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HEALTH LITERACY: A COMMUNITY-BASED MIXED METHODS STUDY OF  
PRESCRIPTION MEDICATION SELF-MANAGEMENT AMONG  
COMMUNITY DWELLING OLDER ADULTS

by

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A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham,  
in partial fulfillment of the requirements for the degree of  
Doctor of Philosophy

BIRMINGHAM, ALABAMA

2011

HEALTH LITERACY: A COMMUNITY-BASED MIXED METHODS STUDY OF  
PRESCRIPTION MEDICATION SELF-MANAGEMENT AMONG  
COMMUNITY DWELLING OLDER ADULTS

JOY P. DEUPREE

HEALTH EDUCATION/HEALTH PROMOTION

ABSTRACT

During the next decade, it is estimated that 7,918 Americans will turn 60 years old every day. This increase is expected to impact future health care costs. The aging population must be knowledgeable about health care needs to self-manage chronic conditions requiring multiple medications.

Nearly half of all American adults have limited literacy skills. Adults at the lowest literacy levels may misunderstand instructions from a health care professional. Confusion about health care instructions can put patients at risk for adverse drug events.

The purpose of this two-phase, explanatory mixed methods study was to explore how community dwelling adults ages 60 to 74 self-manage five or more daily prescription medications. Multiple levels of support and influences were examined within the community to determine how each impacted individual health literacy. Adverse drug events from the past 12 months, barriers, and facilitators to medication self-administration were also explored using the Social Ecological Model as the framework for the study.

Using the maximal variation strategy for purposive sample selection, quantitative data were used to compose three distinct cases stratified by health literacy scores. Nine English-speaking community dwelling adults ages 60 to 74 participated in the follow-up, in-depth, qualitative phase. Three themes emerged during the analysis of each case; accuracy of self-administration of five or more daily prescribed medications, issues related

to prescription medication adherence, and resources for assistance with medication administration. Further, 13 sub-themes emerged; the most prominent sub-themes were community support, patient-provider communication, pharmacy support, confusion related to generic substitutions, medication side effects, self-efficacy and family and friends.

Analysis revealed regardless of health literacy level or the number of daily prescribed medications, participants demonstrated high accuracy of self-management for their medications. A likely explanation for these findings may be attributed to a community resource program which provides multiple levels of support for the senior within the community of interest.

In 2007, limited health literacy was documented to add up to \$238 billion of unnecessary costs to an already overburdened health care system. Future research and interventions should examine factors that influence relationships between health literacy and positive health outcomes.

## DEDICATION

This dissertation is dedicated to my daughter, Jenna. During the past two years she has been an exemplary model of the term “grace under fire.” No matter how challenging her circumstances were, she proved that with hard work any goal is achievable. I love you so much Jenna!

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## LIST OF ABBREVIATIONS

AARP	American Association of Retired Persons
ADE	adverse drug events
ALF	assisted living facility
AMA	American Medical Association
AHRQ	Agency for Healthcare Research and Quality
BCBS	Blue Cross Blue Shield
CME	continuing medical education
CRC	community resource center
DQ	Demographic Questionnaire
FDA	Federal Department of Agriculture
HBM	Health Belief Model
IOM	Institutes of Medicine
IOP	Interview and Observational Protocol
JCAHO	The Joint Commission for Accreditation and Hospital Oversight
MASES	Medication Adherence Self-Efficacy Scale
MM	mixed methods
NAAL	National Assessment for Adult Literacy
NALS	National Adult Literacy Survey

## LIST OF ABBREVIATIONS (Continued)

NCES	National Center for Education Statistics
NCL	National Consumers League
NHES	National Household Education Surveys
OTC	over the counter medications
PDM	Participatory Decision Making
PMAR	Personal Medication Administration Record
PWL	prescription warning label
REALM	The Rapid Estimate of Adult Literacy in Medicine
SAFE	Sylacauga Alliance for Family Enhancement
SBCM	Stages of Behavior Change Model
SEM	Social Ecological Model
SenioRx	SenioRx Medication Wellness Program
TOFHLA	Test of Functional Health Literacy in Adults



## CHAPTER ONE

### INTRODUCTION

According to the U.S. Census Bureau (2007), America's population reached 300 million during 2007. In 2008, there were an estimated 60 million persons ages 60 and older in the U.S., an 11% increase from the 2004 estimate of 50 million older adults (U.S. Census Bureau, 2009). An estimated 7,918 individuals will turn 60 years old each day during the next decade (E-Learning Council, 2008). Such rapid growth among the older adult population will have a major impact on future health care costs, primarily due to management of chronic illnesses among the aging population (Schneider & Guralnik, 1990; Shay, 2004). The National Coalition on Health Care (2009) reported national health care spending was expected to reach \$2.5 trillion by the end of 2009, accounting for 17.6% of the gross domestic product with predictions that health care spending will reach \$4.4 trillion by 2018.

Eighty percent of individuals over the age of 65 have at least one chronic condition and 50% have more than one (Larsen & Hoot-Martin, 1999). Twenty-three percent of patients 65 years and older with chronic conditions take at least five prescription drugs on any given day (Kaufman, Kelly, Rosenberg, Anderson, & Mitchell, 2002). Chronic illness requires individuals to be knowledgeable about their health care needs to effectively self-manage prescription medication(s).

Nearly half of all American adults are low literate and have difficulty understanding and acting upon health information (Baker, Parker, Williams, & Clark,

1998). Patients with low literacy skills have more visits to emergency rooms than their more literate counterparts. Adults who are at the lowest literacy level are described as having difficulty understanding instructions from a health care professional, reading a consent form or a label on a prescription bottle (Quirk, 2000).

S. K. Simonds coined the term “health literacy,” which first appeared in the *Health Education Monographs* published in 1974. Since that time, professional organizations and public health agencies have explored health literacy as it relates to educational and health outcomes. The *National Literacy Act of 1991* defined literacy as “an individual’s ability to read, write, and speak in English, and compute and solve problems at the level of proficiency necessary to function on the job and in society, to achieve one’s goals and develop one’s knowledge and potential” (Nielsen-Bohlman, Panzer, Institutes of Medicine [IOM] Committee on Health, & Kindig, 2004, p. 42). The Joint Committee for National School Health Education Standards (JCNHES) (1995) defined health literacy as the “capacity of individuals to obtain, interpret, and understand basic health information and services and the competence to use such information and services in ways which enhance health” (p. 5). The World Health Organization (WHO) provided a similar definition of health literacy, “the cognitive and social skills, which determine the motivation and ability of individuals to gain access to, understand and use information, in ways that promote and maintain good health” (as cited in Nutbeam, 1998, p. 350).

Following the release of the first *National Standards*, the U.S. Public Health Service adopted the National Library of Medicine’s (NLM) definition of health literacy, which states “health literacy is the degree to which individuals have the capacity to

obtain, process, and understand basic health information and services needed to make appropriate health decisions” (as cited in Selden, Zorn, Ratzan, & Parker, 2000).

Similarly, the American Medical Association (AMA) (1999) defined health literacy as “a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment” (p. 552).

### Statement of the Problem

Patients’ level of knowledge regarding their medical condition(s) influences their understanding of the expected course of an illness and treatment regimen (Baker et al., 1998). Low literacy is adversely related to health outcomes including hospitalization and increased health care costs (Baker et al., 1998). How great is the low health literacy problem in the U.S.? More than 90 million Americans have difficulty reading and computing math problems (IOM, 2004). Poor computational skills may lead to errors when attempting to follow instructions for self-administration of prescribed medication(s) (IOM, 2004). For instance, patients with poor reading literacy may read directions, “take one pill two times a day,” to mean “take two pills at one time for the day.” Conry (2000) reviewed professional literature and found that 28% of hospitalizations of older adults was attributed to polypharmacy and adverse drug events (ADEs) yielding increased health care costs. Limited health literacy has been documented to add between \$106 billion to \$238 billion of unnecessary costs per year to an already overburdened health care system (Vernon, Trujillo, Rosenbaum, & DeBuono, 2007).

According to Zagaria (2006), medication errors rank as the most preventable health threat to the elderly. Dennehy, Kishi, and Louie (1996) projected that nearly all

(95%) ADEs were predictable and a majority (approximately 66%) could be prevented. The *Healthy People 2000 Final Review* (NCHS, 2001) found for older people with chronic health problems, the principle drug safety issue of the future will be related to ADEs from polypharmacy as it relates to the use of multiple prescription and non-prescription medications (Larsen & Hoot-Martin, 1999). Kaufman et al. (2002) found a relationship between chronic disease and polypharmacy. Older adults more often use multiple prescription medication(s) than younger people and, therefore, older adults are at a higher risk of experiencing adverse drug events (Larsen & Hoot-Martin, 1999).

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) tracks sentinel events, including prescription medication errors, adverse drug events, and patient outcomes. The JCAHO (2009) identified medication errors as the fifth most common sentinel event in 2007 and the seventh most common in 2008. Sentinel event outcomes include patient death and loss of physical or cognitive function. These catastrophic outcomes lead to pain, suffering, and unnecessary expenditures. Failure to properly administer multiple prescription medications can lead to adverse drug events requiring hospitalization and can cause recurrent illness thereby perpetuating an increase in health care costs, morbidity, and mortality (IOM, 2004).

With the cost of health care escalating, the focus on health care delivery is predicted to change from inpatient care to community-based outpatient care. In order for patients to assume a greater responsibility to effectively self-manage their own prescription medications, it is necessary to enhance patient health literacy and to improve communication between health care providers and patients (Davis et al., 2006).

### Purpose of the Study

The purpose of this two-phase, explanatory mixed methods study was to explore how community dwelling, English-speaking older adults (ages 60 to 74) who participate in programs offered by the Sylacauga Alliance for Family Enhancement (SAFE) and across three levels of health literacy self-manage five or more daily prescription medications. Additionally, adverse drug events, barriers and facilitators for self-administration of prescribed medication were explored as each specifically relate to the social ecological model.

During Phase I (quantitative) of the study, all English-speaking community dwelling older adults from four community senior citizens centers and a senior living facility who have participated in the SenioRx Medication Wellness Program offered by SAFE (N=200) were invited to join the study. The primary purpose of the quantitative phase was to collect the information needed to select individuals for the qualitative or Phase II of the study. The sample size decreased to 50 based on eligibility for the study (age and number of daily prescribed medications).

