least one child within 2 blocks	234 (6.6)	183 (5.2)
Missing	7(0.2)	6 (0.2)
	Mean (SD)	**Mean (SD)**
Total wealth (total all assets minus debt)	$431,741.13 (1,617,742.32)	$528,355.85 (2,197,855.24)
Missing	0	n=43 (1.2%)
# Children	3.46 (2.32)	3.50 (2.37)
Missing	0	0

TABLE 2.4: CHI-SQUARE TESTS BETWEEN THOSE WHO HAD NO ADES, THOSE WHO HAD ONE ADE IN EITHER YEAR, AND THOSE WHO HAD AN ADE IN BOTH YEARS FOR 2004/2005 VARIABLES (n=3536)

	No ADEs	**One ADE in Either Year**	**One ADE in Both Years**	**X^2**	**P-values**
	n= 2723	n=655	n=158		
Gender				20.573	.000**
Female	1520	427	99		
Male	1203	228	59		
Race				4.787	.310
White/Caucasian	2281	548	139		
Black/African American	382	88	14		
Other	60	159	5		
Hispanic				2.491	.288
Yes	277	67	10		
No	2466	588	14		
Education attained				13.082	.008**
Less than high school	768	146	31		
At least a high school diploma	1504	395	98		
At least a four-year college degree	451	114	29		
Geographic Region				2.054	.915
Northeast	424	92	27		
Midwest	664	162	39		
South	1151	276	63		
West	466	122	28		
Population Density				5.564	.234
Urban	1184	316	73		
Suburban	607	136	37		
Rural	7924	201	48		
Nursing home resident				.495	.781
Yes	33	7	1		
No	2690	648	157		
Able to drive				2.788	.248
Yes	2356	567	144		
No	367	88	14		
Addition private/supplemental insurance				4.722	.094
Yes	1635	405	108		
No	1088	250	50		
Family availability				2.530	.639
No children within 10 miles	1203	293	77		
At least one child within 10 miles	1326	323	73		
At lease one child within 2 blocks	188	38	8		
Family living arrangement				3.280	.512
Lives with no family	771	185	54		

Lives with spouse or child	1700	414	93
Lives with spouse and child	252	56	11

TABLE 2.5: CORRELATIONS BETWEEN ANDERSEN MODEL VARIABLES WITHIN SAME TIMEFRAME (n=3536)

	Number of Comorbidities 04	Number of Comorbidities 06	ADL Score 04	Cognition 04	ADL Score 06	Cognition 06	Private/ Supplemental Insurance 04	Private/ Supplemental Insurance 06
Number of Prescriptions 05	.471**							
Number of Prescriptions 07		.489**						
IADL Score 04			.360**	.313**				
IADL Score 06					.451**	.347**		
Wealth 04							.377**	
Wealth 06								.335**

NOTE: *p<.05, **p<.01

TABLE 2.6: LOGISTIC REGRESSION PREDICTING EXPERIENCING ONE ADE IN 2005 OR 2007 (n=3536)

Independent variables	OR	P-Value
FULL MODEL (X^2=66.285, p<0.000)		
Predisposing Characteristics		
Age	1.001	0.935
Gender		
Female	1.0	
Male	0.627	<.001
Race		
Caucasian/White	1.0	
African American/Black	1.055	0.781
Other	1.349	0.457
Hispanic	1.282	0.256
Geographic Region		
Northeast	1.0	
Midwest	1.274	0.186
South	1.266	0.164
West	1.327	0.145
Urban/Rural Status		
Urban	1.0	
Suburban	0.87	0.32
Ex-Urban/Rural	0.819	0.132
Education		
Less Than High School	1.0	
High School Diploma	1.298	0.089
4-Year College Degree or More	1.363	0.12
Need Factors		
ADL Score	1.259	.002
IADL Score	0.872	0.061
Number of Regular Prescriptions	0.997	0.875
Number of High-Risk Medications	0.867	0.274
Number of Comorbidities	1.207	<.001
Cognition	1.009	0.504
Enabling Resources		
Wealth	1.002	0.821
Number of Children	1.000	0.985
Nursing Home Resident	0.414	0.415
Able to Drive	1.278	0.18
Have Supplemental/Private Insurance	1.103	0.408

Family Availability		
Have no child within 10 miles	1.0	
At Least One Child Within 10 Miles	1.036	0.753
At Least One Child Within 2 Blocks	.723	0.286
Family Living Arrangement		
Live with no family	1.0	
Live with Either Spouse of Child	1.082	0.527
Live with Spouse and Child	1.202	0.415
Constant	.073	.003
REDUCED MODEL (X^2=68.73, P<.000)		
Age	.992	.143
Gender		
Female	1.0	
Male	.707	<.001
Race		
Caucasian/White	1.0	
African American/Black	.845	.200
Hispanic	.972	.848
ADL Score	1.053	.196
Number of Comorbidities	1.220	<.001
Constant	.282	.002

TABLE 2.7 T-TESTS BETWEEN THOSE WHO HAD NO ADES, THOSE WHO HAD ONE ADE IN EITHER YEAR, AND THOSE WHO HAD AN ADE IN BOTH YEARS (n=3536)

	No ADEs n= 2723	No ADE vs One ADE	**One ADE** n=655	One ADE vs One ADEs in Both Years	**One ADE in Both Years** n=158	No ADEs vs One in Both Years
	Mean(SD)	**t**	**Mean(SD)**	**t**	**Mean(SD)**	**t**
Age	72.42 (8.23)	.979	72.07 (8.28)	1.39	71.063 (7.82)	2.02*
2004/2005 Variables						
# children	3.52 (2.41)	.39	3.48 (2.25)	.93	3.26 (2.11)	1.10
ADL score	.32 (.92)	-.393**	.48 (1.16)	-.03	.49 (1.10)	-1.92*
IADL score	.66 (1.12)	-.04	.66 (1.18)	-.55	.72 (1.14)	-.65
Cognition score	21.90 (4.93)	-2.61	22.54 (4.75)	-.82	22.94 (4.38)	-2.48*
Total wealth	446415.93 (1773917)	.673	397072.82 (984589.62)	.98	318366.01 (555855.36)	.91
# prescriptions	4.16 (3.10)	-2.98**	4.64 (4.53)	-1.60	5.27 (2.94)	-4.22**
# HRM	.15 (.44)	-1.81	.19 (.48)	-.70	.22 (.55)	-1.50
# comorbidities	2.14 (1.40)	-6.78**	2.56 (1.50)	-1.31	2.73 (1.42)	-5.18**
2006/2007 Variables						
# children	3.47 (2.36)	.30	3.44 (2.21)	.45	3.38 (2.19)	.67
ADL score	.37 (1.01)	-3.67**	.52 (1.17)	-.09	.53 (1.11)	-1.90
IADL score	.75 (1.28)	.448	.73 (1.27)	-.80	.87 (1.78)	-.65
Cognition score	21.60 (5.41)	-1.71	22.04 (5.12)	-.57	22.32 (4.34)	-1.79
Total wealth	537676.36 (2297215.88)	.169	521163.70 (1952525.39)	.76	397783.43 (118221.72)	.76
# prescriptions	4.41 (3.66)	-4.45**	5.16 (3.56)	-2.66**	6.01 (3.50)	-5.23**
# HRM	.15 (.43)	-.962	.17 (.41)	-1.19	.22 (.47)	-1.75
# comorbidities	2.27 (1.42)	-7.80**	2.75 (1.51)	-1.74	2.99 (1.45)	-6.18**

NOTE: *p<.05, **p<.01

TABLE 2.8: LOGISTIC REGRESSION PREDICTING EXPERIENCING AN ADE IN BOTH 2005 AND 2007 (n=3536)

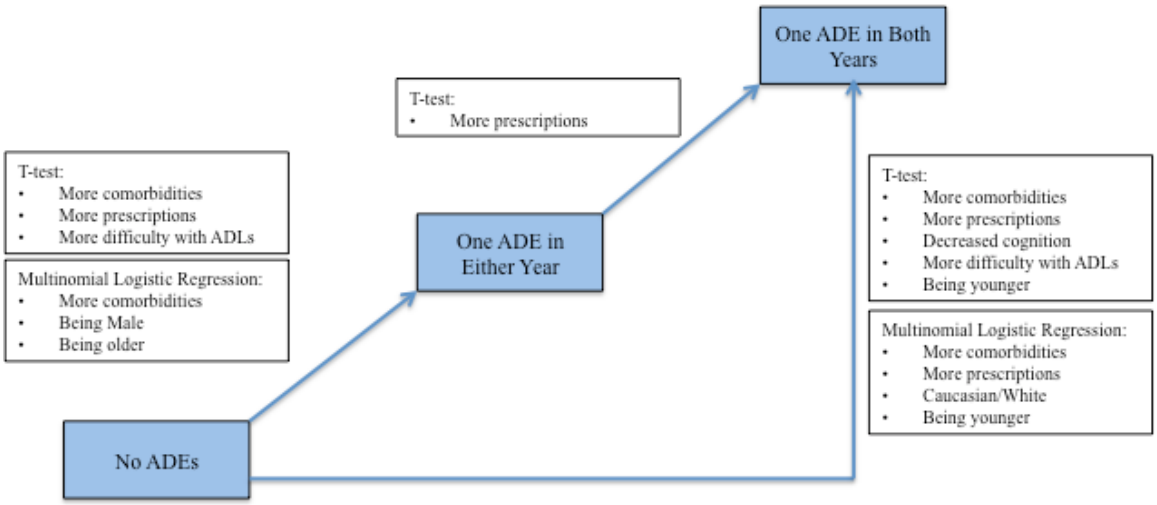
Independent variables	OD	P-Value
FULL MODEL (X^2=56.061, p<0.000)		
Predisposing Characteristics		
Age	0.976	0.134
Gender		
Female	1.0	
Male	0.839	0.427
Race		
Caucasian/White	1.0	
African American/Black	0.428	0.053
Other	2.224	0.211
Hispanic	0.596	0.269
Geographic Region		
Northeast	1.0	
Midwest	1.14	0.691
South	1.246	0.465
West	1.169	0.657
Urban/Rural Status		
Urban	1.0	
Suburban	0.858	0.547
Ex-Urban/Rural	0.674	0.106
Education		
Less Than High School	1.0	
High School Diploma	1.047	0.867
4-Year College Degree or More	1.202	0.606
Need Factors		
ADL Score	1.015	0.915
IADL Score	1.021	0.87
Number of Regular Prescriptions	1.049	0.008
Number of High-Risk Medications	1.104	0.641
Number of Comorbidities	1.404	<.001
Cognition	0.994	0.82
Enabling Resources		
Wealth	1.0	0.57
Number of Children	0.946	0.264
Able to Drive	1.51	0.24
Have Supplemental/Private Insurance	1.153	0.509

Family Availability		
Have no child within 10 miles	1.0	
At Least One Child Within 10 Miles	1.159	0.467
Family Living Arrangement		
Live with no family	1.0	
Live with Either Spouse of Child	0.854	0.478
Live with Spouse and Child	0.473	0.139
Constant	0.104	0.167
REDUCED MODEL (X2=45.286, P<.000)		
Age	0.973	.008
Gender		
Female	1.0	
Male	0.807	0.222
Race		
Caucasian/White	1.0	
African American/Black	0.426	.007
Hispanic	0.512	0.059
Number of Prescription Medications	1.043	.011
Number of Comorbidities	1.265	<.001
Constant	0.21	0.047

TABLE 2.9: MULINOMIAL LOGISTIC REGRESSION PREDICTING EXPERIENCING NO ADE, ONE ADE IN EITHER YEAR, AND ONE ADE IN BOTH YEARS WITH NO ADES AS REFERENCE GROUP

	One ADE in Either Year Compared to No ADEs			**One ADE in Both Years Compared to No ADEs**		
FULL MODEL (X^2=128.64, p<.00)	β	95% CI	P-Value	β	95% CI	P-Value
Predisposing Characteristics						
Age	.998	.981-1.016	.836	.979	.948-1.011	.187
Gender						
Female	1.0			1.0		
Male	1.599	1.265-2.022	.000	1.408	.915-2.167	.120
Race						
Caucasian/White	1.0			1.0		
African American/Black	.997	.681-1.459	.986	2.326	.978-5.535	.056
Other	.687	.310-1.524	.355	.441	.124-1.567	.206
Hispanic	.781	.508-1.201	.261	1.610	.639-4.062	.313
Geographic Region						
Northeast	1.0			1.0		
Midwest	.772	.538-1.107	.159	.818	.427-1.565	.544
South	.773	.553-1.080	.132	.760	.420-1.375	.364
West	.737	.503-1.079	.116	.790	.394-1.585	.507
Urban/Rural Status						
Urban	1.0			1.0		
Suburban	1.166	.884-1.537	.277	1.213	.733-2.008	.452
Ex-Urban/Rural	1.270	.978-1.649	.073	1.551	.959-2.511	.074
Education						
Less Than High School	1.0			1.0		
High School Diploma	.758	.560-1.026	.073	.900	.523-1.549	.703
4-Year College Degree or More	.712	.480-1.055	.090	.770	.381-1.556	.466
Need Factors						
ADL Score	1.259	1.084-1.461	.002	1.095	.837-1.432	.507
IADL Score	.871	.754-1.006	.060	.973	.759-1.248	.831
Number of Regular Prescriptions	1.003	.970-1.037	.845	1.047	1.010-1.084	.011
Number of High-Risk Medications	.874	.675-1.131	.306	1.060	.696-1.614	.786

FIGURE 2.1: RELATIONSHIPS FOUND BETWEEN THOSE WHO HAD NO ADE, ONE ADE IN EITHER YEAR, AND THOSE WHO HAD AN ADE IN BOTH YEARS



Chapter 3

QUANTIFYING POST-ADE BEHAVIORS IN TERMS OF ANDERSEN MODEL OF HEALTH CARE UTILIZATION CONSTRUCTS; PREDISPOSING CHARACTERISTICS, ENABLING RESOURCES, AND NEED FACTORS

Introduction

An adverse drug event (ADE) is defined as an injury due to medical treatment.[1] Adverse drug events cause over 700,000 emergency room visits each year.[2] It has been shown that 31.8% of ADEs were caused by patients inaccurately administering their prescription medication, 41.9% caused by patients modifying their medication regimen, and 21.7% caused by patients not following clinical advice about their medication use.[3] In another study, McDonnell and Jacobs showed that 33% of adverse reactions were due to patient noncompliance.[4] Unintentional overdose has also been attributed to 66% of hospitalizations of older adults in America.[5]

What an individual does during or after experiencing and ADE is termed post-ADE behaviors, and we assert that these behaviors result from a decision-making process. Typically, ADE symptoms are experienced before an individual can acknowledge the cause of those symptoms. For example, those who are experiencing an ADE do not always believe that those symptoms are caused by a medication.[6] Some individuals believe that ADE symptoms of a stomach ache may be due to food

poisoning.[6] Alternatively, some older adults may attribute ADE symptoms to issues with aging. Therefore, the acknowledgment of the origin of the experienced symptoms may impact the post-ADE behavior performed.

In addition, an individual can experience a mild, significant, or severe ADE, and this too may affect what one does following an ADE. If an older adult acknowledges that there is a negative symptom but feels that it is only a mild symptom, they may perform self-care behaviors, like stop taking the prescription without consulting a doctor. However, if an older adult perceives an ADE symptom as severe then they may opt to go to the emergency room.

Finally, different self-care and care-seeking post-ADE behaviors may also be influenced by patient factors and family factors. Older adult health decision research has included instrumental support, family structure, and living arrangement as predictors of healthcare utilization.[7-9] If an older adult has instrumental support in the form of transportation from a nearby child, then he/she may be more likely to go visit a doctor than those older adults without transportation.

Many post-ADE behaviors may be performed including a variety of healthcare service utilization, self-treating, or performing no action; however, only investigation into behaviors of healthcare service utilization has been conducted. Past ADE literature uses six methods to capture the occurrence of ADEs. The National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System (NEISS-CADES) and the Adverse Event Reporting System (AERS) are nationally-representative databases that focus on emergency department visits due to ADEs or reporting of ADEs by health care professionals, patients or drug manufacturers, respectively. Volunteer

reporting by health care professionals, medical chart reviews, patient self-report, and daily observation of patient by health care professionals have also been utilized to capture ADEs that occur either within the emergency department, hospital, nursing home, or outpatient settings.

ADE research has examined health care utilization as an indicator of an ADE. Research on post-ADE behaviors, therefore, is biased towards those ADEs severe enough for the patient to seek services within the healthcare system. The definition of ADE is an injury due to medical treatment,[10] and this definition has no requirement that an individual seek health care after experiencing an ADE. One study determined that not all individuals seek health care professional help after experiencing an ADE.[11] However, less severe ADEs may lead an individual to stop taking their prescription medication without speaking to their physician or telephoning a provider for information or assistance. These non-health care service utilization behaviors may have direct impact on patient adherence and health outcomes.

As illustrated, the post-ADE behavior(s) performed depends on many factors, and the Andersen Model of Health Care Utilization provides a framework for these factors. The Andersen Model includes predisposing characteristics, enabling resources and need. Predisposing characteristics and need factors are patient-related factors while enabling resources include family factors. Predisposing characteristics are those existing aspects that make some individuals to have the propensity to seek and use health care services than others. Demographics, health beliefs, and social structure are deemed predisposing characteristics. Need factors are defined as perceived and evaluative need and may be measured by functional status, perceived/self-report health status, and evaluated health

status. Although an individual may be more likely to use health care services according to their predisposing characteristics, resources need to be in place in order for the individual to seek care. Therefore, the enabling resources are family and community resources that allow health care services to be available to an individual for consumption. Examples of enabling resources are family structure, family availability, transportation, family income, wealth and insurance coverage.

Study Objectives

The objectives of this study were to (1) Determine prevalence of different post-ADE behaviors among Medicare and Medicaid enrollees in 2005 and 2007, and (2) Quantify the relationship between predisposing characteristics, enabling resources, need factors and specific types of post-ADE behaviors.

Hypotheses

It was hypothesized that individuals will perform a variety of post-ADE behaviors. Past research focuses on doctor visits, emergency department visits and hospitalizations. Also, it was predicted that some individuals will also perform no action, talking to a doctor, and cutting down or stopping medication on own. It was hypothesized that having more need factors would be related to doctor/emergency department visits and hospitalization, and those with fewer need factors would be more likely to perform other post-ADE behaviors. It has been shown that more need factors in older adults is a strong determinant to health care utilization. Therefore, having fewer need factors may be related to less or no use of health care services.

Research Methods

Design

This study is a secondary analysis of publically available, nationally representative survey data that was collected as part of the Health and Retirement Study (HRS). This aim consists of cross-sectional analyses utilizing data from the 2005 Prescription Drug Study (PDS), 2007 PDS, 2004 HRS, 2006 HRS, RAND Income and Wealth Imputation File, HRS Tracker File, and the HRS Cross-Wave Region and Mobility File. The Institutional Review Board of University of Michigan approved this study.

Data Sources

This study utilizes data from the following four different data files: 1) Health and Retirement Study, 2) Prescription Drug Study, 3) HRS Tracker File, 4) HRS Cross-Wave Region and Mobility File, and 4) RAND Income and Wealth Imputation File.

Health and Retirement Study. The University of Michigan Health and Retirement Study (HRS) is a longitudinal panel study that surveys a representative sample of more than 26,000 Americans over the age of 50 every two years. The purpose of the Health and Retirement Study is to collect information about income, work, assets, pension plans, health insurance, disability, physical health and functioning, cognitive functioning, and health care expenditures.

Prescription Drug Study. The HRS Prescription Drug Study is a two-wave mail survey designed to track changes in prescription drug utilization coverage, and satisfaction prior and after the implementation of Medicare Part D.

HRS Tracker File. The HRS Tracker file was developed to assist in using HRS data across waves. This is where basic demographic information, interview status, and if, when and how an interview was conducted in each wave.[12]

RAND Income and Wealth Imputation File. The RAND Income and Wealth Imputation Files contains the RAND HRS income and wealth summary measures.[13]

HRS Cross-Wave Region and Mobility File. This file includes: (1) geographic information, (2) child ZIP Codes, (3) respondents' birth region, (4) region where the respondent lived at age 10, (5) for each wave, the region where the respondent was reached for an interview, (6) the HRS Urban-Rural Code, (7) distance-moved variables for each pair of interview years, and (8) information on geographic information processing techniques for each wave.

Study Population

The inclusion criteria consisted of subjects who (1) completed the 2005 PDS and 2007 PDS and (2) completed both the 2004 HRS and 2006 HRS. The PDS sample included HRS respondents born in 1942 or earlier (65th birthday in 2007) or already covered by Medicare or Medicaid at some time between 2002 and 2004.

Measures of Interest

Predisposing Characteristics

Predisposing characteristics included: age, gender, highest degree attained, ethnicity, race, urban/rural status, and geographic region. The interviewer documented

the subject's gender. Level of education was grouped as: 1) less than high school, 2) high school diploma/GED/some college, and 3) 4-year college degree or more. Race categories included: White/Caucasian, Black/African American, and other. Ethnicity was grouped into Hispanic and Non-Hispanic.. The following three categories of population size were created: urban, suburban, and rural. For this study, HRS geographic codes were categorized into Northeast, Midwest, South, and West.

Need Factors

Need factors included: physical functioning (activities of daily living and instrumental activities of daily living), number of comorbidities, cognition, number of regular prescriptions, and number of high risk medications.

Activities of Daily Living (ADLs). The six ADL items were as follows: because of a health do you have any difficulty with dressing, including putting on (1) shoes and socks? (2) Bathing or showering? (3) Using the toilet, including getting up and down? (4) Eating, such as cutting up your food? (5) Walking across a room? (6) Getting in or out of bed? Response options include: Yes, No, Can't do, Don't do, Don't know, Refuse to answer. To be conservative, all responses, other than 'No', were coded as 1. 'No' was coded as 0. For all subjects, a summed ADL score was created.

Instrumental Activities of Daily Living (IADLs). The five IADL items were as follows: because of a health, do you have any difficulty (1) preparing a hot meal? (2) Using a map to figure out how to get around in a strange place? (3) Shopping for groceries? (4) Making phone calls? (5) Taking medications? Response options included: Yes, No, Don't Know, Refuse to Answer. To be conservative, all responses, other than

'No', were coded as 1. 'No' was coded as 0. For all subjects, a summed IADL score was created.

Cognition. Cognition was captured by using the Telephone Interview for Cognitive Status (TICS). TICS is a version of the Mini Mental State Examination [14] and has been adapted for telephone administration.[15] Cognition was a summed score of the subjects, ranging from 0-35.

Number of Comorbidities . Subjects were asked if they have been diagnosed with one of the following 10 common chronic conditions among older adults: heart attack, coronary heart disease, angina, congestive heart failure, or other heart problems), mental health condition (emotional, nervous, or psychiatric problems), arthritis, hypertension, cancer (excluding minor skin cancer), memory-related condition, stroke, and glaucoma. A summed count was calculated to determine how many chronic conditions a subject had.

Number of Regular Prescriptions. Subjects were asked to report how many of their prescription drugs they took on a regular basis and this was kept as a continuous variable during analyses.

Number of High Risk Medications. Subjects were asked to list all prescriptions that they take. A count of the number of high-risk medications for each individual was done using the National Committee of Quality Assurance list of high-risk medications in the elderly (Appendix C).

Enabling Resources

Enabling resources included: wealth, family structure, family availability, ability to drive, family living arrangement, having at least one private or supplemental insurance plan in addition to Medicare, and being a nursing home resident.

Wealth. The RAND imputed wealth variable used in this study is the net value of total wealth (including second home) minus all debt.[13]

Family Structure. Subjects were asked, "What is the total number of children or step-children you have?", and number of children was a continuous variable. Those who previously reported having no children in their first wave of interviews were intentionally skipped in later waves and were recoded as having zero children.

Family Availability. Family availability was determined by asking two questions. Subjects were asked if they have a child that lives within 10 miles, or 2 blocks. Subjects were coded as 0 if they had no child within 2 blocks or 10 miles. Subjects were coded as 1 if they had a child that lived within 10 miles, and coded 2 if they had a child that lived within 2 blocks. Those who reported having no children were intentionally skipped and coded as 0 since they have no children living within 10 miles or 2 blocks.

Ability to Drive. Subjects were asked, "Are you able to drive?" Subjects were coded as 0 if they were not able to drive and 1 if they could drive.

Living arrangement. Living arrangement was determined by asking two questions. First, "Do you live with your spouse/partner?" and "What is the number of children in your household?" A summed living arrangement score of 0 indicates living with no family. A score of 1 indicates living with one family member. A score of 2 indicates living with both spouse and one child.

Private and/or Supplemental Insurance in Addition to Medicare. The subjects were asked if they had Medigap or other supplemental coverage, not including long-term care insurance and this was coded yes or no.

Nursing Home Resident. The interviewer can document this if he/she is able to determine if subject is living in nursing home. If not, the subject is asked, "Are you living in a nursing home or other health care facility?" A dummy variable was created and those who are not living in a nursing home were deemed the reference group during analyses.

Outcome Measures

Outcome variables included: the occurrence of an ADE in the past year and post-ADE behaviors the subject performed after experiencing the ADE. These measures are from the 2005 PDS and 2007 PDS. Subjects were asked, "In the past year, have you had any side effects, unwanted reactions, or other health problems from medications you were taking?" and the responses options were yes or no. If yes, subjects were asked, "Thinking about the MOST SEVERE of reactions you experiences in the past year, what did you do in response? Mark Yes or No for *each* question: (1) Did you cut down or stop taking the drug on your own? (2) Did you talk to a doctor about this reaction? (3) Did you visit a doctor's office or emergency room mostly because of this reaction? (4) Did you cut down or stop taking your medication based on doctor's order? (5) Were you admitted to a hospital overnight mostly because of this reaction?

Statistical Analyses

Overall Statistics. Frequencies were performed to determine how many of those who experienced an ADE did not perform a behavior after experiencing an ADE. In addition, frequencies were also performed on all six post-ADE behaviors. Spearman correlations were conducted between all independent and dependent variables to determine associations.

This study utilized the weighted data provided by the Health and Retirement Study, from the Institute for Social Research, at the University of Michigan. Weights were provided for both 2005 and 2007 PDS data. To determine if performing any post-ADE behavior was explained by predisposing characteristics, enabling resources, and need factors, two binary logistic regressions were performed, one for 2005 and one for 2007. The predisposing characteristics, enabling resources and need factors were taken either from the year before or the year of the experienced ADE. For example, the 2004 HRS contains these predictors while the 2005 PDS collected ADE occurrence. The full regression models were completed. Variables with high standard of error are found in these full models, due to additional multicollinearity. Multicollinearity, determined by VIF values above 5, identified variables to be eliminated from analyses. The model was then re-run until no more multicollinearity existed. A reduced model was then conducted consisting of age, gender, race (Caucasian/African American), and ethnicity (Hispanic/Non-Hispanic), and the variables with significant coefficients in the full model. A binary logistic regression was also conducted on those that experienced an ADE in both years to determine relationships between Andersen Model constructs and performance of any post-ADE behavior.

Predicting the performance of different post-ADE behaviors. Logistic regressions were performed to determine if relationships exist between Andersen Model items and performance of each post-ADE behavior in 2005 and 2007.

Results

There were 3,536 individuals who completed both the 2005 and 2007 PDS. The majority of the sample (n=3536) were female, White, non-Hispanic, had a high school diploma, and, on average, 71 years of age (Table 2.1). The majority of Medicare/Medicaid enrollees sampled were from the South and not from a suburban area (Table 2.1). This sample mostly lived in an urban area (44.5%) or a rural area (33.2%). Clinically, subjects had on average 2 comorbidities, were taking 4 prescription medications, and did not use a high-risk medication (Table 2.2). This sample had very little difficulty in performing ADLs or IADLs (Table 2.2). About half the sample had no children within 10 miles of their home. In addition, the other half did have at least one child living within 10 miles. On average, older adults had 3.5 children (Table 2.3).

For those who completed both the 2005 PDS and the 2007 PDS, 506 (14.3%) had an ADE in 2005 and 465 (13.2%) had an ADE in 2007, which equates to 6,034,077 older adults having an ADE in 2005 and 5,839,490 in 2007. In both years, the most common post-ADE behavior was to talk to a doctor and the least common post-ADE was being admitted to the hospital (Table 3.1). Of those who experienced an ADE in 2005 (n=506), 18 (3.6%) performed no post-ADE behavior and 488 (96.4%) performed at least one post-ADE behavior. In 2007 (n=465), 22 (4.7%) did not perform a post-ADE behavior

and 443 (95.3%) performed at least one post-ADE behavior. Overall, 18.5% of subjects had one ADE in either year, and 4.5% had an ADE in both 2005 and 2007. All subjects who experienced an ADE in both 2005 and 2007 performed at least one post-ADE in either year.

Twelve logistic regressions were run, one for each post-ADE behavior for 2005 and 2007, and six reduced models significantly explained the relationships between predisposing, enabling and need factors and post-ADE behaviors. These reduced models explained all post-ADE behaviors except for taking no action, and the results are presented for each post-ADE behavior measured by the PDS. The remaining six models, found to be insignificant, are presented in Appendix D.

Taking No Action

It was hypothesized that those with fewer need factors would be more likely to take no action after experiencing an ADE. However, when chi-square and t-tests were performed between performing post-ADE behaviors and the Andersen Model variables, only age, a predisposing factor, was shown to be significantly related to performing no post-ADE behavior in 2005 ($t=-2.217$, $p=.027$). Logistic regression predicting no action were not statistically significant. Those who are younger were more likely to take no action compared to those who are older.

Cut Down or Stopping Medication On Own

It was hypothesized that those with fewer need factors would be more likely to cut down or stop their prescription medications on their own. However, it was not need factors that were related to this behavior, but predisposing characteristics. It was shown that having less than a high school diploma was related to stopping or cutting down on medication on your own when compared to those who have a four-year college degree (Table 3.2). This relationship was not significant in 2007.

Cut Down or Stopping Medication with Doctor's Permission

Because speaking on the phone with a doctor would achieve this post-ADE behavior, and it was hypothesized that having fewer need factors would predict this behavior. This behavior does not necessarily require an individual to utilize a healthcare service. Being non-Hispanic and having fewer number of prescription medications predicted cutting down or stopping medication with a physician's permission in 2007 (Table 3.3), yet this relationship was not significant in 2005. Although it was hypothesized that need factors would predict this behavior, it was one predisposing characteristic and one need factor were significantly related to this behavior.

Talk to a Doctor

As with cutting down or stopping medication with doctor's permission, this behavior does not necessarily require an individual to utilize a healthcare service. Therefore, to be conservative, it was hypothesized that having fewer need factors would be related to this post-ADE behavior. It was shown that not being a nursing home

resident, an enabling factor, was indeed related to talking to a doctor after experiencing an ADE in 2005 (Table 3.4). This model further showed that those who live with no family are more likely to talk to their doctor after an ADE than those who live with either their spouse or a child. This relationship was not significant in 2007. Although need factors were hypothesized to be related to talking with a doctor, it was two enabling resources that predicted this post-ADE behavior.

Visit a Doctor or Emergency Department

It was hypothesized that having more need factors would predict visiting a doctor or emergency department, and these results support this hypothesis. Visiting a doctor or going to the emergency room was predicted by having more difficulty with IADLs (Table 3.5). This model additionally states that those who live with spouse and a child, an enabling factor, were significantly more likely to go a doctor or emergency room than those who live with no family. This relationship was not significant in 2005.

Hospitalized

It was hypothesized that having more need factors would be significantly related to being hospitalized. Being hospitalized after an ADE in 2005 was related to being female and living in the South (Table 3.6). In addition, being hospitalized after an ADE in 2007 was predicted by number of prescription medications (Table 3.7). A need factor was found to predict hospitalizations in 2007; however, one predisposing characteristic were predictors in 2005.

Discussion

Overall

For those who completed both 2005 and 2007 surveys, this study showed that for those Americans aged 50 years or older, 6,034,077 individuals reported experiencing an ADE in 2005 and 5,839,490 in 2007. Of those who experienced an ADE, only about 5% visited the doctor, went to the ER or were hospitalized in both 2005 or 2007. In addition, 29.7% of those in 2005 and 27.0% in 2007 performed post-ADE behaviors that would not be captured in the national surveillance system or the Adverse Event Reporting System. This is important because past literature shows that some post-ADE behaviors have a negative impact on health outcomes. An example of this is patients deciding to decrease or stop taking their prescription medication without a physician's order.[16] Approximately 7% of subjects performed this post-ADE behavior in 2005 or 2007, and this finding indicates that it is not only important to understand what post-ADE behaviors lie within the healthcare system but what self-care behaviors older adults perform. The Andersen Model variables that predicted different post-ADE behaviors are further discussed and presented in Table 3.8.

Predisposing Characteristics

In considering predisposing characteristics, females were more likely to be hospitalized after an ADE. Past literature has shown that being female is a risk factor for experiencing an ADE.[17,18] These studies capture ADEs within the healthcare system. Therefore, these studies are really stating that females are more likely to experience an ADE that leads to healthcare utilization. This study's findings do not align with past ADE

literature. It was shown that in 2005 females were more likely to be hospitalized and in 2007 males were more likely be hospitalized after experiencing an ADE.

Non-Hispanics were more likely to contact doctors for their permission to change medication regimens than Hispanics, and this finding may be due to a cultural in health beliefs. It has been shown that different ethnic groups have different medication beliefs[19] and different levels of trust in their physicians.[20] Non-Hispanics may have more trust in their physicians and/or desire getting a physician's permission before changing their medication regimen.

This study shows that those with less than a high school diploma were more likely to cut down or stop taking their prescription medication on their own compared to those with a four-year college degree. Literature on the impact on education on healthcare utilization is mixed.[21-24] This study's findings may indicate that those who have less education are more likely to stop their medication without a physician's authorization.

Need Factors

As expected need factors played a role in post-ADE behaviors. Taking more prescriptions predicted being hospitalized and waiting for a doctor's permission to change their medication regimen. In addition, those taking many medications may be more thoughtful about stopping a medication than those who are on fewer medications and are healthier.

Difficulty performing IADLs was related to being hospitalized. Past findings on the relationship between IADLs and healthcare utilization are mixed. Decreased IADLs has been associated with increased hospitalizations. [25] However, other studies have shown

that doctor visits, emergency department visits, and hospital services are not influenced by IADLs.[26] IADLs are those activities that require more planning and cue to action, such as preparing meals, managing money, or organizing medications. Therefore, difficulties performing daily tasks may also indicate difficulties in performing health maintenance or self-care, and this circumstance may then lead to poor health outcomes which require medical attention. Although past findings from older adult health care utilization research has mixed findings, this study showed that older adults who have difficulty with IADLs are more likely to be hospitalized after experiencing an ADE.