Descriptive statistics of the community dwelling older adults (ages 60 to 74) across three levels of health literacy who self-manage five or more daily prescription medications and participate in programs offered by SAFE were obtained via self-report (n=50). Using the Demographic Questionnaire (DQ) (see Appendix A), characteristics of each participant were obtained including age, race, gender, marital status, employment, type(s) of health insurance, educational level, composition of household, and annual income. The self-reported Personal Medication Record (PMAR) (see Appendix B) completed by the community dwelling older adults from Phase I of the study provided

information about the five or more prescribed medications and any adverse drug events experienced by them during the previous 12 months. The Test of Functional Health Literacy of Adults (TOFHLA) (see Appendix C) was used to assess participants' health literacy level (inadequate, marginal, and adequate) and to stratify the group into three levels of health literacy for the follow up, qualitative Phase II of the study. Again, the sample was decreased when only 15 of the 50 completed all sections of the DQ, PMAR, and TOFHLA.

Using a maximal variation strategy and using the data collected through completion of the DQ, PMAR and TOFHLA, the investigator narrowed the pool of community dwelling older adults (n=15) from Phase I of the study to nine individuals. Of the nine, three of the community dwelling older adults scored at the lowest level of health literacy (inadequate), three scored at the marginal level of health literacy and three scored in the range of the highest level of health literacy (adequate). Three distinct cases for Phase II (qualitative) of the study were established based on the following criteria: all participated in programs offered by SAFE and were between the ages 60 to 74 at the time of the data collection, were prescribed five or more daily medications, and scored within the range of one of the three levels of health literacy. Finally, prior to progression to Phase II of the study, all nine were screened for adequate vision as participants of the SAFE SeniorRx Medication Wellness Program.

The qualitative phase of the study provided an in-depth understanding of how community dwelling older adults ages 60 to 74 from three different health literacy levels self-manage five or more daily prescription medications. Additionally, the qualitative phase helped to identify specific barriers and facilitators for accurate self-management of

daily prescription medications as they relate to the SEM.

Using the mixed methods approach allowed the researcher to generate information about potential relationship(s) between accurate self-management of daily prescription medications and different levels of social support among community dwelling older adults which are independent of his or her health literacy level.

### Quantitative Research Questions

The quantitative phase (Phase I) of this mixed methods sequential explanatory design was guided by the following research questions:

1. What are the characteristics (age, race, gender, marital status, employment, type(s) of health insurance, educational level, composition of household and annual income) of community dwelling older adults who participate in programs offered by SAFE?
2. What level of health literacy do community dwelling older adults who participate in programs offered by SAFE and are prescribed five or more daily prescription medications score within, as measured by the TOFHLA?
3. How many daily medications were prescribed per subject for participants from this study?
4. How frequently did community dwelling older adults ages 60 to 74, who were prescribed five or more daily medications and participated in programs offered by SAFE experience adverse drug events as self-reported on the PMAR?

### Qualitative Research Questions

The qualitative phase (Phase II) of the mixed methods sequential explanatory design was guided by a central research question “How do community dwelling older adults ages 60 to 74 self-manage five or more daily prescribed medications?” The sample population used for the qualitative sub-questions was a group of English-speaking community dwelling older adults (ages 60 to 74) who scored across three levels of health literacy as measured by the TOFHLA and had participated SenioRx Medication Wellness Program offered by SAFE and who were responsible for self-administration of five or more daily prescribed medications.

Sub-questions included:

1. What role does health literacy play in self-management of five or more daily prescribed medications?
2. What are the barriers to accurate self-administration of five or more daily prescribed medications?
3. What are the facilitators for accurate self-administration of five or more daily prescribed medications?
4. How does data collected by the PMAR differ from the participant demonstration of medication self-administration during a planned home observation (i.e. name of drug, dosages, administration form, drug classification, and reasons for use)?
5. How do records on file at SAFE for the SenioRx Medication Wellness Program participants differ from their self-reported PMAR data?
6. How does the level of self-efficacy explain the number of reported adverse



drug events?

7. What role do economic constraints play in accurate self-management of five or more daily prescribed medications?
8. How many constructs of the SEM are useful to explain the outcome(s) of ADEs within the last 12 months?

### Assumptions

The following assumptions were made for the study:

1. Managing multiple prescription medications may be more difficult for community dwelling older adults ages 60 to 74.
2. Regardless of education level, some community dwelling older adults may report difficulty self-managing prescription medications.
3. Environmental and economic influences may serve as barriers or facilitators for self-management of prescription medications.
4. Some medications pose a threat for adverse drug events due to manufacturing changes in physical appearance of the medication (size, color, shape, trade name vs. generic) over time.
5. Community dwelling older adults selected as research participants were able to accurately self-report health conditions, self-administration practices, and adverse drug events.
6. Patient-provider communication often lacks the detail needed for the patient to comprehend importance of proper medication management.
7. Truth space assumption is the expectation that data gathered from participants

is reasonably accurate and believable data, rather than data that are true in some absolute sense.

8. Individuals with a strong support system with multiple levels as outlined by the SEM are able to self-manage multiple daily prescription medications with fewer cases of incidence.
9. High school graduates should score at the adequate level of health literacy as measured by the TOFHLA.

### Framework for the Study

The social ecological model (SEM) was used as the framework to guide this study. The SEM focuses on individual factors, social factors, systematic assessment of and intervention across multiple levels of influence, community organizations, and policy makers to promote change (Stokols, 1996). Within the framework of the study, the researcher examined characteristics of the community-dwelling older adult, participants' interactions with support services, caregivers and others. The home environment in relation to self-management of multiple prescription medications was also explored. For a more detailed description of the SEM, please refer to Chapter Two.

### Definitions of Key Terms

*Adverse drug event* (ADE) is defined as an undesirable health effect due to patient misunderstanding of directions to self-administer medication.

*Community dwelling older adults* are persons ages 60 to 74 who reside independently in the community.

*Concurrent prescription and non-prescription medications* refer to medications (prescribed and over the counter) and taken with or around the same time as prescribed medications.

*Demographic Questionnaire (DQ)* was used to collect information to describe study participants, including age, race, gender, and highest grade completed, number of people they live with and care for, marital status, ability to self-administer prescription medications, employment, type(s) of health insurance, and annual income.

*Explanatory design participant selection model* is the participant selection model used to identify and purposefully select participants for a follow-up, in-depth, qualitative study.

*Functionally illiterate* is a classification of literacy that refers to a person who lacks the skills in reading and writing to cope with the demands of everyday life; one who reads at or below the 5<sup>th</sup> grade level.

*Gestalt effect* refers to the form-fitting capability of our senses, particularly with respect to the visual recognition of figures and whole forms instead of just a collection of simple lines and curves.

*Health literacy* is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

*Legitimation* describes the process used in mixed methods research to make inferences that are credible, trustworthy, dependable, transferable, and/or confirmable.

*Literacy* is broadly defined as the ability to use language to read, write, listen, and speak.

*Low health literacy* is used to classify individuals with limited capacity to read and comprehend written health-related text, e.g. instructions on prescription medicine bottles, appointment slips, informed consent documents, insurance forms, and health educational materials.

*Maximal variation strategy* was used in this study by the researcher to select a small number of units or cases that maximize the diversity relevant to the research question.

*Meta-inference* is a process to integrate the inferences derived from the quantitative and qualitative strands of a mixed methods study.

*Mixed methods study* uses planned quantitative and qualitative data collection and mixing results of the two approaches to yield thick, rich, descriptions of the findings.

*Polypharmacy* is defined in this study as the concomitant use of five or more prescription drugs.

*Self-Efficacy* as defined by Bandura (1985) describes an individual's beliefs about their capabilities to perform a specific action or behavior and exercise influence over events that affect his/her life.

*Truth space* refers to inferential techniques used by the researcher to generalize words and observations derived through careful sampling of the population to represent the underlying context. The researcher strives to represent the reasonably accurate and believable data as represented by participants, rather than data that are true in some absolute sense (Onwuegbuzie, 2003).

## Limitations

Limitations of the study included:

1. The study was limited to one group of people in a small community within a southern state.
2. The use of convenience sampling for the quantitative phase of the study was a limitation because the researcher cannot say with confidence the sample was representative of the population for that age group (Creswell, 2009).
3. Self-reporting bias was minimized because of the multiple resources used to the validate information from the Demographic Questionnaire (DQ) and the Personal Medication Administration Record (PMAR). However, because participants knew that they were going to be held accountable and later questioned again about the information, the answers they recorded may have been influenced by their desire to self-report measures in a socially desirable manner (Adair, 1984).
4. Administration of the Test of Functional Health Literacy of Adults (TOFHLA) was done in accordance with guidelines from the authors of the assessment. When scoring for the TOFHLA, the majority of participants selected for Phase II of this study scored at a high level of accuracy on the questions they did answer. However, few finished the exam due to time constraints which lowered their score. This could have been a limitation for the study. Information from the original study to develop the TOFHLA indicated that there was a statistically significant difference found in scores according to age with older adults scoring

less than younger adults (Williams, Parker, Baker, Parikh, Pitkin, Coates, and Nurss, 1995).

5. A small sample size in the quantitative phase restricted variation in selection of cases for the qualitative follow-up phase.
6. Because of the interpretative nature of qualitative research, the researcher might have introduced bias into the analysis and classification of the themes and sub-themes derived from participant narratives.
7. The analysis and interpretation of the Phase II qualitative data were subjective processes. The researcher's preconceptions and biases may have influenced the analyses and interpretation of the data.
8. Lack of generalizability of the qualitative findings may limit this study.

### Significance of the Study

Health care providers include physicians, nurses, certified health educators, and others. Their roles include promoting, maintaining, and improving individual and community health by assisting individuals and communities through education and the adoption of healthy lifestyle behaviors. Enhancing health literacy among community-dwelling older adults will enable them to more accurately self-manage prescription medications and thereby reduce unnecessary ADEs and health care costs.

Nutbeam (1998) concluded that health literacy is a desirable outcome of health promotion, one that we all seek to improve quality of life. A systematic investigation of the factors related to low health literacy guided by the SEM may contribute to improved outcomes for elders and advance the discipline of health education and health promotion.

It is important to investigate promising programs to improve self-administration of medications for the treatment and management of chronic health conditions due to the increasing population of community dwelling older adults with low literacy skills, increasing prevalence of chronic disease, increasing health care costs, and use of multiple medications found in this age group.

### Summary of the Study

This chapter begins with the introduction of the topics of literacy and health literacy and is followed by the problem statement and purpose statement. Quantitative research questions are outlined, followed by the qualitative research questions and related sub-questions. Assumptions are included for the reader along with details about the framework for the study. Finally, definitions of key terms, limitations of the study and the significance of the study are provided.