Enabling Resources

Family living arrangement predicted both talking to a doctor and visiting doctor or emergency room. Those not living with any family were more likely to talk to a doctor while those living with both spouse and a child were more likely to visit a doctor or an emergency room. Instrumental support may be in the form of transportation, making financial contribution, helping with work obligations, or providing another form of direct relief or material aid.[27] In a study of 1,284 community-dwelling older adults, those who reported having more instrumental support from their informal networks, were more likely to report being hospitalized than those not receiving instrumental support, and decrease home care services.[28] The findings from this study align with past older adult health care utilization literature, and it may be assumed that those who live with their spouse and a child have more instrumental support. Therefore, these individuals would be more likely to visit their doctor or go to an emergency room because of support in scheduling appointments and/or transportation to and from the healthcare system.

Those who do not live in a nursing home were more likely to talk to a doctor than those who live in a nursing home. Those living in a nursing home have a significant level of instrumental support, and it is likely that their nursing staff may take over this behavior for them, while those not living in a nursing have to take on this task themselves.

Due to the way HRS and PDS data collection periods are structured, analyses were limited to performing a statistical model separately for each post-ADE behavior, one for 2005 and one for 2007. This, in turn, created a smaller sample size for each analysis. Overall, the dataset included variables from 2004-2007. For the 2005 post-ADE behavior analyses, variables from 2004 and 2005 were used. For 2007 analyses, 2006 and 2007 variables were included. It would be inappropriate to take the 2007 outcome measure of post-ADE behavior and use number of medications from 2005, or cognition from 2004, as predictors. To create the most valid findings, performing two models, in 2005 and 2007, for each post-ADE behavior is required.

Generalizability

After completing the regression analyses with and without the weights, it was clear that the PDS weights could not be applied due to the instabilities in the data. The technique of using self-weighted data, but controlling for the variables used to create the weights is commonly accepted. The variables used to create the PDS weights were age, sex, race/ethnicity, education, marital status, self-rated health, number of physical limitations, type of drug coverage, and level of out-of-pocket spending on drugs. Although PDS weights could not be utilized, age, gender, race, and ethnicity were controlled in analyses. Type of drug coverage was not controlled because everyone in the

PDS sample had Medicare and/or Medicaid. However, having any additional supplemental or private insurance was measured and included in all full regression models. In addition, all full regression models included ADLs, IADLs, and level of education. ADLs and IADLs control for physical limitations. Although the self-weighted analyses attempted to control for all variables that make up the PDS weights, the HRS and PDS sampling methodologies were strong, and the findings may cautiously be generalized to Medicare and Medicaid Enrollees.

Limitations

There were three major limitations to this study. An important limitation of this study is that the performance of any post-ADE behavior was limited to the five behaviors listed in the PDS. There are potentially other post-ADE behaviors that an individual may perform after experiencing and ADE, but are not captured in the PDS. For example, a person can talk to their community pharmacist or search online for remedies. Because the PDS restricted post-ADE behaviors to these six behaviors, there may be an additional limitation of how subjects responded. For example, an individual may perform a post-ADE behavior then reported performing none of the PDS post-ADE behaviors. Therefore, the subject's data would show that he/she took no action after experiencing an ADE. Therefore, this estimate of performing at least one post-ADE behavior may be an underrepresentation of older Americans actual performance of post-ADE behavior. Future research needs to be conducted determining what other post-ADE behaviors are performed outside of the healthcare system.

The second limitation is that we are unable to control for ADE severity. Therefore, it is not possible to determine if performing a particular post-ADE behavior was due to the severity of the ADE or predisposing characteristics, enabling resources and/or need factors. The only post-ADE behavior that is related to ADE severity is hospitalization, because of clinical evaluation. All other post-ADE behaviors in the PDS may be performed no matter the severity of the experienced ADE. Further investigation into severity of ADE and post-ADE behavior performed needs to be conducted to understand patient behavior and to improve patient care.

The last limitation is sample size. All of the logistic regressions had different results from 2005 to 2007. For example, 2005 the logistic regression predicting talking to a doctor was significant, but the 2007 logistic regression was not. In addition, even if both years were significant, like in the regressions predicting being hospitalized, different predictors were found. This may be due to the small sample size in each year. However, if we pooled both years, there would also be a limitation of causation, as the independent variables would span four years and this would likely decrease the strength of any relationships because the time between the predictor variables and the post-ADE behavior would be too great. Further investigation into creating a dataset from PDS and HRS to handle this limitation for this sample needs to be conducted.

Practice Implications

This study showed that older adults are performing more post-ADE behaviors than previously found. Even if a post-ADE behavior does not include healthcare service

utilization, it does not mean that the ADE does not have an impact on patient health outcomes. It is important for practitioners to understand that patients with different characteristics may perform different post-ADE behaviors. In addition, knowing that patients may perform no action or a non-healthcare service utilization post-ADE behavior, practitioners need to counsel patients on which post-ADE behaviors are appropriate for their specific prescription medications. Patients should discuss with either their physician or pharmacist what to do if they experience a negative side effect in order to receive appropriate care or prevent a worsening of health that would eventually lead to hospitalization or a decreased quality of life.

Medication Therapy Management (MTM) and comprehensive medication review (CMR) service are existing platforms within the healthcare system, being promoted by the federal government for increased provision, which could allow for this provider-patient interaction. MTM services have the ability to capture Medicare/Medicaid enrollees in the outpatient, community, and long-term care settings. MTM services aim to optimize drug therapy and improve therapeutic outcomes for patients. There are six core components of an MTM service: 1) a medication therapy review, 2) the creation of a personal medication record, 3) the development of a medication-related action plan, 4) any necessary therapeutic interventions or referrals, 5) documentation, and 6) a follow-up visit or phone call.

In 2013, the Centers for Medicare and Medicaid Services (CMS) made it mandatory that all Medicare Part D plan sponsors must offer an annual comprehensive medication review (CMR) to qualified beneficiaries as a quality measure of the Part D plan. A CMR is an interactive, person-to-person service where a provider reviews a

beneficiary's medications (including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements) in order to determine any potential medication-related problems. The CMS will use the Part D plan's CMR completion rate to award 1-5 points, with 5 indicating excellent performance. These points will then determine bonus payments to each prescription drug plan. Since the federal government is promoting the provision of CMR and MTM services, this would be an optimal, easily implemented, platform for providers to discuss with patients what the appropriate post-ADE behaviors are for each medication (stop immediately or keep taking until discussing with doctor), and how to perform post-ADE behaviors (ex. provide nursing hotline number). Patient safety can be further improved if an additional section was added to the MTM or CMR documentation, required by CMS, to require provider-patient discussion of which post-ADE behaviors are appropriate for the patients' medications.

Conclusion

Older adults perform a variety of post-ADE behaviors. No predictors were found for taking no action after experiencing an ADE. Those with more Predisposing characteristics predicted cutting down or stopping medication on own, cutting down or stopping medication with physician authorization, and being hospitalized after experiencing an ADE. Need factors were related to cutting down or stopping medication with doctor's permission, visiting a doctor or emergency room, and being hospitalized. Finally, enabling resources were influential in talking to a doctor or visiting a doctor or emergency room after having an ADE.

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TABLE 3.1: FREQUENCIES OF POST-ADE BEHAVIORS FOR THOSE WHO COMPLETED BOTH THE 2005 PDS AND 2007 PDS (n=3536)

Post-ADE Behaviors	2005 N=37,292,177 n (%)	2005 n=3536 n (%)	2007 N=38,644,041 n (%)	2007 n=3536 n (%)
Stopped/Cut down on own	3,571,649	243 (6.9)	4,088,200	257 (7.3)
Talked to Doctor	6,019,489	430 (12.2)	6,261,500	397 (11.2)
Visit Doctor or ER	2,173,918	151 (4.3)	2,200,890	152 (4.3)
Stopped/Cut down with Dr. orders	4,623,796	376 (10.6)	4,517,804	301 (8.5)
Admitted to the hospital	561,206	36 (1.0)	637,015	37 (1.0)

TABLE 3.2: LOGISTIC REGRESSION PREDICTING STOPPING OR CUTTING DOWN ON MEDICATION ON OWN IN 2005 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=506)

REDUCED MODEL (X^2=14.306, P<.026)		
	OR	**p-value**
Age	0.987	0.249
Gender		
Female	1	
Male	0.891	0.159
Race		
Caucasian/White	1	
African American/Black	0.879	0.643
Hispanic	0.623	0.12
Living Arrangement		
Living with no family	1	
Living with spouse or child	0.854	0.399
Education		
Less Than High School	1	
Four-year college degree	0.463	0.003

TABLE 3.3: LOGISTIC REGRESSION PREDICTING CUTTING DOWN ON MEDICATION WITH DOCTOR'S PERMISSION IN 2007 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=465)

REDUCED MODEL (X^2=14.205, P<.014)		
	OR	**p-value**
Age	1.001	0.914
Gender		
Female	1	
Male	0.915	0.816
Race		
Caucasian/White	1	
African American/Black	1.392	0.334
Hispanic	3.521	0.024
Number of Prescriptions	1.079	0.014

TABLE 3.4: LOGISTIC REGRESSION PREDICTING TALKING TO A DOCTOR 2005 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=506)

REDUCED MODEL (X^2=13.980, P<.030)		
	OR	**p-value**
Age	0.979	0.166
Gender		
Female	1	
Male	0.998	0.994
Race		
Caucasian/White	1	
African American/Black	0.68	0.298
Hispanic	0.85	0.693
Nursing home resident	0.064	0.02
Living arrangement		
Live with no family	1	
Live with spouse or child	0.568	0.042

TABLE 3.5: LOGISTIC REGRESSION PREDICTING VISITING A DOCTOR OR GOING TO EMERGENCY ROOM IN 2007 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=465)

REDUCED MODEL (X^2=16.8143, P<.010)		
	OR	**p-value**
Age	1.005	0.688
Gender		
Female	1	
Male	1.364	0.141
Race		
Caucasian/White	1	
African American/Black	1.237	0.5
Hispanic	1.755	0.12
IADL Score	1.213	0.018
Living with both spouse and child	4.016	0.015

TABLE 3.6: LOGISTIC REGRESSION PREDICTING BEING HOSPITALIZED IN 2005 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=506)

REDUCED MODEL (X^2=13.747, P<.033)		
	OR	**p-value**
Age	0.998	0.912
Gender		
Female	1	
Male	0.398	0.037
Race		
Caucasian/White	1	
African American/Black	2.058	0.132
Hispanic	1.87	0.235
Region		
Northeast	1	
South	0.42	0.034
Education		
Less than high school	1	
High school diploma	1.881	0.151

TABLE 3.7: LOGISTIC REGRESSION PREDICTING BEING HOSPITALIZED IN 2007 AFTER EXPERIENCING AN ADVERSE DRUG EVENT (n=465)

REDUCED MODEL (X^2=14.514, P<.024)		
	OR	**p-value**
Age	0.978	0.325
Gender		
Female	1	
Male	1.597	0.229
Race		
Caucasian/White	1	
African American/Black	1.989	0.179
Hispanic	1.522	0.528
Number of Prescriptions	1.126	0.004
Education		
Less Than High School	1	
High School Diploma	0.585	0.156

TABLE 3.8: SUMMARY OF SIGNFICANT PREDICTORS IN LOGISTIC REGRESSION MODELS

	Cutting down or stopping prescription on own	Cutting down or stopping prescription with doctor's permission	Talking to doctor	Visiting doctor or emergency room	Hospitalized
Predisposing Characteristics					
Gender					*
Hispanic		*			
Education	*				
Geographic Region					*
Need Factors					
Number of prescriptions		*			*
IADL				*	
Enabling Resources					
Being a nursing home resident			*		
Family Living Arrangement			*	*	

Chapter 4

PREDICTING SELF-CARE AND CARE-SEEKING POST-ADE BHEAVIORS AMONG OLDER AMERICANS

Introduction

Adverse drug events (ADEs) cost a single hospital approximately 5.6 million per year in the United States.[1] ADEs vary in their severity and even in their correct attribution to drug/s, thus behaviors after experiencing an ADE may be different for different people. A previous study showed that after an ADE, individuals utilize formal health care services, perform self-care, or do nothing.[2] With ADEs rapidly increasing, it is important to determine what patients are doing and what factors predict different post-ADE behaviors. The 1995 Andersen Model is a decision-making model that seeks to explain under what circumstances individuals choose to seek professional health care or to perform other personal health choices. However, past research on ADEs typically focused on which health care services older adults use, excluding other self-care behaviors that are performed outside of the health care system. Health care seeking post-ADE behavior has been the focus of previous research because it is easily captured through medical records or claims data. Few studies look at ADEs that occur in the outpatient setting, particularly those ADEs that lead to no formal health care service

utilization. Past literature on older adult health care utilization does not include the behaviors and predictors of those behaviors that may influence post-ADE behaviors. Understanding post-ADE behaviors is important to improve patient safety and outcomes, and it is important for policy and programs such as Part D Medication Therapy Management and Case Management may be informed by the results about important predictors or risk factors for managing ADEs.

The Andersen Model has frequently been applied to older adult health service use.[3] The Andersen Model of Health Service Utilization was first developed by Andersen in 1968 and has continued to be revised into the most used version, the 1995 Andersen Model.[4] The three components of the Andersen Model are predisposing characteristics, need factors, and enabling resources. One underlying assumption of the predisposing characteristics construct is that there are individuals that have the propensity to seek and use health care services more than others. Within the predisposing characteristic construct there are three dimensions, including demographics, social structure, and health beliefs.

Although an individual may be more likely to use health care services according to their predisposing characteristics, resources are needed to be in place in order for the individual to seek care. Therefore, the enabling resources are those factors that allow health care services to be available to an individual for comsumption.[5] In the 1968 Andersen Model, it is stated that the enabling resources construct is the financial component of the model. However, the construct has evolved into resources that provide the "means" for an individual to consume care.[6] This construct now includes non-financial resources. In the past six years, this is to include instrumental/social/emotional

support and others.

Need is comprised of perceived need and evaluative need. “Perceived need will better help to understand care-seeking and adherence to a medial regimen, while evaluated need will be more closely related to the kind and amount of treatment that will be provided after a patient has presented to a medical care provider.[4] Perceived need includes how people view and experience their illness symptoms, functional state, and overall general health.[4] Evaluative need is determined through professional assessments developed through objective measurements. Throughout the testing of the Andersen Model, it has been shown that need characteristics are the most important determinants to physician visits [7,8] and overall health care utilization. [3,9,10] Need characteristics may be measured by functional status, perceived/self-report health status, and evaluated health status.

By 2030, there will be about 72.1 million older persons, over twice the number in 2000.[11] Elderly tend to utilize health care resources more often than people under the age of 65.[12] The rapid increase of elderly should be an indicator that utilization of health services is likely to increase. However, despite increased likelihood of use, there are many determinants that act as a deterrent to healthcare service utilization and others that can satisfy unmet need for health services. For example, while the population is aging, there are 42.1 million family caregivers in the United States who provide continuous care to an older individual, and about 61.6 million provided care at some time during the year.[13] It has been shown that family structure, family availability, transportation, and living arrangement impact health care utilization and self-care behaviors.[14-16] Although past literature has shown that enabling resources have significant impact on older adult

healthcare utilization, it has not been investigated in ADE behavior research. In addition, how and where ADEs are measured restrict the post-ADE behaviors to those that occur within the healthcare setting, while some post-ADE behaviors may be performed within the home. Background in enabling resources, how ADEs are measured, and where ADE are measured is presented below.

Enabling Resources

If an individual was not able to care for himself or herself then a caregiver or nurse would step in to provide assistance where patient's capabilities fall short. For example, if an older adult experienced ADE symptoms that made him/her have diarrhea, and the older adult was not able to use the toilet on their own, then a family member would have to assist in the process. If there are no family members around to help care for the older adult, or if the family members were not able to perform this type of care, then the older adult may seek care within the health care system. The family's ability to care for their older parent acts an enabling resource.

Although an individual may be more likely to use health care services according to their predisposing characteristics, resources are needed to be in place in order for the individual to seek care. Therefore, the enabling resources are those factors which allow health care services to be available to an individual for comsumption.[5] Family resources and community resources are the two dimensions of enabling resources.[4] Family resources refer to income, health insurance, and having a regular source of health care.[5] Community resources are measured by physician-to-population and hospital-bed-to-population ratios, geographic location, and population density indices.[5] This study will

focus on how family enabling resources impact the type of post-ADE behaviors performed.