## CHAPTER TWO

### REVIEW OF SELECTED LITERATURE

Dr. Richard Carmona, the 17<sup>th</sup> Surgeon General of the United States, embraced the importance of improving health literacy as described in *Healthy People 2010* (U.S. Department of Health and Human Services, 2000). Section 11-2 of *Healthy People 2010* entitled, “Improve the Health Literacy of Persons with Inadequate or Marginal Literacy Skills” states...

Closing the gap in health literacy is an issue of fundamental fairness and equity and is essential to reduce health disparities...The knowledge exists to create effective, culturally and linguistically appropriate, plain language health communications...If appropriate materials exist and people receive the training to use them, then measurable improvements in health literacy for the least literate can occur.

Since 1974 when the term “health literacy” was coined by S. K. Simonds, the volume of researched-based publications on the topic of health literacy has progressively grown. Health care professionals, policy makers, institutions, and patients continue to search for programs that will improve communication between all entities of the health care team.



### Established Research

Most studies conducted to explore the nature of health literacy and self-management of prescribed medication for this study were quantitative in nature; these studies primarily reported the percentage of populations that have difficulty with health literacy (Berkman et al., 2004). As of 2003, several hundred studies had been published related to the topic of health literacy. By 2009, over 3,000 studies were identified, with the majority using quantitative research methods, descriptive in nature and primarily documenting levels of health literacy among selected groups.

DeWalt, Berkman, Sheridan, Lohr, and Pignone (2004) suggested future researchers should examine factors that mediate the relationship between literacy and health outcomes of older adults such as polypharmacy and ADEs leading to medical treatment. This dissertation study used a mixed methods approach sequential explanatory design to understand the perceptions and experiences of older adults who are prescribed five or more daily medications (Creswell, 2009). The outcomes of this study provided an understanding of the barriers and facilitators for accurate medication self-administration among community dwelling older adults.

This study adds to the body of literature and provides valuable information that may be used for future, more in-depth studies. Future studies should explore the gap in professional knowledge about the relationships among health literacy, self-administration of five or more prescription medications and how support services and community resources can assist individuals with decreasing adverse drug events.

Chapter Two of this proposal provides a detailed summary of literacy and health literacy rates in America, the demographics of aging, and information about how

community dwelling older adults are affected by adverse drug events related to polypharmacy. Empirical studies presented provide information about the associations of health literacy and health outcomes. A framework to guide the investigation for this study explored opportunities for how support services and resources at every level of the Social Ecological Model (SEM) may be used for the development of an intervention upon conclusion of the study.

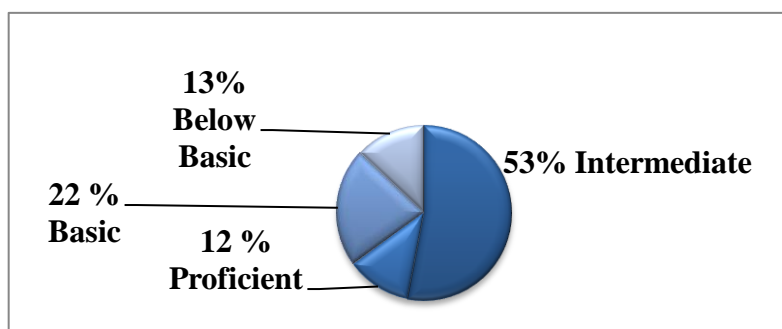
### Demographic Differences in Literacy Rates among Adults in the United States

#### *National Literacy Assessments*

In the past 20 years, studies have been conducted to determine the levels of adult literacy in America. The most frequently cited studies are the 1992 National Adult Literacy Survey (NALS) and the 2003 National Assessment of Adult Literacy (NAAL), both conducted by the National Center for Education Statistics (NCES). There are subtle differences between the two national surveys and how they were conducted; however, the statistical analysis of the data indicates little improvement in the numbers of individuals affected by low literacy from 1992 to 2003 (Hauser, Edley, Koenig, & Elliott, 2005).

Differences between the test items on the NALS and the NAAL are minor. The NALS assessed literacy only for English-speaking participants and the NAAL was available in Spanish or English. Ten years later, the NAAL added a health literacy section and was the first large-scale national assessment to test health literacy. Continued assessment of health literacy could add to the body of research thereby allowing investigators to compare changes across the decade.

Results of the NAAL administered in 2003 revealed that 53% of adults demonstrated “intermediate health literacy.” An additional 12% of adults had “proficient health literacy;” 22% of American adults in the sample were classified as having “basic health literacy skills.” The remaining 13% demonstrated “below basic health literacy” (NCES, 2003). A comparison of these statistics is presented below in Figure 1.



*Figure 1.* Health literacy levels categorized in percentages as reported by the National Assessment of Adult Literacy (NAAL).

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*Note.* From “National Assessment of Adult Literacy” by the National Center for Education Statistics, 2003, Washington, DC: Author. Copyright 2003 by Author. Public domain material.

The NAAL scores determined that there were gender differences in health literacy. Women had higher average health literacy scores than men. Sixteen percent of the men scored at the health literacy level of “below basic,” compared with 12% of women assessed.

Adults ages 65 and older had lower average health literacy than adults in younger age groups. The percentage of adults in the 65 and older age group who ranked as having intermediate and proficient health literacy was lower than the comparable percentage of adults in other age groups.

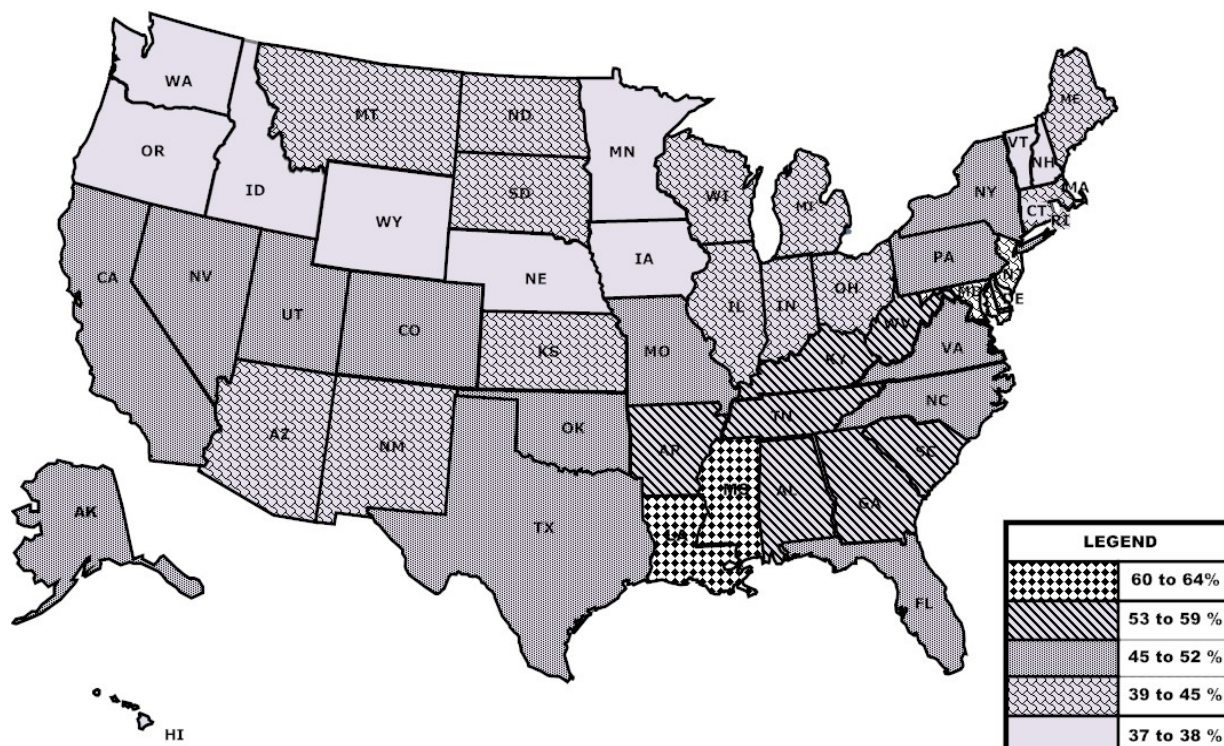
Adults living below the federal poverty level had lower average health literacy than adults living above the poverty threshold. Thirty-six percent of those at the federal poverty level reported having difficulty with literacy; interventions are needed to improve understanding of basic language and computations for this demographic group.

### *State Literacy Data*

Reder compiled a report to describe the states which had scored at the lowest literacy levels of 1 (below basic) or 2 (basic) on the NALS (as cited in Matthews and Sewell, 2002). This report provided valuable information to policymakers and educators so that they could plan and implement initiatives to improve and enhance literacy. Individuals scoring at literacy levels 1 or 2 include those who are functionally illiterate and those who can (a) read and understand basic information through simple prose text in simple documents, (b) follow basic written instructions, and (c) perform easy mathematical operations when the arithmetic operation is specified and easily understood.

The region of the country with the greatest percentages of individuals ranked at literacy levels 1 and 2 was the south as shown in Figure 2. Nine states reported 37-38% of the population scored at the lowest literacy levels; 18 states reported 39-45% of the population scored at the lowest literacy levels. Fourteen states reported 45-52% of their

population scored in the lowest levels, and seven states reported 53-59% of the population scored at the lowest literacy levels. Mississippi and Louisiana reported the largest number of residents ranked in the lowest literacy levels at 64% and 61%, respectively.



*Figure 2. National Adult Literacy Survey Rankings by State 1992: Percentage of Population Within Each State Scoring at Literacy Levels 1 and 2 (Below Basic and Basic).*

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*Note.* From “National Adult Literacy Survey” (1992). Source: U.S. Department of Education. Public domain material.

Alabama reported that 57% of the population in the state scored at the lowest literacy levels (see Table 1 on the following page). Colorado had the most favorable report with only (32%) of the residents scoring at the lowest literacy levels followed by Utah, Alaska, Wyoming, Minnesota, and Washington all with percentages of between 33% and 35%.

Table 1

*Number of States and the Percentage of the Population Scoring at Literacy Levels 1 and*

*2 (Below Basic and Basic) in Rank Order*

Number of States	% Population
9	37-38%
18	39-45%
14	45-52%
7	53-59%*
2	60-64%

*Note.* \*Includes Alabama. Data from Reder (as cited in T. L. Matthews and J. C. Sewell, 2002, *State official's guide to health literacy*. Lexington, KY: The Council of State Governments). Public domain material.