Insurance. Medical insurance is commonly measured as an enabling resource.[17-19] It has been shown that having private insurance as an older adult significantly predicted hosptializations,[8] and physician visits.[8,12] Contrarily, one study showed Medicaid and private insurance had no significant impact on volume of doctor visits.[20] However, it has been shown general health insurance (yes/no),[15] supplemental health insurance,[114] or other government insurance (ex. V.A. coverage)[3] do not impact hospital service use. Additionally, supplemental insurance had no influence on emergency department visits or doctor visits.[9]

Instrumental Support. Instrumental support measures the direct support provided to an individual so he/she may seek medical care. Instrumental support may be in the form of transportation, making financial contribution, helping with work obligations, or providing another form of direct relief or material aid.[22] Those older adults who report having decreased transportation access reported using more ambulatory services, home care and had a greater number of hospital days.[3] It has also been shown that older African Americans who report higher instrumental support use more emergency department services and more doctor visits; however, there is no impact on hospitalization.[17] In a study of 1, 284 community-dwelling older adults, those who reported having more instrumental support from their informal networks, were more likely to report being hospitalized than those not receiving instrumental support, and decrease home care services.[23]

Family Income. Income can be seen as an enabling resource because it can influence the likelihood of healthcare utilization. It has been shown that overall, in the United States, low-income citizens have problems getting care than their counterparts.[24] However, research of older adult healthcare utilization shows that income does not influence hospital admissions,[21] hospital services,[3,9] doctor visits,[9] or emergency department visits,[9] or ambulatory care services.[3]

Wealth. For older adults, wealth is a better indicator of available resources than income, especially for retired adults. Only one study of older adult health care utilization has taken advantage of this measure to date. It was shown that those older adults with assets totaling $1,000-$49,000 predicts more nursing home service utilization than those who have assets totaling $50,000 or more.[19]

Number of Living Children. This measure was found in only one older adult healthcare utilization study. It was found that those who have more living children are more likely to have doctor visits and bed-disability days, but no impact on hospital stays.[14]

Living Arrangement. Those older adults in multigenerational family living arrangements used fewer home health care services.[3] When categorized by race, older African Americans are more likely to live with relatives than their white counterparts and older white adults are more likely to be living with their spouse.[15] Those older adults living with non-relatives are three times less likely to experience short-term hospital stays than those older adults living with their spouse.[15]

Because of the rapid increase of elderly and informal/family caregivers America will be facing in the next 15 years, it is critical for practitioners and researchers to

understand how the relationship between family enabling resources will impact patient health outcomes after experiencing an ADE. This study is the first investigatory step into determining this relationship.

Measurement of ADEs

Past ADE literature uses six methods to capture the occurrence of ADEs. The National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System (NEISS-CADES) and the Adverse Event Reporting System (AERS) are nationally-representative databases that focus on emergency department visits due to ADEs or reporting of ADEs by health care professionals, patients or drug manufacturers, respectively. Volunteer reporting by health care professionals, medical chart reviews, patient self-report, and daily observation of patient by health care professionals have also been utilized to capture ADEs that occur either within the emergency department, hospital, nursing home, or outpatient settings.

The NEISS-CADES is a nationally representative probability sample of hospitals in the United States with a minimum of six beds and a 24-hour emergency department.[25] Trained coders at each hospital reviewed clinical records of every emergency department visit. The coders then identify physician-diagnosed adverse drug events and then report diagnosis, medication implicated in the ADE, and a narrative description of preceding circumstances. Data collection, quality assurance, management, and analyses were all conducted by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration human subject oversight bodies.[26]

The Food and Drug Administration implemented the Adverse Even Report System in 1969 to identify post-marketed drug safety problems and is commonly used in ADE research.[27,28] ADE case reports are submitted by health care professionals, consumers, and drug manufacturers to reporting system.[27] From this system, drugs that are identified as having severe consequences are removed from the market.

Medical chart reviews have been used to capture ADEs in three methods. First is a daily chart review by a health care professional or trained nurse investigator.[29] This method is used during longitudinal studies of patients who are hospitalized. Second, medical chart reviews can be performed at time intervals during a longitudinal study.[30] Lastly, medical chart reviews are used in cross-sectional analyses either to capture all ADE event(s) and health care utilization due to the event(s)[31-38] or to confirm patient self-report of events [29,37,43]

When investigating the incidence of ADEs in already hospitalized patients, observation by healthcare professional has been used to determine when an ADE occurs and what caused the event on a daily basis [40,41] or at time of emergency department visit.[42]Another method to capture ADEs that occur in hospitalized patients is volunteer reporting by health care professionals.[29,37,43]

The least utilized method of capturing ADE incidence is patient self-report. A patient report of an ADE occurrence is usually confirmed by medical chart review.[29,33,35,36] Therefore, if a patient states that they experienced an ADE, but it did not lead to health care utilization, then their report of incidence is excluded from the analyses. Alternatively, patient self-report of ADEs have been confirmed by a pharmacist evaluation of reported negative effects with the patient's medication list.[44]

These six methods of measuring incidence of ADE take place in six different settings: emergency department [26,31,39,42], hospitalization after emergency department visit,[34,45] ADEs that occur in already hospitalized patients,[29,37,40,43,41] general hospital admission,[38,46,47] post-hospital discharge,[33,35,36] nursing homes,[30] and the outpatient setting.[32,44] The incidence rates and risk factors of ADEs vary due to the measure of ADE and the setting in which the ADE occurs. In addition, ADE research has also focused on how to decrease potential ADEs in the hospital and during post-hospital discharge.

In summary, the methods of past research have been limited in their care-seeking post-ADE behaviors. In addition, past literature indicates that enabling resources have an important impact on older healthcare utilization. However, past ADE research has not investigated how enabling resources may play a role in post-ADE behaviors.

The objective of this study was to quantify and characterize post-ADE behaviors performed in 2005 and 2007, and to investigate predisposing characteristics, enabling resources and need factors that are predictive of ADE behaviors. These post-ADE behaviors include seeking care within the health care system, self-care and taking no action. It was anticipated that need factors (including number of comorbidities, number of prescriptions, number of high-risk medications, functionality and cognition) would predict post-ADE behavior that involved care-seeking and that some enabling factors (including family living arrangement, family availability, family structure, wealth, private/supplemental insurance in addition to Medicare and/or Medicaid, and ability to drive) would predict self-care.

Research Methods

Design

This study consists of cross-sectional analyses utilizing data from the Health and Retirement Study (HRS) The Institutional Review Board of University of Michigan approved this study.

Data Source

Data from the following four different data files was utilized: 1) waves 2004 and 2006 of the Health and Retirement Study, 2) the 2005 and 2007 Prescription Drug Study (sub-samples of the HRS), 3) HRS Tracker File, 4) HRS Cross-Wave Region and Mobility File, and 4) RAND Income and Wealth Imputation File.

Health and Retirement Study. The University of Michigan Health and Retirement Study (HRS) is a longitudinal panel study that surveys a representative sample of more than 26,000 Americans over the age of 50 every two years. Since its launch in 1992, the study has collected information about income, work, assets, pension plans, health insurance, disability, physical health and functioning, cognitive functioning, and health care expenditures. The HRS sampling methods can be found in Appendix A.

Prescription Drug Study. The HRS 2005 Prescription Drug Study is the first wave of a two-wave mail survey designed to track changes in prescription drug utilization as Medicare Part D. This was intended to capture prescription drug use, coverage, and satisfaction prior to the implementation of Medicare Part D. Descriptions of the PDS sampling methods and the creation of weights may be found in Appendix A.

HRS Tracker File. The HRS Tracker file was developed to assist in using HRS data across waves. There is one record for each subject that contains basic demographic information, interview status, and if, when and how an interview was conducted in each wave.[48]

RAND Income and Wealth Imputation File. The RAND Income and Wealth Imputation Files contain the component and ownership variables that were used in RAND HRS income and wealth summary measures.[49]

HRS Cross-Wave Region and Mobility File. This file matches the HRS Tracker file Household Identifier (HHID) and Person Number (PN) and contains one record for each subject. This file includes: (1) cross-wave geographic information, (2) child ZIP Codes, (3) region in which the respondent was born, (4) region where the respondent lived at age 10, (5) for each wave, the region where the respondent was reached for an interview, (6) the HRS Urban-Rural Code, an urban/suburban/ex-urban flag derived from the Beale Rural-Urban Continuum Code, (7) distance-moved variables for each pair of interview years, and (8) information on geographic information processing techniques for each wave.

Study Population

The inclusion criteria consisted of subjects who (1) completed the 2005 PDS and 2007 PDS and (2) completed both the 2004 HRS and 2006 HRS. The PDS sample included HRS respondents born in 1942 or earlier (65th birthday in 2007) or already covered by Medicare or Medicaid at some time between 2002 and 2004.

Measures of Interest

Predisposing Characteristics

Predisposing characteristics included: age, gender, highest degree attained, ethnicity, race, urban/rural status, and geographic region. Greater detail of how variables were handled can be found in Appendix B.

Demographics. The interviewer documented the subject's gender. Level of education was grouped as the following: 1) less than high school, 2) high school diploma, and 3) at least a 4-year college degree. Race categories included: White/Caucasian, Black/African American, and other. Ethnicity was grouped into one dummy variable for Hispanic and Non-Hispanic. The following three categories of population size were created: urban, suburban, and ex-urban (rural). For this study, HRS geographic codes were categorized into Northeast, Midwest, South, and West.

Need Factors

Need factors included: physical functioning (activities of daily living and instrumental activities of daily living), number of comorbidities, cognition, number of regular prescriptions, and number of high risk medications.

Activities of Daily Living (ADLs). All subjects were given an initial evaluation of mobility to determine skip patterns during the interview. Further details of this and how skip patterns were handled for ADLs can be found in Appendix B. The six ADL items were as follow: because of a health do you have any difficulty with dressing, including

putting on (1) shoes and socks? (2) Bathing or showering? (3) Using the toilet, including getting up and down? (4) Eating, such as cutting up your food? (5) Walking across a room? (6) Getting in or out of bed? Response options included: Yes, No, Can't do, Don't do, Don't know, Refuse to answer. To be conservative, all responses, other than 'No', were coded as 1. 'No' was coded as 0. For all subjects, a summed ADL score was created, with a final summed score of 0 to 6 (no difficulty to difficulty with all ADLs).

Instrumental Activities of Daily Living (IADLs). The five IADL items were as follows: because of a health, do you have any difficulty (1) preparing a hot meal? (2) Using a map to figure out how to get around in a strange place? (3) Shopping for groceries? (4) Making phone calls? (5) Taking medications? Response options included: Yes, No, Don't Know, Refuse to Answer. To be conservative, all responses, other than 'No', were coded as 1 and 'No' was coded as 0. For all subjects, a summed IADL score was created ranging from of 0 to 6 (no difficulty to difficulty with all IADLs).

Cognition. Cognition was captured by using the Telephone Interview for Cognitive Status (TICS). TICS is a version of the Mini Mental State Examination [50] and has been adapted for telephone administration.[51] Cognition was a summed score of the subjects, ranging from 0-35, where 35 represents the highest possible score.

Number of Comorbidities . Subjects were asked if they have been diagnosed with 10 common chronic conditions among older adults. The conditions included: diabetes, lung disease, heart disease (heart attack, coronary heart disease, angina, congestive heart failure, or other heart problems), mental health condition (emotional, nervous, or psychiatric problems), arthritis, hypertension, cancer (excluding minor skin cancer),

memory-related condition, stroke, and glaucoma. A summed count was calculated to determine how many chronic conditions a subject had.

Number of Regular Prescriptions. Subjects were asked to report how many of their prescription drugs were taken on a regular basis, and this report was kept as a continuous variable during analyses.

Number of High Risk Medications. In the PDS, subjects were asked to list all prescriptions that they take. From these self-reported medication names, a count of the number of high risk medications for each individual was done using the National Committee of Quality Assurance list of high risk medications in the elderly (Appendix C) A count of the number of reported prescription that are also found on the National Committee of Quality Assurance list of high risk medications in the elderly was computed.

Enabling Resources

Enabling resources included: wealth, family structure, family availability, ability to drive, family living arrangement, having at least one private or supplemental insurance plan in addition to Medicare, and being a nursing home resident.

Wealth. The RAND imputed wealth variable used in this study is the net value of total wealth (including second home) minus all debt. Assets are added from primary residence, second home, other real estate, transportation, business, IRA retirement account, stocks, CDs, bonds, and any other reported assets in savings. From these assets

debts from primary mortgage, second home mortgage, other homes loans and debts were subtracted.

Family Structure. Subjects were asked, "What is the total number of children or step-children you have?" This was kept as a continuous variable during analyses.

Family Availability. Family availability was determined by asking two questions. Subjects were asked if they have a child that lives within 10 miles, or 2 blocks. Subjects were coded as 0 if they had no child within 2 blocks or 10 miles. Subjects were coded as 1 if they had a child that lived within 10 miles, and coded 2 if they had a child that lived within 2 blocks. Those who reported having no children were intentionally skipped and coded as 0 since they have no children living within 10 miles or 2 blocks.

Ability to Drive. Subjects were asked, "Are you able to drive?" Subjects were coded as 0 if they were not able to drive and 1 if they could drive.

Living arrangement. Living arrangement was determined by asking two questions. First, "Do you live with your spouse/partner?" and "What is the number of children in your household?" A summed living arrangement score of 0 indicates living with no family, 1 indicates living with one family member and 2 indicates living with both spouse and at least one child.

Private and/or Supplemental Insurance in Addition to Medicare. The subject is asked, "Now, we'd like to ask about all the other types of health insurance plans you might have, such as insurance through an employer or a business, coverage for retirees, or health insurance you buy for yourself, including any (Medigap or) other supplemental coverage. Do NOT include long-term care insurance, or anything that you have just told

me about. How many other such plans do you have?" This variable was categorized into having at least one additional private or supplemental insurance plan or not.

Nursing Home Resident. Subjects were asked, "Are you living in a nursing home or other health care facility?" A code of 0 was given for 'No' and a code of 1 for 'Yes'.

Outcome Measures

Outcome variables included: the occurrence of an ADE in the past year and post-ADE behaviors the subject performed after experiencing the ADE. These measures are from the 2005 PDS and 2007 PDS. Subjects were asked, "In the past year, have you had any side effects, unwanted reactions, or other health problems from medications you were taking?" yes/no? Subjects were coded as 0 if they did not experience an ADE and 1 if they did experience an ADE. If yes, subjects were asked, "Thinking about the MOST SEVERE of reactions you experiences in the past year, what did you do in response? Mark Yes or No for each question: (1) Did you cut down or stop taking the drug on your own? (2) Did you talk to a doctor about this reaction? (3) Did you visit a doctor's office or emergency room mostly because of this reaction? (4) Did you cut down or stop taking your medication based on doctor's order? (5) Were you admitted to a hospital overnight mostly because of this reaction?

Statistical Analyses

Descriptive statistics were determined for all groups of post-ADE behaviors (no action, stop medication on own, talk to doctor, visit doctor/hospitalization,

hospitalization). In this analysis, the post-ADE behavior of stopping medication on own was considered a self-care behavior. The post-ADE behaviors that were considered care seeking were: talking to doctor, visiting doctor office or ER, stopping medication with doctor's permission, and hospitalization. Frequencies and descriptive statistics were then performed on the categorization of post-ADE behavior groups (no action, self-care, care seeking). Chi-square and t-tests were conducted between these groups to determine any statistical significant differences in predisposing characteristics, enabling resources and need factors.

To determine if the type of post-ADE behavior was explained by predisposing characteristics, enabling resources, and need factors, two binary logistic regressions were performed. The predisposing characteristics, enabling resources and need factors were taken either from the year before or the year of the experienced ADE. For example, the 2004 HRS contains these predictors while the 2005 PDS collected ADE occurrence. The full regression models were completed. Variables with high standard of error are found in these full models, due to additional multicollinearity. Multicollinearity, also determined by VIF values above 5, revealed variables that needed to be deleted from the model. The model was then re-run without multicollinear variables. A reduced model was then produced consisting of age, gender, race (Caucasian/African American), and ethnicity (Hispanic/Non-Hispanic), and the variables with significant coefficients in the full model. Interactions between living arrangement and need factors were also tested. It was believed that this interaction is important because immediate instrumental support may be provided more if an individual is living with their spouse or child. For example, if an

older adult has a large number of prescription medications, but lives with his/her child, that child may manage his/her medications for them.

A multinomial logistic regression was conducted to determine the predictors of type of post-ADE behavior. Multinomial logistic regression compares multiple groups through a combination of binary logistic regressions. Multinomial logistic regression provides a set of coefficients for each of the comparisons. The resulting equations can be used to compute the probability that a subject is a member of each of the three groups. When separate logistic regressions are performed between groups, standard errors are slightly larger than the standard errors in a multinomial logistic regression.

Post-ADE Behavior Group (no action, self-care, care-seeking) = β_1Age + β_2Gender + β_3Hispanic + β_4Race1 + β_5Race2 + β_6 Education1 + β_7 Education2 + β_8 + Nursing Home Resident + β_9Cognition+ β_{10} #Comorbidities + β_{11}Private/Supplemental Insurance+ β_{12} #Rx + β_{13} #HRM + β_{14}Wealth+ β_{15}ADL + β_{16} IADL+ β_{17}#Children+ β_{18} Able to Drive + β_{19} Family Availability1 + β_{20}Family Availability2 + β_{21} Family Living Arrangement1 + β_{22}Family Living Arrangement2 + β_{23}Urban/Rural1 + β_{24}Urban/Rural2 + β_{25}Region1 + β_{26}Region2 + β_{27}Region3 + β_{28} FLA1*ADL + β_{29} FLA2*ADL + β_{30} FLA1*IADL + β_{31} FLA2 *IADL + β_{32} FLA1*#Rx + β_{33} FLA2*#Rx + β_{34}FLA1*#HRM + β_{35}FLA2*#HRM + β_{36}FLA1*#Comorbidities + β_{37}FLA2*#Comorbidities

It was hypothesized that older adults who have a higher number of total prescription medications, more high-risk medications, decreased physical functioning, a higher number of comorbidities, report a lower health status, and have decreased

cognition were more likely to perform care-seeking post-ADE behaviors (talk to doctor, visit doctor/emergency room, hospital admission) than their counterparts. It was also hypothesized that those who have a smaller family structure or decreased family availability, no transportation issues and lived alone would be more likely to perform no action or self-care post-ADE behaviors.

Results

There was an end sample of 3,536 Medicare/Medicaid enrollees that met the inclusion criteria. The majority of the sample (n=3,536) were female, White, non-Hispanic, had a high school diploma, and on average were 71 years old (Table 2.1). In addition, the majority of subjects were from the South and either in an urban or rural setting. Very few subjects had difficulty with ADLs, IADL, and cognition (Table 2.2). Subjects had, on average, just over 2 comorbidities, 4 prescription medications and no high-risk medications (Table 2.2). Very few subjects reporting having children living within two blocks, living with both spouse and child, and being a nursing home resident (Table 2.3). Many subjects were able to drive and had a supplemental and/or private insurance plan in addition to Medicare. Subjects had, on average, 3 children (Table 2.3).

Of the total sample, 506 (14.3%) had an ADE in 2005 and 465 (13.15%) had an ADE in 2007.[52] This equates to 5,218,953 older adults in 2005 and 6,319,298 in 2007.[52] Post-ADE behaviors were grouped into no action, self-care, and care-seeking. On a national level, subjects were most likely to seek care (39.4%-48.0%) or perform both

self-care and care-seeking behaviors (43.4%-48.3%) (Table 4). Very few subjects (2.2%-4.6%) took no action in either 2005 or 2007 (Table 4.1).

There were drastic and important differences in results when chi-square and t-tests were performed using weights and not using weights. A conservative approach was used and the analysis was performed without weights. Chi-square and t-tests were performed, between those who performed different types of post-ADE behaviors in 2005 and 2007 (Tables 4.2-4.5). Chi-square tests and t-tests were conducted on the 506 subjects who experienced an ADE in 2005 to determine if there were differences between the groups of individuals who perform different types of post-ADE behaviors. Education was found to be statistically significant and living arrangement was close to significance. Those with higher education were more likely to seek care while those with less than a high school diploma were more likely to self-care (Table 4.2).

Chi-square and t-tests were also performed on the 465 subjects who experienced an ADE in 2007 to determine significant differences between those who perform different types of post-ADE behaviors. Those who performed a care-seeking post-ADE behavior were more likely to have worse ADL and IADL scores (Table 4.5). In addition, those who performed both care-seeking and self-care behaviors were more likely to have more comorbidities than those who only performed care-seeking. Those who performed both a care-seeking and self-care behavior were more likely, on average, to have more high-risk medications, more regular prescriptions, worse ADL scores, and worse IADL scores than those who performed only a self-care post-ADE behavior (Table 4.5).

Logistic regressions were performed for each type of post-ADE behavior in 2005 and 2007. Multicollinearity was tested for each of these regressions, and the variables

with VIF values greater than 5 were excluded. The following three Andersen Model variables were excluded from analyses due to their variation inflation factors being greater than 5.0: 1) live with spouse or child, 2) live with spouse and child, and 3) number of prescription medications. These two variables were highly correlated with the living arrangement interaction terms. In addition, the four interaction terms excluded from analyses due to multicollinearity were: 1) live with spouse and child * number of comorbidities, 2) live with spouse and child * IADL score, 3) live with spouse or child * number of prescriptions, and 4) live with spouse and child * number of prescriptions. These interaction terms for 2005 and 2007 were not highly correlated with other variables. However, very few individuals were living with both their spouse and child. Very few individuals in this group created the large standard error, and the exclusion of these interaction terms in this study's regression analyses.

To attempt to increase group size, family living arrangement was then categorized into 0) live with no family and 1) live with some family. Interaction terms where then created with this new family living arrangement variable and need factors. The same high VIF was found for the new family variable and interaction terms as found above.

Regressions were unweighted but controlled for age, gender, being African American/Black, and being Hispanic. Full regression models were conducted, followed by reduced models. These reduced regression models included the control variables (age, gender, being African American, and being Hispanic) and any statistically significant variables from the full model.

The following logistic regressions had insignificant full and reduced models: taking no action in 2005, performing self-care post-ADE behavior in 2005, performing

self-care post-ADE behavior in 2007, performing both self-care and care-seeking post-ADE behaviors in 2005, and performing both self-care and care-seeking post-ADE behaviors in 2007. The reduced logistic regression for performing care-seeking in 2005 was statistically significant (Table 4.6). This model states that those having a four-year college degree are more likely to seek care within the health care system than those who have less than a high school diploma. In addition, it shows that those who are from the Midwest are more likely to seek care than those living in the Northeast (Table 4.6).

Six multinomial logistic regressions were performed, with different reference groups (no action, care-seeking, and both self-care and care-seeking) for each 2005 and 2007. Only one of these regressions was significant: the reduced 2007 model with care-seeking as reference group.

The reduced 2007 model with care-seeking as reference group, when looking at self-care relative to care-seeking, three relationships were significant (Table 4.7). As a subject's IADL score increases (illustrating more difficulty with the tasks), individuals performed more care-seeking post-ADE behaviors compared to self-care. Moving from the Northeast to the Midwest, preferring self-care to care-seeking decreased. As a subject's number of comorbidities increased, subjects preferred to perform both types of behaviors compared to care-seeking only. Adding self-care, in addition to care-seeking, is related to having more comorbidities. This model also states that older adults in rural areas prefer to perform both types of post-ADE behaviors than care-seeking only, compared to those older adults who live in an urban area.

Discussion

Adverse drug events result in 700,000 emergency room visits, and of these visits, 120,000 require further hospitalization for the experienced ADE.[45] The study presented in Chapter 2, illustrated that approximately 2,200,000 Medicare enrollees visited a physician or emergency room due to adverse drug events in 2007. This same study also illustrated that in 2007, 400,000 Medicare enrollees stopped taking their prescriptions without physician recommendation, and 10,700,000 either talk to their doctor or decrease/stop taking their prescription medication with physician recommendation. Chapter 2 and Chapter 3 showed that Medicare enrollees are experiencing more ADEs and performing more post-ADE behaviors than previously determined by capturing ADEs within the healthcare system. It is important to determine what individuals are doing in and out of the healthcare system after experiencing an ADE because post-ADE behaviors outside of seeking care within the healthcare system may have detrimental impacts on health outcomes. Overall, after grouping post-ADE behaviors into self-care and care-seeking, this study determined that the majority (80.0%-89.7%; Table 4) of Medicare and Medicaid enrollees either seek care or perform both care-seeking and self-care post-ADE behaviors.

Predisposing Characteristics

It was not hypothesized that predisposing characteristics were related to type of post-ADE behavior. However, U.S. region, and population density of city, and education were found to be significant in predicting type of post-ADE behavior. Those who were less educated were more likely to self-care than those who have a four-year college

degree. This is potentially due to educated individuals being more aware of the importance of following their physician's directions, making it less likely for them to stop taking their medication without doctor permission.

Throughout the analyses, there was a stark difference between those in the Northeast and those in the Midwest. Overall, Medicare enrollees living in the Midwest were more likely to seek care. Different regions might have different healthcare policies and insurance plans.[5] In addition, there may be differing social norms on spending on healthcare services. A study illustrated that Midwesterners had more out-of-pocket health care spending than those individuals in the Northeast.[52] This study also revealed that more than one-third of Midwesterners were unable to obtain the care they needed because of cost. This is called cost-related access problems and is most common in the Midwest and the South.[52]

The study conducted also showed that Medicare enrollees that live in a rural area are more likely to perform both self-care and care-seeking behaviors after experiencing an ADE. This may be due to the decreased accessibility that rural individuals have to healthcare services. These individuals may have performed a self-care behavior first, and when that did not decrease the ADE symptoms, they would then seek care. Alternatively, these individuals may perform self-care behaviors while waiting to seek care.

Need Factors

Applying Andersen's Model of Healthcare Utilization to post-ADE behaviors, need factors included: number of prescription medications, number of comorbidities, ADLs, IADLs, cognition and number of high-risk medications. It has been shown that

need factors play a role in healthcare utilization. It was hypothesized that those adults who had more need factors would be more likely to perform care-seeking post-ADE behaviors (talk to doctor, visit doctor/ emergency room, hospital admission) than their counterparts.

This study demonstrated that *some* need factors play a large role in the type of post-ADE behaviors performed. The t-tests illustrated that physical functioning, number of comorbidities, number of prescription medications, and number of high-risk medications were related to type of post-ADE behavior performed. First, those who performed care-seeking were more likely to have worse physical functioning (ADL and IADL abilities). This may be thought to occur because older individuals who have difficulty performing ADL and IADLs may not be able to self-care. It was also shown that an increased number of comorbidities were related adults preferring to perform both self-care and care-seeking post-ADE behaviors compared to care-seeking only. It may be assumed that those who have more need factors have more complex medical needs, are sicker, and require more health care utilization.

Lastly, those who perform both types of behaviors are more likely to have more high-risk medications, more regular prescription medications, worse ADL abilities, worse IADL abilities than those who self-cared after experiencing an ADE. As already discussed, those who have difficulties performing ADLs and IADLs are more likely to not have the capacity to perform self-care behaviors. The relationship between number of prescriptions and high-risk medications and performing both self-care and care-seeking is thought to occur because the self-care behavior of interest is the older adult reducing or stopping their medication regimen without physician permission. Those older

adults taking more prescription medications and high-risk medications may be more likely to stop their medication after experiencing an ADE due to more concern beliefs about their medications.

Beliefs exist about particular medications to treat health condition, and medication beliefs impact adherence.[53] Medication beliefs may be positive or negative. For example, patients strive to avoid prescription medication side effects, adverse drug events, and negative long-term effects from taking a medication. Therefore, they have concern about a medication, which may lead to non-adherence in order to avoid negative medication-influenced events. However, patients may feel the benefit of a medication out-weighs any risk. In that case, a patient may be more adherent to the medication. According to Horne, medication beliefs are a "hidden determinant to treatment outcome".[54] Those older adults who are on more prescription medications, and especially, high-risk medications may have more concern beliefs about their medications and these concerns may contribute to their willingness to stop taking their prescription without doctor permission.

Enabling Resources

This study hypothesized that those older adults with fewer enabling resources would be more likely to perform no post-ADE behavior or to self-care. Having a larger family structure has been shown to be related to more doctor visits[14] and having a greater amount of family availability/instrumental support has been shown to be related to more emergency department visits. [17] Those with increased instrumental support were more likely to be hospitalized than those who did not have instrumental support.[23] Older adults

who live with another person use health care services more than those that live alone.[14,15] Older adults with transportation issues are more likely to use ambulatory services and have greater hospital stays.[3]

Although the previous study, presented in Chapter 3, illustrated that family living arrangement predicted visiting a doctor or emergency department, this study found no statistically significant relationships between enabling resources and type of post-ADE behavior performed. This may be due to the small sample size and group sizes in three enabling categories: living with a child, being a nursing home resident, and not able to drive. Further investigation needs to be conducted, capturing those with more enabling resources, to determine if enabling resources impact post-ADE behavior.

Practice Implications

With transition to value-based purchasing, hospitals are taking on infrastructure and practice changes in order to improve health outcomes and avoid tax penalties. Health informatics is leading the way in patient and provider surveillance to lead to practice changes to improve patient care from actual hospital data. This study illustrates that it may be beneficial for hospitals to add a section into patient electronic medical records for practitioners to document any patient self-care post-ADE behaviors performed before calling a doctor, coming to a doctor's visit, or going to the emergency department. This would benefit patient care in two ways. First, practitioners can then better counsel individual patients on appropriate self-care behaviors. For example, some medications should not be stopped without physician permission, while others may be discontinued

immediately if experiencing a side effect. Also, it is important for practitioners to counsel patients on appropriate post-ADE behaviors for their specific prescription medications and to take into consideration the differences in level of education and where the patient lives. The second way surveillance of self-care post-ADE would help hospitals is if they are able identify if there is a certain subpopulation that is utilizing emergency department visits or hospitalizations more than others due to improper post-ADE self-care behaviors. Then the hospital may target specific practitioner guidelines to potentially decrease risk of over utilization of healthcare and improve patient health outcomes.

Future Research

This study was conservative at categorizing post-ADE behaviors because of the wording of the items in the PDS. Only cutting down or stopping medication on own was considered a self-care behavior. Qualitative research needs to be conducted to determine what other self-care post-ADE behaviors individuals perform and what enabling resources assist in performing those behaviors. These findings can then be applied in a study that captures these additional self-care behaviors, enabling resources, and care-seeking behaviors.

Limitations

There were three major limitations in the study. The most important limitation to these analyses was our inability to control for physician-determined ADE severity. Therefore, it is not possible to determine if performing particular post-ADE behaviors is due to a severe ADE and/or predisposing characteristics, enabling resources and/or need factors. This logistic regression has the underlying assumption that the post-ADE relationship performed is not related to ADE severity. However, within the regression there are variables that have been shown to be risk factors for experiencing a severe ADE. Future research is needed to link ADE severity with post-ADE behavior, this analyses controls for the proven risk factors for experiencing severe ADEs. An alternative consideration is that we are indeed predicting varying levels of ADE severity in that a mild ADE will be managed with self-care while individuals with ADEs that meet a particular threshold will seek care. Predicting the different behaviors in response to an ADE remains important because improving patient safety and quality of care will benefit practitioners and clinics in the current value-based purchasing healthcare delivery system.

There was no ability to link a particular medication or medication belief to the occurrence of an ADE or the post-ADE behavior performed. It would be greatly beneficially for older adults to report what post-ADE behaviors they performed, which family member assisted in that behavior, and the medication that they attribute to the ADE. This was a clear limitation in the study when trying to determine the relationship between enabling resources and type of post-ADE behavior performed.

Another limitation is that the performance of post-ADE behaviors was limited to the five selected behaviors in the PDS. Of those five selected behaviors, there was still a bias toward healthcare service utilization. There are potentially other post-ADE behaviors that an individual may perform after experiencing and ADE, but are not captured in the PDS. For example, an individual may speak to their community pharmacist, or take advise from information on the Internet. Therefore, there may be an underrepresentation of older Americans performance of post-ADE behavior. This study does however provide initial insights into self-care as a post-ADE behavior.

Generalizability

After running the analyses with and without the weights, it was clear that the PDS weights could not be applied to the chi-square, t-tests, and regressions due to the instabilities in the data. The technique of using self-weighted data, but controlling for the variables used to create the weights is commonly accepted. Although the self-weighted analyses controlled for most of the variables that make up the PDS weights, the HRS and PDS sampling methodologies were strong, and the findings may cautiously be generalized to who Medicare and Medicaid enrollees.

Conclusion

In summary, number of comorbidities and physical functioning were related to performing a self-care post-ADE behavior. Predisposing characteristics (education,

geographical region and living in a rural area) were also related to performing a self-care post-ADE behavior. Enabling resources were not related to type of post-ADE behavior. Further research on the impact of predisposing characteristics, need factors, and enabling resources type of post-ADE behavior needs to be conducted linking a specific ADE experienced to the actual post-ADE behavior.

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TABLE 4.1: FREQUENCIES AND PREVALENCE OF TYPES OF POST-ADE BEHAVIORS PERFORMED IN 2005 AND 2007:

Type of Post-ADE Behavior	**2005 (n=506)** **n (%)**	**2005 Weighted (n=5169855)** **n (%)**
No Action	18 (3.6)	113,958 (2.2)
Care-Seeking	245 (48.4)	2,484,066 (48.0)
Self-Care	34 (6.7)	327,294 (6.3)
Both Self-Care and Care-Seeking	209 (41.3)	2,244,537 (43.4)
Type of Post-ADE Behavior	**2007 (n=465)** **n (%)**	**2007 Weighted (n=5839490)** **n (%)**
No Action	22 (4.7)	267,982 (4.6)
Care-Seeking	186 (40.0)	2,298,658 (39.4)
Self-Care	33 (7.1)	452,787 (7.8)
Both Self-Care and Care-Seeking	224 (48.2)	2,820,063 (48.3)

TABLE 4.2: CHI-SQUARE TESTS BETWEEN THOSE WHO PERFORMED DIFFERENT TYPES OF POST-ADE BEHAVIORS IN 2005 (n=506)

	No action	**Care-seeking**	**Self-care**	**Both care-seeking and self-care**	**P-values**
	n=18	n=245	n=34	n=209	
Female	9	153	22	140	0.457
Race					0.93
White/Caucasian	14	207	30	175	
Black/African American	3	30	4	27	
Other	1	8	0	7	
Hispanic	3	28	3	18	0.603
Education attained					0.025
Less than high school	5	44	10	57	
At least a high school diploma	11	146	21	127	
At least a four-year college degree	2	55	3	25	
Geographic Region					0.499
Northeast	1	33	6	40	
Midwest	4	67	8	42	
South	8	96	16	83	
West	5	47	4	42	
Population Density					0.852
Urban	8	114	15	95	
Suburban	3	49	10	50	
Rural	7	80	9	64	
Nursing home resident	0	2	1	1	0.492

Able to drive	14	219	32	178	0.189
Addition private/supplemental insurance	9	163	22	128	0.413
Family availability					0.79
No children within 10 miles	9	112	15	86	
At least one child within 10 miles	9	122	16	110	
At lease one child within 2 blocks	0	11	3	12	
Family living arrangement					0.079
Lives with no family	4	70	6	79	
Lives with spouse or child	12	151	27	113	
Lives with spouse and child	2	24	1	17	

TABLE 4.3: CHI-SQUARE TESTS BETWEEN THOSE WHO PERFORMED DIFFERENT TYPES OF POST-ADE BEHAVIORS IN 2007 (n=465)

	No action	**Care-seeking**	**Self-care**	**Both care-seeking and self-care**	**P-values**
	n=22	n=186	n=33	n=224	
Female	15	115	18	153	.314
Race					.845
White/Caucasian	20	159	28	193	
Black/African American	1	21	5	25	
Other	1	6	0	6	
Hispanic	2	11	2	20	.681
Education attained					.536
Less than high school	5	38	4	45	
At least a high school diploma	16	110	21	139	
At least a four-year college degree	1	38	8	87	
Geographic Region					.180
Northeast	2	25	9	26	
Midwest	10	50	5	54	
South	7	75	15	100	
West	3	33	4	42	
Population Density					.097
Urban	7	106	14	101	
Suburban	7	32	9	48	
Rural	8	45	10	73	
Nursing home resident	1	3	0	1	.242