## Low Literacy and Health Literacy

Literacy levels are measured nationwide by the National Center for Education Statistics (NCES). The most recent comprehensive literacy report, the National Assessment of Adult Literacy (NAAL), indicated little improvement of the literacy of Americans during the last decade (NCES, 2003). Data from the NAAL reveal that 71% of adults 60 years of age and older demonstrate limited literacy for prose and quantitative skills (Kutner, Greenburg, & Baer, NCES, 2005). Native-born Caucasian speakers of English, ages 65 years and older represent the largest demographic group of Americans with low literacy (Nielsen-Bohlman, Panzer, & Kindig, 2004; Institute of Medicine Committee on Health Literacy, 2004).

### *Health Literacy*

Studies have shown that individuals with low health literacy have limited knowledge about their medical condition(s) and are less likely to understand instructions for self-care (Schwartzberg, VanGeest, & Wang, 2005). Individuals with low health literacy are less likely to understand the intended purpose of a prescription medication and how to administer it (Parker, Baker, Williams, & Nurss, 1995). Another study indicated that diabetics with low health literacy have less knowledge of how to manage nutritional needs and may not understand the importance of regular exercise (Williams, Baker, Parker, & Nurss, 1998). Furthermore, Williams, Davis, Parker and Weiss (2002), concluded that 33% of patients ages 65 and older had inadequate literacy skills and experience difficulties in self-managing their health care needs. In summary, consequences of inadequate health literacy include lower levels of health knowledge,

poorer health status, higher rates of health services utilization, and higher health care costs (Schwartzberg et al., 2005).

### *Health Care Professionals' Understanding of Health Literacy*

Bass, Wilson, Griffith, and Barnett (2002) reported that some health care providers are unaware of older patients' inability to understand health issues and instructions for self-management of medication. Within a managed care system, physician-patient contact is limited; providers may not take the time needed to ensure that patients understand diagnosis and treatment information, including instructions for self-care (Swartzburg et al., 2005). A study of diabetic patients reported primary care physicians rarely assess patient recall or comprehension of new concepts when caring for patients with low health literacy (Schillinger et al., 2003).

Health care providers report that individuals with low health literacy are less likely to be able to describe their condition as compared to those with higher health literacy (Roter, 2000). Physicians and health care providers should be skilled to recognize the problem of low health literacy because many patients are unwilling to admit that they have inadequate literacy (Safeer & Keenan, 2005). Results of a 2003 study indicated that physicians believe they provide patients with information to properly administer prescribed medications; however, only 41% of their patients agreed. Results of another study revealed that patients are unable to recall more than 50% of what the physician told them after an office visit (Ong, de Haes, Hoos, & Lammer, 1995). Metlay and associates (2005) reported primary health care providers often assume patients treated in their offices can read, understand, and act on brief instructions found on medication labels.



Metlay, et al. (2005) concluded the assumptions of the primary health care providers may be inaccurate.

### *Patients' Attitudes and Health Literacy*

Patients with low health literacy may feel humiliated or embarrassed, which impedes active communication with their primary health care provider (PHCP).

Bernhardt and Cameron (2003) found that some persons with low health literacy are ashamed to admit they need help with understanding health care issues or health care information, which may impede their ability to self-manage prescription medication(s).

One-third of those with low health literacy deny that they have a problem, perhaps due to stigma and related feelings of fear, inadequacy, and low self-esteem (Parikh, Parker, Nurss, Baker, & Williams, 1996).

### *Associated Costs of Limited Health Literacy*

Each year, Americans spend billions of dollars on health care and related problems arising from the complications of low health literacy (Bernhardt & Cameron, 2003; Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005; Sudore et al., 2006). Despite the abundance of health information available to community dwelling older adults, those with low health literacy are ill equipped to interpret and apply the knowledge for self-care (Safeer & Keenan, 2005). Misinterpretation of medication instructions may result in ADEs requiring medical intervention (Kripalani et al., 2006). The need to investigate health literacy and how it relates to health knowledge, attitudes, and practices is apparent and urgent (Davis et al., 2006).

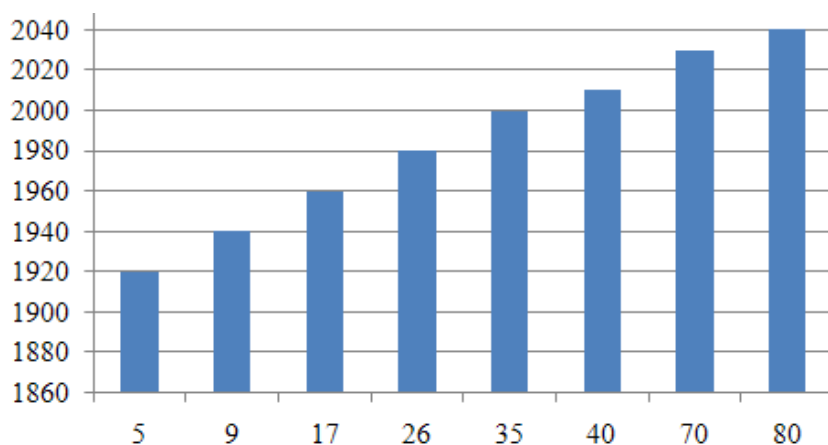
Schwartzberg, et al. (2005) reported excess hospitalizations, illness, and mortality related to limited health literacy costs the U.S. health care system between \$50 billion and \$73 billion each year. By 2007, limited health literacy was documented to add between \$106 trillion and \$238 billion of unnecessary costs per year to an already overburdened health care system (Vernon et al., 2007). The National Coalition on Health Care (NCHC) (2009) reported national health spending was expected to reach \$2.5 trillion by the end of 2009 and \$4.4 trillion by 2018. The need to eliminate unnecessary health care costs is apparent.

Low health literacy may be one explanation for nonuse or misuse when community-dwelling older patients self-manage prescribed medication(s) (Nielsen-Bohlman et al., 2004). Two-thirds of U.S. adults 60 years and older have inadequate or marginal literacy skills, which means they read at or below a 5th-grade level (Nielsen-Bohlman et al., 2004). Williams, et al. (1998) concluded that 81% of patients ages 60 and older treated at a public hospital could not read or understand basic materials such as prescription labels. For many patients, complex instructions found on prescription medication labels are difficult to read and understand. Each year, Americans spend billions of dollars on health care and related problems arising from the complications of low health literacy (Bernhardt & Cameron, 2003; Paasche-Orlow et al., 2005; Sudore et al., 2006).

### The Demographics of Aging

In 1999, the population of persons 65 years or older represented about one in every eight Americans (U.S. Census Bureau, 2004). The aging population of persons 65

years and older is predicted to continue to grow exponentially in the future (Figure 3).



*Figure 3.* Future Growth Projections of Persons Ages 65 and Older in the U.S.

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*Note.* Decades are displayed on the vertical axis, numbers of individuals in millions are represented on the horizontal axis. From “Maps representing levels of education and states’ rankings related to percentage of Americans age 65 and older” by U.S. Census Bureau, 2004, Washington, DC: Author. Copyright 2004 by U.S. Census Bureau. Public domain material.

Overall, the population of community dwelling older adults has grown faster in the nation’s southern states. The percentage of adults ages 65 years or older exceeded the national average of 12.4% in seven Southern states: Alabama, Arkansas, Florida, Kentucky, Oklahoma, Tennessee, and West Virginia. Florida has the largest share of people ages 65 and older, while Georgia has the lowest (US Census Bureau, 2004).

Southern states reported between 8-14% of residents are 65 years or older, as shown in Table 2 (U.S. Census Bureau, 2004).

Table 2

*Percentage of the Population 65 Years and Older in the Southern States*

State	Percentage
Florida	14%
Alabama	13%
Tennessee and Mississippi	12%
Georgia	8%

*Note.* From U.S. Census Bureau (2004). Public domain material.

Race, class, or educational attainment cannot reliably predict low health literacy (Reinhard, Scala, & Stone, 2000). The Center for Health Care Strategies, Inc. (2003) reported that regardless of educational background more than two-thirds of U.S. adults ages 60 years or older have low or marginal literacy skills. One study indicated that participants who graduated from college had some of the lowest health literacy scores (Thrall & Bent, 2006). Healthcare providers should assume that every patient is affected by low health literacy and be treated with “universal precautions” for health literacy, especially when prescribing medications or implementing a new health care regime

(Russell Rothman, personal communication, March 25, 2008). Individuals with limited health literacy are 12 to 18 times more likely to be unable to identify medications or distinguish between prescribed medications when many look alike (Agency for Healthcare Research and Quality, 2008). State governments are struggling to find innovative ways to improve outcomes for elders related to polypharmacy and ADEs (Andrus & Roth, 2002).

Medication issues affecting community dwelling older adults have been identified within the pharmaceutical professional literature (Zagaria, 2006). Prescription warning labels (PWL) are problematic for those with low literacy skills. Correct interpretation of the eight most commonly used prescription-warning labels was very low for patients reading at or below the 6th-grade level (Davis et al., 2006).

Complexities related to medication management of common chronic conditions among the elderly can be overwhelming (Wolf, Gazmararian, & Baker, 2005). Davis and associates (2006) reported that low-literate patients have difficulty understanding prescription medication labels and patients across all literacy levels had difficulty understanding instructions with multiple steps. Interventions to provide safe medication labels for low-literate older patients may reduce morbidity. When guidance is provided to aging patients for the purpose of helping them self-manage medications the number of deaths related to polypharmacy and expensive emergency room visits related to misuse of medications may decrease.

### Adverse Drug Events and Polypharmacy of the Elderly

The majority of older adults (80%) in the U.S. have at least one chronic condition; 50% have more than one. Approximately 25% of older adults report the use of five or more prescription drugs in any given week (Kaufman et al., 2002). The literature related to adverse drug events (ADEs) outlined in this chapter indicates common confusion and misunderstanding among patients prescribed multiple medications.

Improving health literacy is one strategy to reduce the occurrence of ADEs related to polypharmacy. In addition to encouraging patients of all ages to become more involved in their health care, states are implementing health literacy classes to enhance skills for self-management and understanding personal health (Braddock, Edwards, Hasenberg, Laidley, & Levinson, 1999).

Through a collaborative effort with thousands of individuals, the Joint Committee on National Health Standards (2007) developed the *National Health Educational Standards* (NHES). Participants of the review included health and education professionals, parents, and community members. The goal of the initiative is to develop a framework for schools that will produce superior health education in America with an emphasis on health literacy (Joint Committee on National Health Education Standards, 2007). The NHES provides a framework for curriculum development, instruction, and student assessment in health education and utilizes benchmarks for what students should know by the 2nd, 5th, 8th, and 12<sup>th</sup> grades in order to promote personal, family, and community health.

Adult education initiatives are another important piece of the framework to enhance health literacy and diminish the ADEs related to polypharmacy. Alabama, Alaska, Georgia, Louisiana, California, Massachusetts, Missouri, New Jersey, and Rhode Island all reported that they had programs to decrease disparities in literacy levels among their residents (National Survey on Health Literacy Initiatives, 2003). Georgia hired a coordinator of health literacy to implement classes throughout the state at senior centers, hospitals, community and mental health centers. Alabama's Medicaid Agency pilot tested educational materials to determine the reading level (for its enrollees). The Agency concluded that all readers, regardless of reading level, prefer easy-to-read materials. Unfortunately, these programs serve a small percentage of those who could benefit from the instruction (Nielsen-Bohlman et al., 2004). For states with the lowest levels of literacy, aggressive approaches may be needed for adults and children to improve literacy levels. Recent census data (U.S. Census, 2004) indicates that as the demographic group of older adults increases in proportion to the total population, there will be an increased likelihood for ADEs related to errors with self-management of prescription medication(s). All regions of the country could be affected.

Elders prescribed multiple medications for concurrent conditions may suffer negative health consequences if unable to understand how to self-manage each prescription medication (Zagaria, 2006). Cognitive decrements and declining psychomotor skills increase vulnerability for medication errors among older adults (Lilley & Guanci, 1996). Of particular concern are community-dwelling seniors with chronic conditions and low health literacy who are responsible for self-management of prescription medications (Lilley & Guanci, 1996). Schwartzberg, et al. (2005) found that

a large proportion of elderly patients lack the ability to follow the instructions provided to them by the pharmacist; however, they rarely ask questions due to fear of embarrassment.

Limited time spent with the health care provider within the managed care system restricts the quality of patient education for self-management of prescribed medications. On average, patients can expect to see the physician for a maximum of 20 minutes (Schwartzberg et al., 2005). For individuals who have multiple chronic conditions and complex medication schedules, this may be inadequate. Barrett, Puryear, and Westpheling (2008) surveyed primary care practitioners to determine barriers to physician-patient communication; eighty-three percent reported lack of time as the most prominent reason patients leave an office visit without all the information needed for self-management. Additionally, 60% of the sample of health care providers reported a need to understand how to identify low health literate patients (Barrett et al., 2008).

More health care services are delivered in outpatient rather than inpatient settings. Medication self-management is more often viewed as the responsibility of the patient and less often believed to be the responsibility of the physician, (Davis et al., 2006). Self-care may be very confusing for older adults with low health literacy, as it requires the ability to follow complex written instructions, often without direct assistance from another person (Schwartzberg et al., 2005). Researchers have asserted that most ADEs cannot be prevented by clinicians alone (Shojania, Duncan, McDonald, & Wachter, 2001). Efforts are needed to coordinate care among the health care team, family members, friends, and peers.

Patient education is an important component of preventing ADEs related to polypharmacy (Lilley & Guanci, 1996). Health educators are needed to support



individual, family, and community well-being through facilitation of informed decisions in response to health choices. Educational support may come from certified health education specialists, registered nurses, advanced practice nurses, physician assistants, or physicians (Daniel, Hess, & Merson, 2005).

Consumers of health care are inundated with health care information. Health care professionals provide advice and instructions to patients for proper medication management. Certified Health Education Specialists assist patients with interpretation and application of information to enhance health. Pharmacists provide information with every prescription filled; television networks, newspapers, and magazines offer information about the latest research findings; and the Internet is the portal to endless information about health issues (Bernhardt & Cameron, 2003; Weinreich, 1999). Regardless, patients with low health literacy may not be able to access and interpret public sources of health information (Safeer & Keenan, 2005). The need to investigate health literacy and how it relates to older adults' health knowledge, attitudes, and practices is apparent and urgent (Davis et al., 2006).

Gurwitz and colleagues (2003) concluded that errors associated with preventable ADEs for older patients may occur at any stage, from initial prescription to continuous use of a medication. Furthermore, these researchers reported that (a) one-fourth or greater of identified ADEs were preventable; (b) 38% of ADEs were categorized as serious, life-threatening or fatal; (c) 58.4% of the errors related to ADEs occurred during the stages of prescribing (i.e. health care provider writes the prescription, the pharmacist fills the prescription and provides it to the patient or caregiver); and (d) over 20% of ADEs were found to be directly related to patient adherence (Gurwitz et al., 2003).

## Empirical Studies Which Examine Associations of Health Literacy and Health Outcomes

The “Impact of Health Literacy on Longitudinal Asthma Outcomes” (Mancuso & Rincon, 2006) used a longitudinal cohort design to conduct research over a two-year period. The researchers sought to determine an association between health literacy and asthma outcomes and to evaluate how health literacy affects outcomes as measured by the *Asthma Quality of Life Questionnaire* (AQLQ). One hundred and seventy-five asthma patients agreed to take part in the study. At the time of enrollment, data were collected to measure the following independent variables: (a) demographic attributes; (b) self-management of asthma (ranking their self care as *very difficult* to *very easy*); (c) depressive symptoms as measured by the *Geriatric Depression Scale* (GDS) (a highly reliable 30-item scale that has been shown to be valid in younger patients [Yesavage & Brink, 1983]); (d) the *Asthma Self-efficacy Scale* (80-items to assess confidence to self-manage asthma when encountering precipitants, [Tobin, Wigal, Winder, Halroyd, & Creer, 1987]); and (e) asthma knowledge as measured by the *Check Your Asthma IQ* (a 12-item survey that measures awareness of asthma characteristics, mechanisms, and self-management [IOM, 2004]). Health literacy was measured with the *Test of Functional Health Literacy in Adults* (TOFHLA), which is considered to be highly reliable (Parker et al., 1995). Since the TOFHLA is used in this dissertation study, the reliability of the TOFHLA will be covered in depth in Chapter 3.

The desired outcome of the study conducted by Mancuso & Rincon (2006) was to determine the overall asthma-related quality of life (dependent variable) as measured by

the AQLQ taking into consideration the number of acute episodes of asthma. The AQLQ is a 32-item highly reliable scale that measures how symptoms, activity limitations, the environment, and emotions affect asthma. Functional status of asthma patients was estimated by scores on the SF-36, composed of Physical and Mental Component Summary scores (Ware et al., 1995). A query was conducted each 3- to 6-months to determine how often asthma patients used the emergency department resources during a two-year period.

Health literacy and covariates were analyzed for associations using t-tests, analysis of variance (ANOVA), and Chi-square test to determine if associations exist. Health literacy was dichotomized using the titles of “adequate” or “marginal/ inadequate” as measured by the TOFHLA. Spearman’s correlations were used to determine associations between health literacy and asthma self-efficacy, depressive symptoms, and asthma self-management knowledge. Mixed-effect models using a random subject effect were used to analyze the outcomes.

“Sequential models were set up with AQLQ (or SF-36) scores as the dependent variable. Independent variables found to be significant at  $p < .05$  in bivariate analyses were entered into the models in a forward stepwise fashion, starting with health literacy” (p. 814). To carry out the analysis, PROC MIXED in SAS (SAS Institute) was used. Using PROC GENMOD, resource utilization outcomes were dichotomized as having or not having had an emergency department visit for asthma during the study period.

Results of the multivariable analysis demonstrated a statistically significant association between low health literacy and poor quality of life ( $p = .009$ ), low health literacy and worse physical function ( $p = .0007$ ), and low health literacy and an increase

in emergency department usage ( $p = .03$ ). Researchers postulated that low health literacy is associated with poor asthma outcomes over time. Study recommendations support enhancing literacy skills to increase understanding and implementation of effective self-management of asthma.

A second study entitled “Low Literacy Impairs Comprehension of Prescription Drug Warning Labels” (Davis et al., 2006) provides further insight into the relationship between health literacy and health outcomes. The objective of this study was to examine “adult patients receiving primary care services at a public hospital clinic to determine if they were able to correctly interpret commonly used prescription medication warning labels” (p. 847) Davis and colleagues collected data in-person via structured interviews in conjunction with literacy assessments. Two hundred fifty-one adult patients ages 18 to 86, mostly female (70.9%) and African American (66.1%), participated in the study.

An expert panel of community pharmacists (N=9) and primary care physicians (N=5) determined the eight most commonly used prescription warning labels. The reading difficulty for all eight labels was measured using the Lexile Framework (Stenner, Horabin, Smith, & Smith, 1998) to gauge the reading level of the text on each PWL. A Lexile score was derived for each PWL and each respondent after a structured interview conducted by the same expert panel of physicians and pharmacists.

Correct patient interpretation of the PWLs varied according to reading difficulty and complexity. Correct interpretation rates ranged from 83.7% for the simplest label (“take with food,” Lexile = beginning reading) to 7.6% for a label with multistep instructions (“do not take dairy products, antacids, or iron preparations within one hour of this medication,” Lexile = 10<sup>th</sup> grade level). Patients with low literacy skills were less

likely to identify and correctly interpret the meaning of seven of the eight PWLs. The exception was found through the correct interpretation of “take with food,” a single-step instruction. These findings support the need for easier to read PWLs and possibly incorporating pictographs.

The Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis, Crouch, & Long, 1993) was administered to each participant upon completion of the structured interview. The REALM is the most commonly used measurement of adult literacy in health care settings, and is highly correlated with standardized scores of the TOFHLA (Parker, Williams, Baker, & Nurss, 1996).

Descriptive statistical analysis was performed on each variable using the statistical software package “STATA” version 8.0. Chi-square and ANOVA tests helped to determine “the association between literacy, socio-demographic characteristics, and correct interpretation of each of the eight PWLs” (Davis et al., 2006, p. 848). Multivariate analyses of the eight binary repeated responses were conducted using a generalized linear model. The research team used a generalized estimating equation approach as used by Zegar, Liang, and Albert (1988) to adjust the model coefficients and standard error for within-patient correlation. “The final multivariate model included potential confounding variables of age, gender, race, number of medications currently taken, and the additional risk factor of the Lexile score” (p. 848).

Results indicated that patient health literacy was limited, with 29.5% of the 251 patients reading at or below a 6<sup>th</sup> grade level (considered low-literate by the REALM), and 31.1% reading at a 7<sup>th</sup> to 8<sup>th</sup> grade level (marginal literacy). Slightly less than half

(42%) reported they did not graduate from high school or receive a graduate equivalency diploma.