Able to drive	18	159	30	191	.794
Addition private/supplemental insurance	12	106	21	125	.854
Family availability					.888
No children within 10 miles	11	94	17	101	
At least one child within 10 miles	11	87	14	114	
At lease one child within 2 blocks	0	5	1	8	
Family living arrangement					.776
Lives with no family	5	57	13	66	
Lives with spouse or child	14	109	17	132	
Lives with spouse and child	3	15	3	14	

TABLE 4.4: T-TESTS BETWEEN THOSE WHO PERFORMED DIFFERENT TYPES OF POST-ADE BEHAVIORS IN 2005 (n=506)

	Care-Seeking n=245	Tests Between Care-Seeking and Self-Care	**Self-Care** n=34	Tests Between Self-Care and Both	**Both** [A] n=209	Tests Between Both [A] and Care-Seeking
	Mean(SD)	**t**	**Mean(SD)**	**t**	**Mean(SD)**	**t**
Age	71.71 (8.54)	.275	71.29 (6.65)	.046	71.22 (7.74)	.629
# Children	3.25 (1.99)	-.986	3.62 (2.38)	.356	3.46 (2.23)	-1.063
ADL score	.48 (1.18)	-.869	.67 (1.31)	.853	.49 (1.10)	-.110
IADL score	.67 (1.28)	-.997	.91 (1.28)	.828	.72 (1.19)	-.425
Cognition score	22.97 (4.59)	.444	22.52 (5.60)	-.030	22.55 (4.59)	.824
Total wealth	399447.69 (1429157.42)	-.004	400372.21 (535505.14)	.472	347793.70 (611603.83)	.486
# Prescriptions	5.29 (6.24)	1.147	3.96 (2.83)	-1.585	4.86 (2.89)	.878
# HRM	.22 (.52)	.474	.17 (.38)	-.489	.22 (.49)	.006
# Comorbidities	2.63 (1.43)	-.177	2.67 (1.24)	.059	2.66 (1.53)	-2.10

A) Both: care-seeking and self-care

TABLE 4.5: T-TESTS BETWEEN THOSE WHO PERFORMED DIFFERENT TYPES OF POST-ADE BEHAVIORS IN 2007 (n=465)

	Care-Seeking n=186	Tests Between Care-Seeking and Self-Care	**Self-Care** n=33	Tests Between Self-Care and Both	**Both** [A] n=224	Tests Between Both [A] and Care-Seeking
	Mean(SD)	**t**	**Mean(SD)**	**t**	**Mean(SD)**	**t**
Age	74.31 (8.27)	.888	72.94 (7.39)	-.332	73.44 (8.14)	1.068
# children	3.30 (2.08)	-.383	3.45 (2.36)	-.209	2.37 (.16)	-1.101
ADL score	.53 (1.21)	3.078**	.18 (.39)	-3.654**	1.15 (.07)	-.266
IADL score	.77 (1.28)	2.971**	.33 (.65)	-3.089**	1.16 (.08)	.119
Cognition score	22.14 (4.50)	.387	21.79 (4.04)	-.539	22.29 (4.66)	-.286
Total wealth	742060.93 (568376.89)	.290	3425714.74 (667421.10)	.704	435717.87 (1050120.29)	1.265
# prescriptions	5.24 (3.41)	1.717	4.15 (2.60)	-2.541*	3.94 (.27)	-1.955
# HRM	.15 (.41)	1.209	.06 (.24)	-1.819**	.21 (.45)	-1.287
# comorbidities	2.66 (1.51)	.748	2.45 (1.23)	-1.939*	3.00	-2.229*

A) Both: care-seeking and self-care

TABLE 4.6: LOGISTIC REGRESSION PREDICTING CARE-SEEKING POST-ADE BEHAVIORS IN 2005 (n=506)

Independent variables	β	p-value
FULL MODEL (X^2=39.168, p=0.122)		
Predisposing Characteristics		
Age	1.016	
Gender		
Male	1.0	
Female	.891	.653
Race		
Caucasian/White	1.0	
African American/Black	.692	.382
Other	1.896	.410
Hispanic	.603	.258
Geographic Region		
Northeast	1.0	
Midwest	.463	.050*
South	.949	.884
West	.530	.106
Urban/Rural Status		
Urban	1.0	
Suburban	1.413	.243
Ex-Urban/Rural	.980	.946
Education		
Less Than High School	1.0	
High School Diploma	.622	.149
4-Year College Degree or More	.268	.002**
Need Factors		
ADL Score	1.091	.700
IADL Score	1.246	.301
Number of High-Risk Medications	1.415	.289
Number of Comorbidities	.885	.406
Cognition	.996	.890
Enabling Resources		
Wealth	1.000	.678
Number of Children	.953	.392
Nursing Home Resident	4.058	.287
Able to Drive		
Have Supplemental/Private Insurance	.800	.409
Family Living Arrangement		
Live with No Family	1.0	
Live with Either Spouse or Child (FLA1)	1.116	.832
Live with Spouse and Child (FLA2)	.532	.285
Interaction Terms		

FLA1* ADL	.719	.288
FLA1* IADL	.671	.133
FLA1* Number of High-Risk Medications	.726	.480
FLA1* Number of Comorbidities	1.410	.056
FLA2* ADL	.765	.527
FLA2* Number of High-Risk Medications	.603	.723
REDUCED MODEL (X^2=19.541, p=.013)		
Age	1.000	.841
Gender		
Male	1.0	
Female	1.051	.802
Race		
Caucasian/White	1.0	
African American/Black	1.051	.861
Hispanic	1.550	.159
Education		
Less Than High School	1.0	
Four-Year College Degree	2.566	<.001
Geographic Region		
Northeast	1.0	
Midwest	1.675	.020
Living Arrangement		
Live with no family	1.0	
Live with spouse or child	.771	.521
Number of comorbidities	.936	.540
FLA1* Number of Comorbidities	1.168	.248

FLA1: Living with spouse or child
FLA 2: Living with spouse and child

TABLE 4.7: REDUCED MULTINOMIAL LOGISTIC REGRESSION PREDICTING PERFORMING TYPE OF POST-ADE BEHAVIOR IN 2007 WITH 'CARE-SEEKING' AS REFERENCE GROUP (n=465)

	No Action Compared to Care-Seeking		**Self-Care Compared to Care-Seeking**		**Performing Both Care-Seeking and Self-Care Compared to Care-Seeking**	
Independent Variables	β	P-Value	β	P-Value	β	P-Value
REDUCED MODEL (X^2=52.673, p=0.036)						
Age	1.040	.196	.979	.405	.992	.526
Gender						
Male	1.0		1.0		1.0	
Female	1.577	.400	.841	.672	1.484	.086
Race						
African American/Black	1.0		1.0		1.0	
Caucasian/White	2.019	.519	.433	.161	1.039	.912
Geographic Region						
Northeast	1.0		1.0		1.0	
Midwest	1.411	.291	.112	.009**	.934	.859
South	1.201	.794	.133	.105	1.155	.615
West	1.279	.735	.624	.094	1.233	.480
Urban/Rural Status						
Urban	1.0		1.0		1.0	
Suburban	1.36	.360	1.636	.046	1.328	.164
Ex-Urban/Rural	1.452	.452	1.532	.125	1.423	.032*
IADL Score	1.055	.766	.502	.022*	.941	.498
Number of High-Risk Medications	1.887	.192	.374	.196	1.221	.435
Number of Comorbidities	1.135	.427	.915	.514	1.150	.049*
Family Living Arrangement						
Live with No Family	1.0		1.0		1.0	
Live with Either Spouse of Child	1.234	.595	.192	.145	1.132	.518

NOTE: *p<.05, **p<.01

Chapter 5

DISCUSSION

Chapter 1 presented a literature review, which revealed gaps in ADE research. Chapter 2 determined that using a self-reported ADE measure resulted in a drastic increase in ADE prevalence in the United States Medicare/Medicaid population. Chapter 3 and 4 applied the partial proposed post-ADE framework to determine if the Andersen Model constructs predicted different post-ADE behaviors. This chapter will consist of five sections. First, the three main limitations of past ADE research will be presented in detail. Second, a discussion of how these three conducted studies addressed the gaps in ADE knowledge. Then the findings of the studies will be compared to past literature and what the implications are on research and policy. Lastly, future research directions will be presented.

Gap in ADE Research

Past ADE research investigating ADE risk factors and post-ADE behaviors has three limitations. First, the method of *how* ADE occurrence is captured excludes the patient perspective. The second limitation is *where* ADE occurrence is collected. These two limitations create a bias of capturing only those severe ADEs that lead to healthcare service utilization, such as hospitalization. The third limitation of past ADE research is

that ADE risk factors and determinants of post-ADE literature do not include a comprehensive view of the patients. For example, family support may play a role in *if* a patient experiences an ADE and *what* a patient does after experiencing an ADE. The previous literature focuses on clinical characteristics as risk factors and does not encompass enabling resources or some predisposing factors. This is due to two reasons.

First, past ADE measures capture ADEs in the healthcare setting or based on voluntary reporting of serious adverse drug events. For example, the FDA's NEISS-CADES, described in detail in Chapter 1, underlying definition of an ADE limits measuring ADEs to the emergency department. Another example is the FDA Adverse Event Reporting System (FAERS), which depends on volunteer reporting of ADEs by healthcare professionals and patients. Medical chart reviews are another common ADE measure, but does not allow for the inclusion of ADEs that result in a behavior that does not include healthcare service utilization. Overall, past ADE measures are biased towards capturing those acute, onset ADEs. The second reason why need factors have been of primary interest in ADE research is due to the fact that ADEs have mostly been captured in healthcare settings, such as the hospital or emergency departments. It is logical that when an individual ends up being hospitalized, the clinical characteristics are of interest and easy to measure. However, patients may experience an ADE and perform a post-ADE behavior that would not be able to be captured in past ADE measures. For example, a patient experiences a mild ADE and drives to their community pharmacist to ask what to do. The pharmacist contacts the physician, who in turn, recommends to stop taking the prescription medication and for the pharmacist to change the dose. This post-ADE behavior would not be captured in past ADE measures.

ADE literature had used the following six methods to capture the occurrence of ADEs: The National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance System (NEISS-CADES), the Adverse Event Reporting System (AERS), volunteer reporting by health care professionals, medical chart reviews, patient self-report, and daily observation of patient by health care professionals. The least utilized method of capturing ADE incidence is patient self-report. A patient report of an ADE occurrence is usually confirmed by medical chart review.[1-4] Therefore, if a patient states that they experienced an ADE, but it did not lead to healthcare service utilization, then their report of incidence is excluded from the analyses. These six methods of measuring incidence of ADE take place in six different settings: emergency department [5-8], hospitalization after emergency department visit,[9,10] ADEs that occur in already hospitalized patients,[1, 11-14] general hospital admission,[15-17] post-hospital discharge,[2-4] nursing homes,[18] and the outpatient setting.[19,20]

Finally, the methods and settings to capture ADEs in the previous literature share a common assumption; after experiencing an ADE, the patient utilizes health care in some form. These previous measures of ADEs therefore have a selection bias by including only ADEs that are severe enough for the patient to utilize health care services. The definition of ADE is an injury due to medical treatment. Yet, this definition has no requirement that an individual must seek health care after experiencing an ADE. [21] One study determined that not all individuals seek health care professional help after experiencing an ADE.[22] ADE research has looked only at health care utilization as an indicator of an ADE. However, minor ADEs may lead an individual to stop taking their prescription medication without speaking to their physician. These self-care behaviors

that do not involve the healthcare system may have direct impacts on patient adherence and health outcomes. To our knowledge, before the studies reported here, ADEs leading to self-care have never been studied in any systematic and representative manner.

The final limitation of past ADE research is the narrow view of ADE risk factors and determinants of post-ADE behaviors. As discussed in the literature review, the risk factors for experiencing an ADE were: age, gender, number of comorbidities, number of prescription medications, taking certain medications, number of newly prescribed medications, physical functioning, cognitive ability, weight, and being a new nursing home resident. Not only are these risk factors narrowly focused on clinical characteristics, but the findings on all of these factors are generally mixed because studies had different *methods* of capturing ADEs, different *settings* where ADEs were captured, and different *populations* being studied. In the research focused on older adult healthcare utilization, it has been shown that a more broad view of a patient, including family characteristics, is needed to reveal the determinants of health behavior. Thus, there exists a gap between ADE research and older adult healthcare utilization research, that if filled, would provide a comprehensive look at *who* is experiencing an ADE and *what* behaviors those individuals are performing after experiencing the ADE.

These three studies used a theoretical framework from healthcare utilization research and applied it to ADE research. The objectives of these studies were to determine over time, in the Medicare and Medicaid enrollee population, who experiences ADEs, what post-ADE behaviors these individuals perform, and the role of enabling resources on the occurrence of an ADE and post-ADE behaviors.

Proposed ADE Framework

Past literature has focused on how need factors, such as clinical characteristics, influence the occurrence of ADEs. However, healthcare utilization states that enabling characteristics, such as insurance, wealth, and family characteristics play roles in care and health decision-making. The occurrence of an ADE and the post-ADE behavior performed was proposed to depend on patient and family factors. As discussed in Chapter 1, the Andersen Model of Health Care Utilization provides the skeleton of the proposed framework while the Health Belief Model, Common Sense Model, and Self-Care Deficit Theory explain additional factors that apply to post-ADE behaviors. Combining these models and theories provides the overall proposed theoretical framework to predict ADE occurrence and post-ADE behavior performed. Combined, these predicting factors include patient factors (predisposing characteristics -- health beliefs, medication beliefs, illness representation, socio-demographic characteristics; need factors -- clinical characteristics, ability to self-care) and enabling resources – wealth, insurance, and family factors (Figure 1.2).

The three studies reported here measured only Andersen Model variables of the proposed theoretical framework due to three reasons. First, while the Health Belief Model, Common Sense Model, and Self-Deficit Theory provide evidence that post-ADE behaviors are a result of a decision-making process, the Andersen Model is more comprehensive in that all three general constructs are included, namely patient factors, family factors, and outcome. The second reason to test the Andersen Model portion of the proposed framework was because the Health and Retirement Study (HRS) and the Prescription Drug Study (PDS) were developed to determine the changes in labor force

participation and the healthcare utilization as individuals age. Therefore, it is natural that the HRS and PDS include variables found in the three Andersen Model constructs; predisposing characteristics, need factors, and enabling resources. The final reason why the Andersen Model portion of the overall proposed framework was selected was because the Andersen Model of Health Service Utilization is a commonly accepted framework for researching healthcare decision-making. It was first developed by Andersen in 1968 and has continued to be revised into the most used version, the 1995 Andersen Model (Figure 1.1).[23] Because of these three reasons, it was determined that testing Andersen Model constructs of the proposed framework would be appropriate for the initial investigation into ADE risk factors and ADE post-ADE behaviors, in the Medicare/Medicaid population, that would begin to close the gaps from previous ADE research (Figure 1.3). By using this framework combined with the available data, health beliefs, medication beliefs, and illness representation were the predisposing characteristics that were not included in the studies. Enabling resources excluded from the analyses were family financial contribution to care and having a paid caregiver.

Overview of Findings

ADE Occurrence. In Chapter 2, the Andersen Model was applied to the occurrence of ADEs. The Andersen Model not only captures the clinical characteristics (need factors) that past ADE research focuses on, but also enabling resources that have been shown to play a role in chronic care. For example, those who have self-care deficits may take on a caregiver (family member or paid) or nurse who then perform these behaviors (such as instrumental support and medication management). Therefore, these

enabling resources may influence if an individual experiences an ADE. If an individual has family support in organizing, administering, and/or monitoring the effects of their medications, this support may decrease the likelihood of the individual having an ADE from improper adherence or drug-drug interactions. Subjects' experiences of ADEs were collected in 2005 to 2007.

When nationally representative weights were applied to the data for those who completed both the 2005 PDS and 2007 PDS, it was found that 6,034,077 Medicare/Medicaid enrollees had an ADE in 2005 and 5,839,490 in 2007. Only predisposing characteristics and need factors were related to ADE occurrence. Age, race, and gender were the predisposing characteristics that were related to Medicare/Medicaid enrollees experiencing an ADE. The significant need factors were number of prescriptions and number of comorbidities. It was found that those who were female and had a greater number of comorbidities were more likely to experience one ADE in either year. Those who have one ADE in either year have, on average, more comorbidities and were more likely to be male than those who have no ADEs. Lastly, those that have one ADE in both years were more likely to be younger, have more comorbidities and more regular prescription medications than those that have no ADEs. Figure 5 shows the significant Andersen Model variables that were found to be risk factors for experiencing of ADEs.

Post-ADE Behaviors. Chapters 3 and 4 focused on what post-ADE behaviors Medicare and Medicaid enrollees performed. Chapter 3 determined what different types of behaviors were performed in 2005 and 2007. In order to begin investigation acknowledging that individuals may perform post-ADE behaviors outside of the

healthcare system, post-ADE behaviors were categorized into self-care and care-seeking. Chapter 4 tested how well the Andersen Model constructs predicted self-care or care-seeking post-ADE behaviors. There were six post-ADE behaviors included in the Prescription Drug Study: no action, cutting down or stopping medication on own, stopping medication with doctor's permission, talking to a doctor, visiting a doctor or emergency room, and hospitalization.