Patients self-reported taking an average of three prescription medications and almost two-thirds (64.5%) reported having no insurance for medication assistance. For this study,  $p$  values revealed a positive association between low literacy and African American race ( $p < .001$ ), female gender ( $p < .05$ ), and less than a high school or equivalent education ( $p < .001$ ). There were no significant differences reported between literacy level and age, number of medications, or source of payment for medication.

Multivariate analyses revealed that low literacy was a significant independent predictor associated with the incorrect interpretation of a PWL. Results indicated that African American females of any age were more likely to have low literacy, thereby contributing to poor health outcomes.

Limitations of the Davis, et al. (1993) study include selection of an adult sample that is not representative of the patient population nationwide. The participants were primarily female, proficient in the English language only, with the majority representing the African-American population. Other limitations mentioned include selecting a sample of patients from a public hospital, as well as a small sample size. A broader study is needed with equal representation of race, gender, and age to confirm these findings.

In summary, a correlation between two variables does not imply that one causes the other. Health literacy is the end result of a convergence of education, health services, and social and cultural factors (IOM, 2004). Low health literacy is associated with poor health outcomes and astronomical costs, especially when considering chronic diseases

(Schwartzberg et al., 2005). Future research should elucidate interrelationships between health literacy and health outcomes.

### Framework to Guide This Dissertation Study

Conceptual framework and theory guides health behavior research and practice (Glanz, 2002). A solid framework provides structure and should be used when conducting any research or planning an intervention to produce lasting positive effects (Weinreich, 1999).

A comprehensive review of the literature on the topics of limited health literacy and the aging population reveals few published studies were guided by a theoretical or conceptual framework (DeWalt et al., 2004). As a relatively new field, research on health literacy has gained momentum in the past decade. A database search of *PubMed* conducted on November 5, 2008 using the keywords “health literacy and health outcomes” yielded over 1,600 publications. A second search using keywords “health literacy and poor health outcomes” yielded over 300 articles. Less than three years later, a database search of *Google Scholar* conducted on April 25, 2010 using the keywords of “health literacy and health outcomes” yielded 183,000 publications and 121,000 for “health literacy and poor health outcomes.”

The few studies that were found to include a framework using health education and health promotion models utilized one of two approaches: (a) the health belief model (HBM) (Hochbaum, 1958; Rosenstock, 1960, 1974) or (b) the stages of behavior change model (SBCM) (Prochaska & DiClemente, 1983).

The HBM and the SBCM have been used to guide successful interventions for behavior change (Weinreich, 1999). Each is supportive of individual-level interventions to influence choice among volitional behaviors for instance, using birth control and acting to reduce risk of infection (Eisen, Zellman, & McAlister, 1992; Kretzer & Larson, 1998).

The HBM and the SBCM are representative of intrapersonal approaches to study health beliefs and behavior. Application of the HBM, SBCM or others for an investigation of ADEs among community dwelling older adults due to errors of self-management of prescription medications may yield new insights of value to health promotion program planners. Enhancing health literacy and reducing the occurrence of ADEs among community dwelling older adults who self-manage prescription medications may require a systematic approach across levels of person, behavior, and environment. For instance, policy changes may increase the focus on health education for children in grades K-12 (the future generation of older adults), mandate training in patient communication skills for students in health professions, and implement Joint Commission on Accreditation of Health Care Organizations (JCAHO, 2007) recommendations as they relate to health literacy. Public policy action plans may include recommendations to improve patient safety, including presenting patient health information written at or below the 6th-grade level (Bergman-Evans, Adams, & Titler, 2006; Brown, 1991; Green, Richard, & Potvin, 1996; Hohn, 1997; JCAHO, 2007; McLeroy, Bibeau, Steckler, & Glanz, 1988; Rudd, Kirsch, & Yamamoto, 2004; Stokols, 1996).

The Social Ecological Model (SEM) was used as the framework of this study



to guide a systematic assessment across multiple levels of influence (Glanz, 2002; McLeroy et al., 1988; Stokols, 1996). The SEM focuses on individual factors, social factors, community organizations, and policy makers to promote change (Stokols, 1996). Within the framework of this study, the researcher will examine: (a) characteristics of the community-dwelling older adult (ages 60-74), (b) their interactions with caregivers and others, (c) their home and community environment, and (d) their ability to demonstrate accurate self-management of multiple prescription medications (Brown, 1991; Oetzel, Ting-Toomey, & Rinderle, 2006).

Data collected during this study suggests areas for improvement of limited health literacy and self-management of prescription medications among community dwelling older adults, ages 60 to 74. Insight into systems, organizations, and policy will provide information as to how each can play a role to improve low health literacy and decrease ADEs in the aging population as it relates to self-management of multiple prescription medications. Emphasizing the importance of collaboration among individuals, environments, systems, and public policies; the SEM will provide a framework for how change within organizations at the community and state level can influence health literacy for the target population (Brown, 1991).

### Background of the Social Ecological Method

The SEM emerged in the mid 1970s through the scholarship of Urie Bronfenbrenner (1977, 1979). Bronfenbrenner's ecological systems theory distinguished four levels of influence for change: intercultural, community, organization, and intrapersonal or individual. Bronfenbrenner's model focused on the person, the

environment, and the continuous interaction between the two.

McLeroy and colleagues (1988) specified five levels of the SEM as influential to health promotion: (a) intrapersonal or individual, (b) interpersonal, (c) institutional or organizational, (d) community, and (e) public policy. Some older adults may not be able to initiate changes in self-care without support and assistance. Change across multiple levels (person, behavior, and environment) may improve patient outcomes (JCAHO, 2007) including enhanced health literacy and accurate self-management of medications (Hohn, 1997; Schwartzberg et al., 2005).

#### *Intrapersonal or Individual Level*

The individual characteristics that influence behavior such as knowledge, attitudes, beliefs, and psychological, cognitive, and personality traits are represented at the intrapersonal level and may affect receptivity to health information (Gregson et al., 2001; McLeroy et al., 1988). Elderly individuals may have difficulty managing medications due to low health literacy and changes with aging (e.g., declining visual acuity, delayed speed to process new information, and impaired motor skills) (Parker, Ratzan, & Lurie, 2003). Older adults may benefit from one-on-one assistance from a health care provider allowing for repetition of the prescribed drug regime for improved medication management (Kilker, 2000; Simon & Gurwitz, 2003).

Health instruction and applied learning activities are the cornerstones of health literacy (Nash, 1997). Repeated exposure to health literacy initiatives using plain language to improve medication management will enhance older adults' abilities within the intrapersonal level (Archambault, 2003). This format for enlightening individuals

may require education delivered through multiple channels of communication (Kripalani et al., 2007).

### *Interpersonal Level*

Influences from primary social referents, family, peers, and co-workers, comprise the second or interpersonal level of the SEM (Moore, 2008). Interpersonal influences may exert positive, neutral, or negative influences on health outcomes (Glanz, 2002). Behavior is not merely a result of knowledge, attitudes, and values, but is influenced by the individuals with whom we associate, organizations we support and belong to, and environments in which we live (McLeroy, Norton, Kegler, Burdine, & Sumaya, 2003). A review of professional literature supports the involvement of interpersonal factors to improve health literacy for individuals (Kim, Love, Quistberg, & Shea, 2004).

Individuals aged 60 years or older face the greatest disparities related to health literacy. An estimated two-thirds of older Americans are estimated to have inadequate or marginal literacy skills (Zagaria, 2006). Someone with inadequate health literacy skills is unable to read and interpret health texts, and those with marginal health literacy skills may also have difficulty with such tasks (Baker et al., 1996). Older individuals who lack basic numeracy and reading skills needed to manage multiple medications are at the highest risk for dangerous drug interactions (Lilley & Guanci, 1996).

An important social tool for health care decision-making is participatory decision making (PDM). PDM emphasizes a collaborative relationship between the patient and the health care team characterized by active communication to improve patient understanding and involvement in decision making for enhanced health (Epstein, Alper, & Quill, 2004).

Participatory decision-making has emerged as a focus of clinical, ethical, and medical research within the past few decades (Schwartzberg et al., 2005). Barriers to effective PDM include low socioeconomic status, limited educational attainment, cognitive changes with aging, poor English language skills, and poor health status (Chewning & Sleath, 1996).

It may be more difficult for patients with low literacy to engage in PDM due to one or more of these barriers (Cooper-Patrick et al., 1999). A report issued by the Commonwealth Fund (2001) indicated that low health literacy, as measured by the ability to read and understand prescription drug labels, is associated with poor communication between health care providers and patients. The lack of communication included less participation in decisions that affect medication management (Collins et al., 2002).

Participatory decision-making is less common and more complicated among patients who are culturally different from their health care provider (Schwartzberg et al., 2005). Studies have found that physicians deliver less information, have less supportive communication, and are less proficient in their clinical performance to patients who have a lower socioeconomic status or are from a different culture or racial background than the health care provider (Bartlett et al., 1984).

Having family members present during a visit to a physician, health care practitioner, or hospital to assist with comprehension of health and self-care information can be vital for patients of all ages (Lilley & Guanci, 1996). For those who are unable to demonstrate their ability to perform the task of medication management, support from friends, family, and peer groups may be essential.

*Healthy People 2000* and *Healthy People 2010* (NCHS, 2000, 2001) focused

much attention on efforts to improve health disparities in America. Regardless of this effort, persistent and widening disparities related to health status continue to exist due to employment level, age, and educational achievement which may be an influence for the development of chronic and infectious diseases (Pincus, Esther, DeWalt, & Callahan, 1998).

*Healthy People 2020* retained the objectives from *Healthy People 2010*, and focuses on Health Communication and Health Information Technology (HC/HIT). Specifically, *Healthy People 2020* seeks to validate improved health literacy of the population through an increase in the proportion of persons who report (a) that their health care provider always gave them easy-to-understand instructions about what to do to take care of their illness or health condition, (b) their health care provider always asked them to describe how they will follow the instructions, (c) their health care providers' office always offered help in filling out a form, (d) their health care providers have satisfactory communication skills, (e) their health care provider always explained things so they could understand them, (f) an increase in the proportion of persons who report that their health care provider always showed respect for what they had to say, (g) their health care provider always spent enough time with them, and (h) their health care providers always involved them in decisions about their health care as much as they wanted (PDM). All of these objectives have baseline data for measurement so that improvement can be determined at the end of the decade (Healthy People 2020, n. d.).

### *Institutional or Organizational Level*

The organizational level includes factors that influence group behavior in the private, public, and nonprofit sectors. It is possible to influence health behaviors of groups through organizations, such as “businesses, schools, churches, public agencies, service organizations and professional organizations” (Gregson et al., 2001, p. S11). Even though volunteerism is not specifically named as an element of the SEM, investigators have documented the positive influence that trained volunteers provide when facilitating primary and secondary prevention among specific intended audiences (Sewell, 2003). Lay health workers who are volunteers provide outreach to groups at risk for health conditions, build linkages between service providers and disparate groups, promote increased access to clinical care and appropriate use of services, and enhance patient-provider communication (Witmer, Seifer, Finocchio, Leslie, & O’Neil, 1995).

Organizations that promote health literacy may include schools that offer adult basic education classes or outreach programs. One example is a citywide literacy organization which can improve basic literacy skills for whom English is their second language. Work sites may support individuals through benefits specific to medication management and a SenioRx Medication Wellness Program. Physician’s offices may guide and direct persons with low health literacy and medication management. Health departments may offer special programs to assist low health-literate individuals, and hospitals may provide assistance through social services (Brown, 1991; McLeroy et al., 2003; St. Leger, 2001; Stokols, 1996).

In recent years, patients' contact time with their health care provider has been restricted by rules of health insurers to contain costs and maximize reimbursement (Foreman, 2005; Moran, 2001; Weijer & Emanuel, 2000). The average health care visit has been estimated to last only 15 to 20 minutes within the U.S. health care system (Elder, Jacobson, Zink, & Hasse, 2005; Gilcrest et al., 2005). Partnerships with organizations or institutions should be developed to provide support services (Bergman-Evans et al., 2006) for aging individuals. The self-management of prescribed medication(s) may be accomplished through organizational support services at the time of the health care visit but after the health care provider meets with patients, allowing for an in-depth educational session.

Another approach that may be useful to promote assistance with self-management of prescribed medication(s) is the social marketing approach. Advertising, publicity, promotions, and interventions are helpful to assist individuals (i.e. the elderly) with medication management at the organizational level (Weinreich, 1999).

Organizational outreach for health promotion is an important component of successful health communication campaigns (Brown, 1991, Green & Kreuter, 2004). Limited resources impair organizational involvement to improve low health literacy among the aging population; therefore, funding should be sought from multiple sources for implementation of any program. Stakeholders may include health insurers, pharmaceutical companies, and employers (George Isham, personal communication, November 28, 2007). Indicators of success related to the organizational level of the SEM may include a decrease of ADEs for community dwelling older adults taking multiple

medications as well as an improvement of community dwelling older adults overall understanding as it relates to their health literacy and prescribed medications.

### *Community Level*

Comprised of social networks, norms, and standards that exist formally or informally, the community level fosters partnerships among individuals, groups, and organizations (Green & Kreuter, 2004; Gregson et al., 2001). Residents of a community can actively participate and contribute to solving health and social problems (Green & Kreuter, 2004). Extensive community support for health literacy programs could create a positive environment for behavior change and produce a shared commitment to improved health outcomes for all who reside in the community (Berkman et al., 2004; Green & Kreuter, 2004). Community-wide partnerships could result in policy changes necessary to implement an intervention to improve self-management of prescribed medications.

Through community mobilization, residents could demand accountability of physicians, hospitals, and health departments. The standard 15 to 20 minute managed care visit may be insufficient to meet the needs of some older adult patients; a community watch group could identify the need for appropriate time allotment for those who need more time during a office visit to the physician.

A solution to assist older adults with the self-management of prescribed medications can be developed through collaboration between community agencies, local physicians, nurses, and the local hospital. Possibilities include the utilization of trained health educators such as certified health education specialists, nurse educators and nurse practitioners. The addition of a specific educator as a community health educator for the



purpose of better provider-patient communication could greatly enhance the knowledge of aging patients as it relates to prescribe regimen or proper self-administration of prescribed medications. These individuals could be incorporated into primary care facilities to enhance primary preventative care.

### *Social Structure, Policy, and Systems*

The broadest level of influence in the SEM is that of social structure, policy, and systems (Stokols, 1996). Guided by local, state, and federal policies, this level provides support to organizational or institutional behavior (Gregson et al., 2001; McLeroy et al., 1988). Action at the federal level is needed as health care providers become increasingly aware of the difficulties community-dwelling patients face when trying to self-manage multiple medications due to limited health literacy (Parker et al., 2003). *Healthy People 2010* (NCHS, 2000), *Healthy People 2020* (NCHS, 2001) and a JCAHO white paper (2007) have all challenged health care providers to improve health literacy levels by presenting information in plain language relevant to patients' conditions (Archambault, 2003). To improve health literacy among the aging population, "policymakers and leaders outside of the health sector must be aware of the critical elements that contribute to health illiteracy" thereby "influencing social, economic and environmental determinants" (Ratzan, 2001, p. 208).

Government regulations, institutional policies, payer rules, and informal structures may influence health outcomes positively or negatively (Brown, 1991; Glanz, 2002; Green et al., 1996). Identification, treatment, and management of chronic disease

(The Milken Institute, 2007) produce an enormous drain on the American economy. Economic forecasts from a recent study suggest a \$218 billion annual cost savings by 2023 following modest improvements in prevention and management of disease in the U.S. (The Milken Institute, 2007). A comprehensive approach to improve health outcomes should prevent disease, discourage health-damaging personal behaviors, and facilitate health-promoting behaviors (Brown, 1991; Glanz, 2002).

The American Medical Association's educational program, *Health Literacy: A Manual for Clinicians* (Weiss, 2003), is an example of how professional membership organizations may increase awareness among their members leading to improvement of health outcomes for patients with low health literacy. A series of modules followed by case studies provides insight to physicians from the perspective of the patient. Following completion of the educational program, a continuing medical education (CME) questionnaire is issued to participants. No studies were found from a review of the literature related to success of this program. Contact with the AMA suggested there was a pilot study to develop the CME program; however attempts to reach Dr. Barry Weiss, Professor of Medicine at Arizona University who developed the tool were unsuccessful. If the CME tool is proven to be successful, educating physicians to understand how to identify patients at risk through incremental changes may improve health literacy.

An attempt to implement policy change for improved health literacy took place in October 2007, when Senate Bill 2424 was introduced. U.S. Senators Thomas Harkin and Norman Coleman (Krisberg, 2008) introduced the bill known as the National Health Literacy Act of 2007. Calling for each state to have a health literacy center to serve as a

central organization charged with improving health literacy, the bill failed to progress without a sponsor from the House and has not been reintroduced for consideration.

Despite initiatives promoted by the AMA and the U.S. Surgeon General, the charge to improve health literacy among the aging population will most likely take years to accomplish.

At the policy and government level, in 2010, the Department of Health and Human Services, Office of Disease Prevention and Health Promotion released a *National Action Plan to Improve Health Literacy (2010)*. This plan could have an impact on health literacy in America across all levels of the SEM during the next decade. The report seeks to engage organizations, professionals, policymakers, communities, individuals, and families in a linked, multi-sector effort to improve health literacy. The plan is based on the philosophy that (a) everyone has the right to health information that helps them make educated decisions, and (b) health services should be delivered in ways that are logical and helpful to health, long life, and quality of life (U.S. Department of Health and Human Services, 2010).

### CHAPTER THREE

#### METHODOLOGY

This chapter provides a description of the methods used for the quantitative and qualitative phases of the study. An overview of the mixed methods sequential explanatory design/participant selection model selected for the dissertation study is described. The rationale for why the researcher chose this design including consideration of advantages and disadvantages is specified. Priority, implementation and integration of the quantitative and qualitative data are discussed.

This chapter includes a description of how the sample was selected for both phases of the study. Convenience sampling was used for quantitative data collection. For the qualitative phase, purposeful sampling with the maximal variation strategy used to select three qualitative cases is described in detail. Strategies used to verify accuracy of data collection and the quality of the data during quantitative and qualitative phases are explained.

Data analysis techniques are presented for both quantitative and qualitative study phases. Other information provides the reader with: how mixing/integration of the data were accomplished, the types of mixed methods legitimation used in the study, and ethical considerations including the role of the researcher.

### Mixed Methodology

Teddlie and Tashakkori (2009) defined mixed methods (MM) as “a procedure for collecting, analyzing, and ‘mixing’ or integrating both quantitative and qualitative data at some stage of the research process within a single study for the purpose of gaining a better understanding of the research problem” (p. 3). For social and behavioral sciences, the mixed methods research approach has in recent years gained momentum (Creswell, 2009). During the past few decades, an increasing number of social and behavioral scientists have utilized a mixed methods approach for research (Teddlie & Tashakkori, 2009). Pragmatic and transformative data resulting from mixed methods research can be advantageous to the researcher because it uses both inductive and deductive reasoning to determine the best approach to explain social and behavioral research (Creswell, 2009).

Mixed methods research can incorporate the data collected from open or closed-ended questions. The use of emerging data and predetermined approaches can make way for an analysis using both quantitative and qualitative data. The researcher presents the rationale for mixing the data at a specific stage of inquiry and provides a visual image of the study procedures (Creswell, 2009).

Creswell and Plano Clark (2007) report that mixed studies are often necessary to combine approaches for a complete understanding of a phenomenon of interest. A mixed methods study can be more advantageous than a single approach; the researcher maximizes representation of the issue through the strengths of two approaches (quantitative and qualitative).

Quantitative data are derived from closed-ended questions to collect demographic and personal characteristics (Creswell & Plano Clark, 2007). Quantitative study methods

include surveys and self-reported behavior logs that yield numerical data gathered at a single point in time (Onwuegbuzie & Johnson, 2006).

Qualitative data provides thick rich descriptions for the research. Qualitative methods capture real life accounts expressed using words rather than numbers. Examples include in-depth interviews, direct observation, and review of written documents. Additionally, artifact examination and review of anecdotal information may yield qualitative data.

When choosing a MM design, researchers must consider that the design is more than separate collection and analysis of two types of data. Data are gathered sequentially or concurrently depending on the research questions. Creswell and Plano Clark (2007) have identified four types of MM designs, Triangulation, Embedded, Exploratory and Explanatory. Below is a brief consideration of each design.

*The Triangulation Design* is the most common MM design. The purpose of a triangulation design is to obtain different but complementary data on the same topic to answer the research questions. The researcher weights equally data obtained through quantitative and qualitative methods during a single study period. Data collection and analysis may be concurrent (Creswell & Plano Clark, 2007).