All three Andersen Model constructs were related to post-ADE behaviors, but significant variables within the constructs varied for each post-ADE behaviors. Having less than a high school diploma was related to stopping or cutting down on medication on your own when compared to those who have a four-year college degree. Taking fewer prescriptions and being non-Hispanic predicted cutting down or stopping medication with a physician's permission in. Being a nursing home resident and those who live with no family were related to talking to a doctor after experiencing an ADE. Visiting a doctor or going to the emergency room was predicted by having more difficulty with IADLs. Those who live with spouse and a child, an enabling factor, were significantly more likely to go a doctor or emergency room than those who live with no family. Finally, Being hospitalized after an ADE was related to living in the South and number of prescription medications.

In Chapter 4, it was shown that those having a four-year college degree are more likely to seek care within the health care system than those who have less than a high school diploma. In addition, those who are from the Midwest are more likely to seek care than those living in the Northeast. As a subject's IADL score increases (illustrating more difficulty with the tasks), individuals performed more care-seeking post-ADE behaviors

compared to self-care. Moving from the Northeast to the Midwest, preferring self-care to care-seeking decreased. It was also found that as a subject's number of comorbidities increased, subjects preferred to perform both types of behaviors compared to care-seeking only. Medicare/Medicaid enrollees in rural areas prefer to perform both types of post-ADE behaviors than care-seeking only, compared to those older adults who live in an urban area. Figure 6 illustrates the final model of significant Andersen Model variables that predicted post-ADE behaviors from chapter 3 and 4.

Findings Compared to Past ADE Research

ADE Occurrence. Past literature has shown that approximately 700,000 adverse drug events occur each year in the United States.[24] This number was determined by using the Adverse Event Reporting System (AERS) established by the Food and Drug Administration. The AERS collects voluntarily reported ADEs by patients and healthcare professionals. Therefore, this system captures severe ADEs, for the entire United States population, that mostly end in hospitalization, severe injury, or death. This study found that just within the Medicare and Medicaid enrollees, people are experiencing more ADEs than captured before. These studies measured ADEs by self-report, and this methodology leads to capturing ADEs that may be mild or severe. When collecting self-reported ADEs, it was found that almost 8.5 times the amount of ADEs are occurring in just a portion of the population (Medicare and/or Medicaid enrollees).

Post-ADE Behaviors. There has been no past research conducted that applies the Andersen Model of Healthcare Utilization to post-ADE behaviors. However, literature in older adult healthcare utilization has stated that income, wealth, insurance, instrumental

support, number of living children, and living arrangement are predictors of using health services. This study partially aligned with these findings. It was found that family living arrangement and living in a nursing home (proxy for instrumental support) predicted certain care-seeking post-ADE behaviors. However, no other enabling resources that were found to predict health care utilization were found to predict post-ADE behaviors. Although enabling resources impacted certain post-ADE behaviors, when post-ADE behaviors were grouped into type (self-care/care-seeking), enabling factors were not determinants. This may be due to the fact that there was only one self-care behavior captured by the PDS. This not only decreased conceptually self-care into one behavior, but also greatly decreased the sample size.

Evaluation of Proposed ADE Framework

Although the Andersen Model provided a framework to research ADE occurrence, primarily need factors were found to be risk factors, and this aligns with past ADE research. Although literature shows mixed results on all need factors studied, it is generally accepted that need factors are the largest ADE risk factor. Enabling resources were not found to be significant in a sample of 3536 in determining if an individual would experience an ADE. Therefore, when predicting ADE risk factors, a reduced Andersen Model of the predisposing characteristics and need factors constructs was found to provide substantial understanding of who experiences an ADE.

Past literature has focused on post-ADE behaviors that lead to emergency department visits and hospitalizations. These studies focused primarily on the severe ADEs. However, the 1995 Andersen Model of Healthcare Utilization states that

individuals proceed through a health-care decision process to seek care. This disconnect between theory and literature leads to the question: For those who experience a mild ADEs, what do patients do? It was thought that enabling resources would play a critical role during this decision-making process to seek care or to self-care, not just ADE severity. Therefore, the Andersen Model was applied to post-ADE behaviors. Although not all of the proposed framework (Figure 1.2) variables could be measured using the HRS and PDS, the findings herein show that some enabling resources were related to post-ADE behavior performed. Predisposing characteristics and need factors were significant in predicting ADE (Figure 5.1); while the addition of enabling resources helped explain post-ADE behaviors (Figure 5.2).

Future Research

ADE Occurrence. Chapter 2 indicated that those who are disabled might have an increased risk of experiencing multiple ADEs over time. In terms of research, there are two directions that research may take to further ADE research. First, studies need to be completed to confirm that those with disabilities have more ADEs over time. This will add to existing ADE knowledge about what individual characteristics of disabled individuals are related to patient safety, health outcomes, and cost to healthcare system. Another direction is to determine the effectiveness of MTM services on increasing patient safety by decreasing ADEs over time in this vulnerable population. According to the Centers for Medicare and Medicaid Service (CMS), one of the goals of MTM services is to reduce the risk of adverse events. MTM services provide an already existing platform of one-on-one provider-patient interaction to review medications and make

recommendations to optimize therapy. If it is found that MTM greatly impacts patient safety, research to influence policy to capture more of disabled individuals in the clinical or community setting to receive this service.

Post-ADE Behaviors. Following the findings from chapter 3 and chapter 4, there are three research directions that may be taken. First research needs to be conducted to determine what other post-ADE behaviors people are performing. A large limitation to the PDS is that there are only six behaviors measures and of those six, only one is a self-care post-ADE behavior. Qualitative research should be performed to determine what post-ADE behaviors are performed for different populations/predisposing characteristics. For example, findings from these studies clearly showed that geographical region and rural/urban status had a significant role in post-ADE behavior performed. There may potentially be alternative self-care post-ADE behaviors that those in rural areas perform that urban individuals do not. Focus groups should be conducted to determine any alternative post-ADE behaviors and if these post-ADE behavior vary between populations.

The second research direction is to determine how the severity of the ADE links to the post-ADE behavior performed. The self-reported ADE in the PDS could not be tied to a measure of severity (perceived or clinically). These studies illustrated that family living arrangement and being a nursing home resident were related to different post-ADE behaviors. First, future post-ADE research needs to be conducted to confirm this thought. Then, research needs to be conducted to determine the relationship between ADE severity, enabling resources, and post-ADE behaviors. For example, it may potentially be found that those with more instrumental support may perform post-ADE

behaviors that seek care within the healthcare setting, no matter what the severity. Enabling resources may have the opposite impact. For example, those with more instrumental care will seek fewer healthcare services after an ADE because they have individuals to care for them.

The final research direction that is proposed from these chapters' findings is to investigate the cost to the healthcare system for different post-ADE behaviors. Cost to the healthcare system has been focused on emergency department visits and hospitalizations. However, doctor's visits, speaking to a doctor over the phone, or taking a community pharmacist's time away from dispensing to counsel or call a physician, creates cost consequences. This is important to investigate because the findings may be able to identify potential policy changes to make post-ADE behavior more cost-effective. For example, providing more in-home coverage for high-risk ADE patients may be a more-cost effective approach than for that patient to frequently use ambulance and emergency department services.

Practice Implications

There are three implications from these studies to measure ADEs and decrease patients' risk of experiencing ADEs. Due to changes in healthcare law, there has been a shift in focus for hospitals, physicians, and pharmacists. Hospitals are now paid for services based on the *quality* of care, not just *quantity* of the services they provide, and this will require research to be conducted differently. The change to value-based purchasing in hospitals, how the findings from these three studies may be applied to this new model, and needed changes to ADE research to align with value-based purchasing

will be discussed.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized the Hospital Inpatient Quality Reporting Program. This program implemented infrastructure to collect hospital quality data. The congress then authorized hospital value-based purchasing (HVBP) as part of the 2010 Affordable Care Act. The HVBP is part of the Centers for Medicare & Medicaid Services' (CMS') effort to link Medicare's payment system to improve healthcare quality, including the quality of care provided in the hospital setting. This program is designed to promote better clinical outcomes, decrease cost, and improve patient experience of care. One goal of the HVBP program is to eliminate or reduce the occurrence of adverse drug events.

This shift in administrative focus will trigger changes in research. Hospitals will be more interested in decreasing potential adverse events. Chapter 2 findings illustrated that within the Medicare/Medicaid enrollees, there exists a subpopulation that are at higher risk for experiencing more ADEs. It would be beneficial for hospital administration and health service researcher to design, implement, and measure the effectiveness of an ADE element, such as a section for practitioners to complete and enter documentation during appointment or consultations. This element would lie within the already existing hospital electronic medical records (EMR) in reducing potential ADEs in hospitalized and community-dwelling patients. This EMR element would allow nurses and practitioners to enter information about self-reported ADE experience since last visit, post-ADE behaviors performed, enabling resources available to assist in this time of need, and the ability to link directly with any past healthcare service utilization for ADE for any clinical validation for severe ADEs. Future ADE research should not only be looking at

healthcare utilization (like past literature only looking at ADEs leading to hospitalizations and death), but on the quality/value of healthcare services. This simple addition to the EMR system may reduce potential ADEs, improve patient care experience, and decrease cost. These outcomes align directly with the new HVBP.

Another value-based purchasing strategy CMS has implemented is the star rating system for health insurance plans. The goal of this program is to educate consumers on the quality of their Medicare Advantage Plans by making quality data transparent. Scores are calculated and stars (ranging from 0-5 stars) are awarded and published annually for viewing by all Medicare members prior to Open Enrollment. One of the four domains of start ratings for Medicare Part D is patient safety. Because of the star rating criteria based on quality of care, pharmacists are in a prime position to provide MTM services that may indeed affect these criteria. Although MTM services are already offered and reimbursed, the provision of MTM services is low. As well, CMS has recently changed the eligibility for MTM to include more people. Like the addition to hospital EMRs presented above, if CMS adds an explicit ADE/post-ADE element to the MTM services, pharmacists then have the time to discuss patients' medications, how to identify ADEs specific to those medications, and the appropriate post-ADE behaviors to perform given their enabling resources available. Not only may this improve patient care, but it also allows for the tracking of patients self-reported ADE and post-ADE behaviors performed. These data would contribute to policy changes to assist different populations in reducing ADEs and to provide mechanisms for individuals to perform appropriate post-ADE behaviors.

With changes in healthcare to focus on quality not quantity of care, a change in how ADEs are measured is needed. This became apparent in these three studies. These studies found that individuals are self-reporting almost 8.5 times the amount of ADEs as captured by the FDA Adverse Event Reporting System (FAERS). This is because the FAERS documents severe ADEs. This is important, because if more Medicare/Medicaid enrollees are self-reporting experiencing ADEs more than previously captured within the healthcare system, then this implies that not all individuals are seeking care within the healthcare system. This may be a good thing to keep costs down by self-care, but it may indicate that Medicare/Medicaid beneficiaries are not accessing the care they need. In the ideal situation the measure of an ADE would be a summed account of self-reported ADE and a clinical evaluation of severity. It is important to include self-report to capture mild ADEs that may occur in the outpatient setting. The clinical evaluation, if applicable, is commonly determined at emergency department visit or hospitalization. The clinical evaluation would capture severe ADEs. These two items would then create a more accurate measure of ADE experience and severity. This combined measure of ADE experience would be better related to post-ADE behavior performed.

There are two additional health policy and practice implications to assist patients, family, and caregivers to seek information on how to handle an ADE and the ability to perform appropriate post-ADE behaviors. First, a telepharmacy or telehealth practice could be established to assist those who live in rural areas. This study found that those in rural areas were more likely to self-care and stop taking their medication without physician permission. Therefore, a telehealth practice that offers comprehensive medication reviews (CMR), MTM, and provides emergency ADE services to rural

patients may decrease not only the risk of experiencing an ADE, but the ability for patients to speak to a practitioner directly for proper post-ADE advice. Rural patients would then be able to perform proper post-ADE behaviors under the supervision of a practitioner.

This study illustrated that family living arrangement played a role in seeking health care services. In addition, Chapter 2 findings indicate that there exists a subpopulation of Medicare/Medicaid enrollees that experience ADEs more often than others. Therefore, health policy may be developed to identify these high-risk patients, measure the amount of instrumental care these patients have, and provide additional in-home care to those who have deficit in instrumental care. It was also discussed in Chapter 2 that there is a great possibility that those who have more ADEs are those Medicare/Medicaid enrollees who are disabled. Therefore, it may be beneficial for health policy to evaluate their provided in-home care to determine if there are additional services that may be provided to enable patients to utilize health care services under the stressful situation of experiencing an ADE. For example, Medicare and Medicaid may establish an emergency ADE hotline. Patients, family, and caregivers may call this hotline while an ADE is being experienced, talk with a practitioner to determine best course of action, and to provide immediate in-home care or transportation services if decided to be necessary to seek health care services.

These findings also indicate that pharmacy education curriculum must change to include aspects of self-reported ADEs and post-ADE behaviors. Patient counseling is a critical content area within pharmacy education. Instructors should teach that when a patient comes in with a new prescription, pharmacists should counsel on what post-ADE

behaviors are appropriate to that specific prescription medication. In addition, when subjects come in for a refill, pharmacists should ask, "have you experienced an unwanted effect from your medication?" If the patient answers, 'Yes', then this is a time where pharmacists can follow-up on what post-ADE behaviors the patient performed. If a patient performed an improper post-ADE behavior, the pharmacists can then provide information on appropriate behaviors. If the pharmacist determines that the patient experienced an ADE and did not talk to their physician, the pharmacist can then inform their physician of this. It is important to take these findings and apply them to pharmacy education.

Overall, this study illustrates that changes need to be made in order for ADEs to be captured accurately and practitioners need to discuss appropriate post-ADE behaviors to their patients. Second, additional documentation could become a component of MTM services and added to institutional EMR systems. These actions would assist in risk management and allow for surveillance of patient and provider behavior to assist in improving the quality of healthcare. Finally, this study also indicated that rural Medicare/Medicaid patients may benefit from telehealth or similar technology, and potential additions may need to be made to Medicare and Medicaid provided in-home care services for those beneficiaries who are considered to be high-risk ADE patients.

Conclusions

These studies aimed to determine if there exist relationships between the Andersen Model constructs (predisposing characteristics, need factors, and enabling resources) and ADE occurrence and post-ADE behaviors. Predisposing characteristics

and need factors were significant in predicting ADE risk factors, while all three constructs helped explain post-ADE behaviors.

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FIGURE 5.1: FINDINGS FROM TESTED FRAMEWORK FOR ADE OCCURRENCE

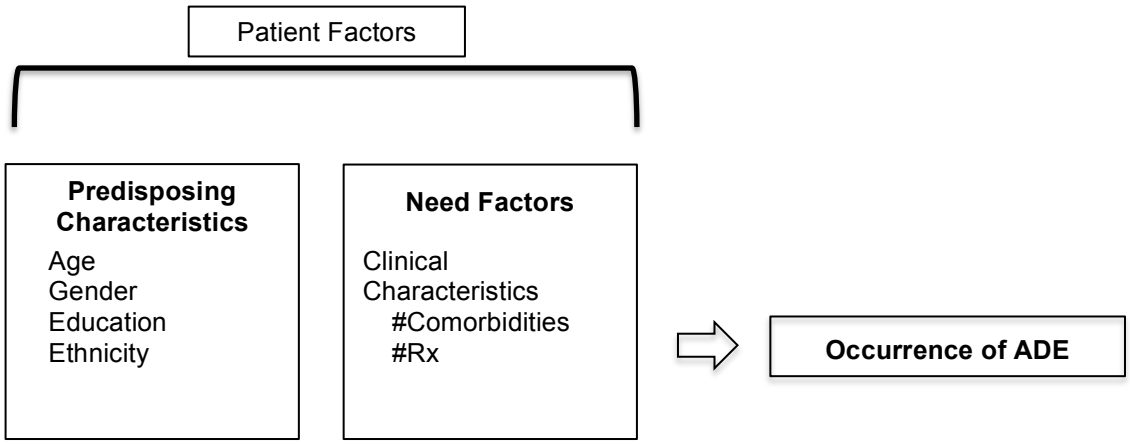
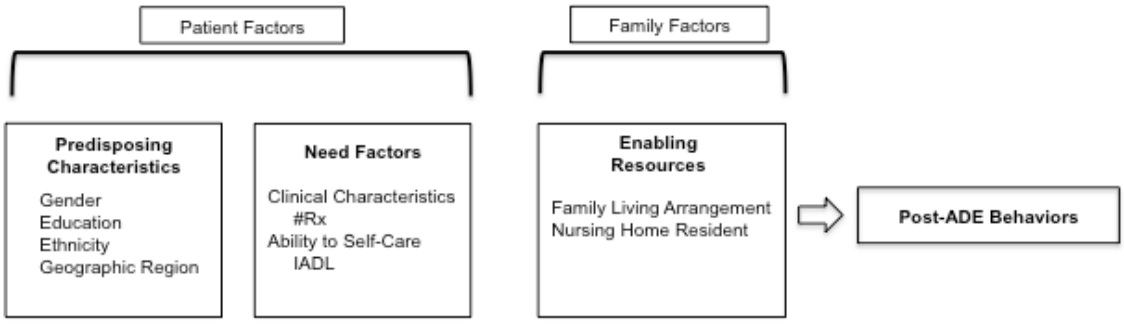


FIGURE 5.2: FINDINGS FROM TESTED FRAMEWORK FOR POST-ADE BEHAVIORS



APPENDIX A: HEALTH AND RETIREMENT STUDY AND PRESCRIPTION DRUG STUDY SAMPLING METHODS AND WEIGHTS

HRS Sampling

The HRS sample is comprised of five sub-samples. Quoted from "Health and Retirement Study 2004 Core: Data Description and Usage. Final, Version 1.0" The Institute for Social Research, The University of Michigan. October 2006. "The first sub-sample, the HRS sub-sample, consists of people who were born 1931 through 1941 and were household residents of the conterminous U.S. in the spring 1992, and their spouses or partners at the time of the initial interview in 1992 or at the time of any subsequent interview. The HRS sub-sample was interviewed in 1992 and every two years thereafter.

The AHEAD sub-sample consists of people who were born in 1923 or earlier, were household residents of the conterminous U.S. in the spring 1992, and were still household residents at the time of their first interview in 1993 or 1994, and their spouses or partners at the time of the initial interview or at the time of any subsequent interview. The AHEAD sub-sample was interviewed in 1993-94, 1995-96, 1998 and every two years thereafter.

The War Baby (WB) sub-sample consists of people who were born in 1942 through 1947, were household residents of the conterminous U.S. in the spring 1992, who, at that time, did not have a spouse or partner born before 1924 or between 1931 and 1941, and were still household residents at the time of the first interview in 1998, and

their spouses or partners at the time of the initial interview or at the time of any subsequent interview. The War Baby sub-sample was interviewed in 1998 and every two years thereafter.

The Children of the Depression (CODA) sub-sample consists of people who were born in 1924 through 1930, were household residents of the conterminous U.S. when first interviewed in 1998, and who, at that time, did not have a spouse or partner who was born before 1924 or between 1931 and 1947, and their spouses or partners at the time of the initial interview or at the time of any subsequent interview. The Children of the Depression sub-sample was interviewed in 1998 and every two years thereafter.

The Early Baby Boomer (EBB) sub-sample consists of people who were born in 1948 through 1953, were household residents of the U.S. when first interviewed in 2004, and who, at that time, did not have a spouse or partner who was born before 1948, and their spouses or partners at the time of the initial interview."

PDS Sampling

The sample for the Prescription Drug Study (PDS) was drawn from respondents to HRS 2004. Of the 20,129 respondents from the HRS 2004, 14,242 met the criteria for selection into PDS. The study sample included HRS respondents born in 1942 or earlier (65^{th} birthday in 2007), *or* already covered by Medicare or already covered by Medicaid at some time between 2002 and 2004. Approximately 40% of those who were eligible were excluded because they were participants in the Consumption and Activities Mail

Survey, an additional study that sampled from the HRS and occurred at the same time as the PDS. A sample of 5,654 persons was drawn from the remaining eligible respondents, with oversamples of persons lacking prescription drug coverage or having low income and wealth.

The survey was mailed to selected respondents in October 2005. Initial non-respondents to the mail survey were contacted by phone and asked to complete a telephone interview. The field period continued through March 2006. It was determined that 340 persons died prior to the October 2005 start of the first wave of the Prescription Drug Study and therefore excluded from the study. Of the 5,314 remaining eligible cases, 4,684 returned questionnaires or completed a telephone interview, for a response rate of 88.1%. Both 2005 and 2007 PDS questionnaire weights are a product of the HRS sampling weight, adjustment factor for sample selection, and non-response adjustment factors.

Prescription Drug Study Weights

From: http://hrsonline.isr.umich.edu/sitedocs/sampleresponse.pdf

As quoted by "2007 Prescription Drug Study: Data Description and Usage" The Institute for Social Research, The University of Michigan. Final Release V1.0, March 2011. The HRS (Health and Retirement Study) is sponsored by the National Institute on Aging (grant number NIA U01AG009740) and is conducted by the University of Michigan.

"The PDS questionnaire weight is the product of the HRS core sampling weight, an adjustment factor for sample selection, and a non-response adjustment factor. The HRS sampling weight from the most recent preceding interview (HRS 2004 or 2006) was used as the base weight. The sample selection adjustment is the inverse of the sampling rate among eligibles in each of the sample strata defined by prescription drug coverage and household income and wealth levels in 2004. The non-response adjustment factor was obtained from a propensity model predicting the probability of completing the PDS questionnaire among those selected and eligible to participate. The propensity model was estimated by logistic regression and weighted by the base weight, adjusted for PDS sample selection. Predictor variables included age, sex, race/ethnicity, education, coupleness, self-rated health, number of physical limitations, type of drug coverage, and level of out-of-pocket spending on drugs. Predictor variables were taken from the most recent preceding interview, either 2004 or 2006. The inverse of the fitted probability of completion formed the non-response adjustment factor. Finally, the weights were post-stratified to closely match the HRS 2006 sample composition by age, gender, and race.

The medication analysis weight is the product of the PDS questionnaire weight and a non-response adjustment for non-response. The non-response adjustment factor is calculated for each level of self-reported drug count (from 1 to 10+). The inverse of the weighted probability of completing Section E (drug information section) forms the non-response adjustment factor."

APPENDIX B: DESCRIPTION AND HANDLING OF MEASURES

Beale Codes

Metro counties are coded as follows: 0 (Central counties of metro areas of 1 million population or more), 1 (Fringe counties of metro areas of 1 million population or more), 2 (Counties in metro areas of 250,000 to 1 million population), 3 (Counties in metro areas of fewer than 250,000 population). Non-metro counties are coded as: 4 (Urban population of 20,000 or more, adjacent to a metro area), 5 (Urban population of 20,000 or more, not adjacent to a metro area), 6 (Urban population of 2,500 to 19,999, adjacent to a metro area), 7 (Urban population of 2,500 to 19,999, not adjacent to a metro area), 8 (Completely rural or less than 2,500 urban population, adjacent to a metro area), 9 (Completely rural or less than 2,500 urban population, not adjacent to a metro area), 88 (Unknown-Alaska State/not official USDA Beale code), and 99 (Unknown/not official USDA Beale code).

HRS Geographic Codes

HRS codes geographic regions as follows: (1) Northeast Region: New England Division (ME,NH,VT,MA,RI,CT), (2) Northeast Region: Middle Atlantic Division (NY,NJ,PA), (3) Midwest Region: East North Central Division (OH,IN,IL,MI,WI), (4) Midwest Region: West North Central Division (MN,IA,MO,ND,SD,NE,KS), (5) South Region: South Atlantic Division (DE,MD,DC,VA,WV,NC,SC,GA,FL), (6) South

Region: East South Central Division (KY,TN,AL,MS), (7) South Region: West South Central Division (AR,LA,OK,TX), (8) West Region: Mountain Division (MT,ID,WY,CO,NM,AZ,UT,NV), (9)West Region: Pacific Division (WA,OR,CA,AK,HI), (10) DK, NA; US, NA state; (11) Not in a Census Division (includes U.S. territories and Puerto Rico); (12) Foreign Country, and (13) Blank (Not interviewed this wave).

Initial evaluation of mobility to determine skip pattern in Section G (Physical Limitations) of HRS.

In order to make subject interviews as efficient as possible, HRS developed an initial evaluation of mobility to determine if the subject was able to skip certain physical functioning items. This initial evaluation includes 10 items. They are as follows: because of a health problem, do you have difficulty with (1) walking one block? (2) sitting for about two hours? (3) getting up from a chair after sitting for long periods? (4) climbing several flights of stairs without resting? (5) climbing one flight of stairs without resting? (6) stooping, kneeling, or crouching? (7) reaching or extending your arms above shoulder level? (8) pulling or pushing large objects like a living room chair? (9) lifting or carrying weights over 10 pounds, like a heavy bag of groceries? (10) picking up a dime from a table? Response options include: Yes, No, Can't do, Don't do, Don't know, Refuse to Answer

HRS then completed a count of the number of items the subject answered Yes, Can't do, Don't do, or Don't know. If subject scored a zero on this count, it illustrates that he/she has no difficulty in mobility due to a health problem. If this were the case, the

subject was intentionally skipped over the ADL items. If the subject had a count of one or greater, they were given the ADL items.

The HRS created a summed score of the initial mobility evaluation. Subjects were intentionally skipped over the ADL items if they had no mobility issues. In this study, these subjects with no mobility issues, were recoded as 'No' to all ADL items. For all subjects, a summed ADL score was created. Subjects can have a final summed score of 0 to 6 (no difficulty to difficulty with all ADLs).

APPENDIX C: NATIONAL COMMITTEE OF QUALITY ASSURANCE LIST OF HIGH-RISK MEDICATIONS

HIGH RISK MEDICATIONS

as specified by NCQA's HEDIS Measure: Use of High Risk Medications in the Elderly

Antianxiety (includes combination drugs)	• aspirin-meprobamate • meprobamate
Antiemetics	• scopolamine • trimethobenzamide
Analgesics (includes combination drugs)	• acetaminophen-diphenhydramine • ketorolac • diphenhydramine-magnesium salicylate
Antihistamines (includes combination drugs)	• APAP/dextromethorphan/diphenhydramine • APAP/diphenhydramine/phenylephrine • APAP/diphenhydramine/pseudoephedrine • acetaminophen-diphenhydramine • atropine/CPM/hyoscyamine/PE/PPA/scopolamine • carbetapentane/diphenhydramine/phenylephrine • codeine/phenylephrine/promethazine • codeine-promethazine • cyproheptadine • dexchlorpheniramine • dexchlorpheniramine/dextromethorphan/PSE • dexchlorpheniramine/guaifenesin/PSE • dexchlorpheniramine/hydrocodone/phenylephrine • dexchlorpheniramine/methscopolamine/PSE • dexchlorpheniramine-pseudoephedrine • dextromethorphan-promethazine • diphenhydramine • diphenhydramine/hydrocodone/phenylephrine • diphenhydramine-

	tripelennamine • diphenhydramine-magnesium salicylate • diphenhydramine-phenylephrine • diphenhydramine-pseudoephedrine • hydroxyzine hydrochloride • hydroxyzine pamoate • phenylephrine-promethazine • promethazine • tripelennamine
Antipsychotic, typical	• mesoridazine • thioridazine
Amphetamines	• amphetamine- dextroamphetamine • benzphetamine • dexmethylphenidate • dextroamphetamine • diethylpropion • methamphetamine • methylphenidate • pemoline • phendimetrazine • phentermine
Barbiturates	• amobarbital • amobarbital-secobarbital • butabarbital • mephobarbital • secobarbital • pentobarbital • phenobarbital
Long-acting benzodiazepines (includes combination drugs)	• amitriptyline-chlordiazepoxide • chlordiazepoxide-clidinium • flurazepam • chlordiazepoxide • diazepam
Calcium channel blockers	• nifedipine—short-acting only
Gastrointestinal antispasmodics	• dicyclomine • propantheline
Belladonna alkaloids (includes combination drugs)	• atropine • atropine/hyoscyamine/PB/scopolamine • atropine-difenoxin • atropine-diphenoxylate • atropine-edrophonium • belladonna • belladonna/caffeine/ergotamine/pentobarbital • belladonna/ergotamine/phenobarbital • butabarbital/hyoscyamine/phenazopyridine

	• digestive enzymes/hyoscyamine/ phenyltoloxamine • hyoscyamine • hyoscyamine/methenam/m-blue/phenyl salicyl • hyoscyamine-phenobarbital
Skeletal muscle relaxants (includes combination drugs)	• ASA/caffeine/orphenadrine • ASA/carisoprodol/codeine • aspirin-carisoprodol • aspirin-meprobamate • aspirin-methocarbamol • carisoprodol • chlorzoxazone • cyclobenzaprine • metaxalone • methocarbamol • orphenadrine
Oral estrogens (includes combination drugs)	• conjugated estrogen • conjugated estrogen- medroxyprogesterone • esterified estrogen • estropipate • esterified estrogen- methyltestosterone
Oral hypoglycemics	• chlorpropamide
Narcotics (includes	• ASA/caffeine/propoxyphene • meperidine-promethazine
combination drugs)	• acetaminophen-pentazocine • acetaminophen-propoxyphene • belladonna-opium • meperidine • naloxone-pentazocine • pentazocine • propoxyphene hydrochloride • propoxyphene napsylate
Vasodilators	• cyclandelate • ergot mesyloid • dipyridamole—short-acting only • isoxsuprine
Others (including androgens and anabolic steroids, thyroid drugs, urinary anti-infectives)	• methyltestosterone • nitrofurantoin macrocrystals- • nitrofurantoin • nitrofurantoin macrocrystals monohydrate • thyroid desiccated

http://www.ncqa.org/Portals/0/newsroom/SOHC/Drugs_Avoided

APPENDIX D: ADDITONAL TABLES FOR CHAPTER 3

TABLE D.1: INSIGNIFICANT FULL MODELS FOR DIFFERENT POST-ADE BEHAVIORS

	Taking No Action 2005 (n=506)	**Taking No Action 2007 (n=465)**	**Stop or Cut Down on Own 2007 (n=465)**	**Stop or Cut Down with Doctor's Permission 2005 (n=506)**	**Talk to Doctor 2007 (n=465)**	**Visit Doctor's Office/ Emergency Department 2005 (n=506)**
Model	X^2=15.497, p=.929	X^2=24.895, p=.302	X^2=21.455, p=.718	X^2=24.104, p=.625	X^2=16.543, p=.867	X^2=18.579, p=.854
	OR	**OR**	**OR**	**OR**	**OR**	**OR**
Predisposing Factors						
Age	1.071	1.113*	1.002	1.003	1.010	.989
Gender						
Female	1.0	1.0	1.0	1.0	1.0	1.0
Male	1.250	.679	.597	1.229	1.161	.968
Ethnicity						
Non-Hispanic	1.0	-	1.0	1.0	1.0	1.0
Hispanic	.830	-	3.530	1.306	1.609	1.862
Race						
White/Caucasian	1.0	1.0	1.0	1.0	1.0	1.0
Black/African American	2.123	.957	1.084	1.839	.672	1.032
Other	4.932	-	.515	1.174	-	.771

Geographic Region						
Northeast	1.0	1.0	1.0	1.0	1.0	1.0
Midwest	1.845	3.959	.602	2.041	1.737	2.267
South	2.316	.673	1.150	1.339	1.909	1.360
West	3.704	.800	.887	1.137	1.787	1.904
Population Size						
Urban	1.0	1.0	1.0	1.0	1.0	1.0
Suburban	.543	4.101	1.391	.811	.515	.795
Rural	1.203	2.969	1.966*	1.057	.818	.945
Education						
Less than High School	1.0	1.0	1.0	1.0	1.0	1.0
High School/GED	2.082	.992	1.321	.994	.724	1.526
At least 4-year degree	2.071	1.219	1.675	.979	.845	1.991
Enabling Resources						
Private/Supplemental Insurance						
No	1.0	1.0	1.0	1.0	1.0	1.0
Yes	.636	.366	.973	1.176	1.103	.952
Ability to Drive						
No	1.0	1.0	1.0	1.0	1.0	1.0
Yes	.551	1.593	1.542	1.051	1.452	.789
Family Living Arrangement						
Live with no family	1.0	1.0	1.0	1.0	1.0	1.0
Live with spouse or a child	2.398	1.231	1.069	.499*	1.481	.616
Live with spouse and a child	4.734		1.516	1.046	.377	.872
Family Availability						
No children within 10 miles	1.0	1.0	1.0	1.0	1.0	1.0
At least one child within 10 miles	1.370	1.302	.955	.689	1.104	1.117
At lease one child within 2 blocks	-		.615	.816	-	1.524
Number of Children	1.055	.971	1.013	.992	.952	.964
Nursing Home Resident						
No	-	-	-	1.0	-	-
Yes	-	-	-	1.149	-	-
Wealth	1.000	1.000	1.000	1.000	1.000	1.000

Need Factors						
ADL	.641	.643	1.099	1.063	1.114	1.071
IADL	.997	1.599	.960	.935	1.183	1.174
Number of Comorbidities	1.069	1.364	1.050	.878	.951	1.001
Number of Prescriptions	.931	.891	1.029	1.084	1.051	.982
Number of High-Risk Medications	.826	4.118	.875	1.226	1.296	.937
Cognition	.937	.984	1.006	1.025	1.044	1.006

*p<0.05

TABLE D.2: INSIGNIFICANT REDUCED MODEL OF TAKING NO ACTION IN 2007

REDUCED MODEL (X^2=5.920, P=.314)		
	OR	**p-value**
Age	0.998	0.272
Gender		
Female	1	
Male	0.847	0.404
Race		
Caucasian/White	1	
African American/Black	1.132	0.687
Hispanic	1.468	0.714
Population Size		
Urban	1	
Rural	0.1.401	0.116

TABLE D.3: INSIGNIFICANT REDUCED MODEL OF STOPPING OR CUTTING BACK ON PRESCRIPTION ON OWN IN 2007

REDUCED MODEL (X^2=5.920, P=.314)		
	OR	**p-value**
Age	0.987	0.965
Gender		
Female	1	
Male	0.847	0.404
Race		
Caucasian/White	1	
African American/Black	1.132	0.687
Hispanic	11.468	0.297
Population Size		
Urban	1	
Rural	0.1.401	0.116

TABLE D.4: INSIGNIFICANT REDUCED MODEL FOR STOPPING OR CUTTING DOWN ON PRESCRIPTION WITH DOCTOR'S PERMISSION IN 2005

REDUCED MODEL (X^2=7.758 P=.170)		
	OR	**p-value**
Age	1.001	0.911
Gender		
Female	1	
Male	1.130	0.544
Race		
Caucasian/White	1	
African American/Black	0.952	0.867
Hispanic	1.87	0.235
Family Living Arrangement		
Live with no family	1	
Live with spouse or child	0.578	0.006