*The Embedded Design* mixes different data sets at the design level with one type of data being embedded within a methodology framed by the other data type. This design can be a one or two-phase approach (Creswell & Plano Clark, 2007).

*The Exploratory Design* may be used to guide a study of two sequential phases. Qualitative data are collected during the first phase to explore a phenomenon, which is further studied during a second or quantitative phase. It may be used to develop new

instruments or to identify new variables during research (Creswell & Plano Clark, 2007).

*The Explanatory Design*, chosen for this study, is characterized by collection and analysis of quantitative data followed by the collection and analysis of qualitative data with the purpose of elaborating on the initial quantitative results (Creswell & Plano Clark, 2007). Strengths of the design include data collection in separate phases; however, it may take longer to collect and analyze data than a concurrent process (Creswell & Plano Clark, 2007).

### Overview of the Study Design

#### *Mixed Methods Sequential Explanatory Design/Participant Selection Model*

The mixed methods sequential explanatory design/ participant selection model is derived from the Explanatory MM design. Chosen for this study, it features both quantitative and qualitative data collection but places priority on the qualitative phase. Mixing results of the two approaches yields thick, rich, descriptions of the findings. Green, Caracelli, and Graham (1989) suggested that merging data from both strands of a MM study yields a more robust analysis; each approach (quantitative and qualitative) is used to complement the other.

For this study, the quantitative data were used to provide a description of the sample and to purposefully select participants for the in-depth qualitative phase. The researcher stratified older adults' health literacy scores into three levels, documented the number of daily prescribed medications, age, and highest grade completed to select seniors who would be invited to participate in the qualitative phase of the study. Subsequently, three distinct cases with three participants in each were established. During

the qualitative phase of the study, information was gathered to determine support systems provided to participants for management of daily prescribed medication.

To summarize, a mixed methods sequential explanatory design/participant selection model guided this dissertation study of two phases. Findings from the quantitative phase of the study guided the selection of the qualitative cases for detailed exploration during the subsequent qualitative phase of the study. Qualitative data provided an in-depth understanding of how support services aid seniors who self-manage five or more daily prescribed medications. The next section of this dissertation provides the rationale for prioritizing the data from Phase II. Implementation is discussed as it relates to sequencing of study methods. Integration is demonstrated in Figure 4 as the results from Phase I and Phase II are considered together to suggest implications for future research and practice.

#### *Priority, Implementation, and Integration*

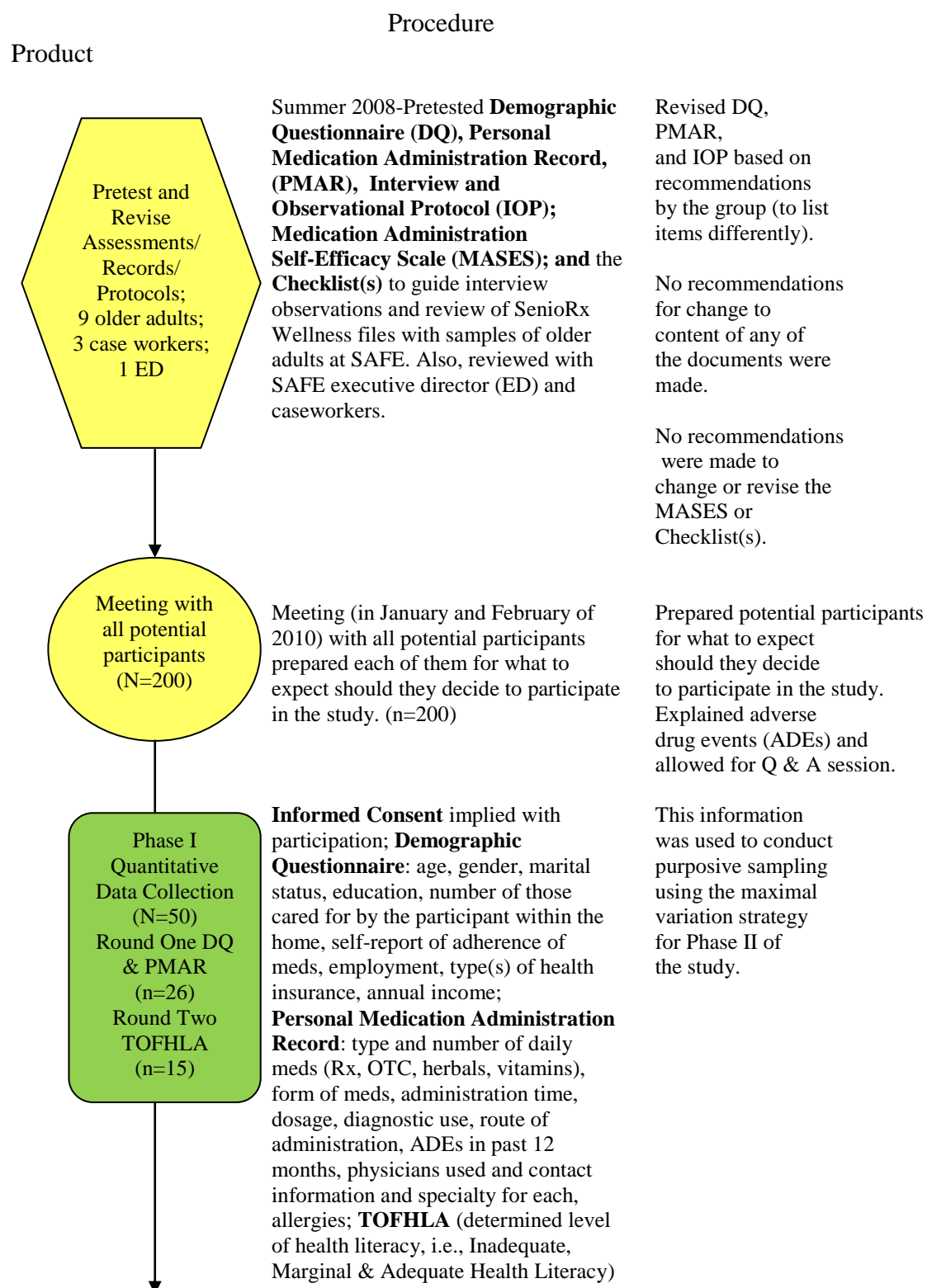
Priority, implementation and integration are all important components of a mixed method study. Priority (quantitative or qualitative) is assigned by the researcher to the type of data collected and during its analysis and integration (Creswell & Plano Clark, 2007). For this study, priority was given to the second or qualitative phase because this phase entailed an extensive data collection using multiple sources. Exploration of how English-speaking older adults who reside in the community self-administer five or more daily prescribed medications across three levels of health literacy was the goal of the study. An in-depth analysis of the qualitative data is described in Chapter Four.

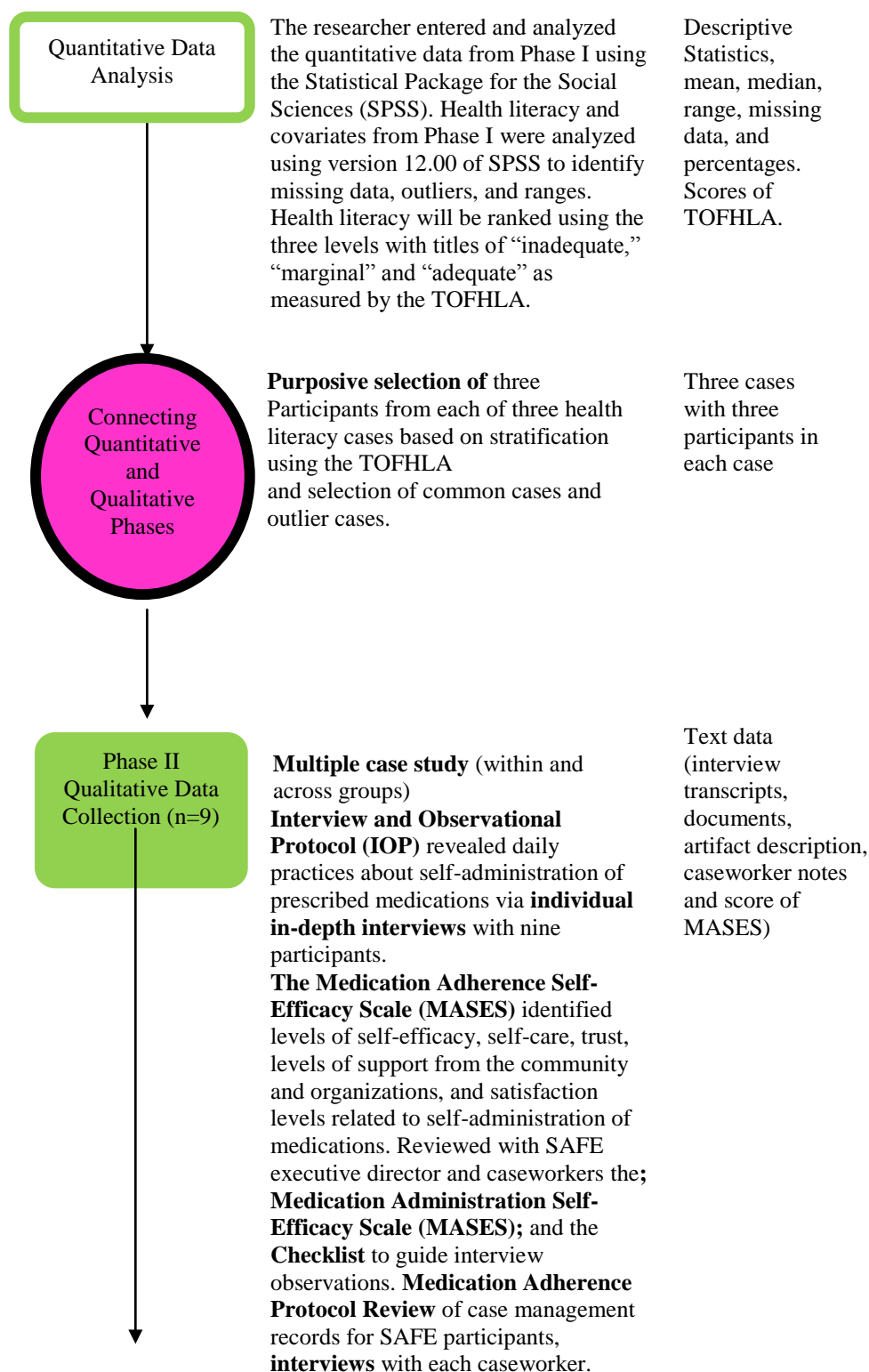


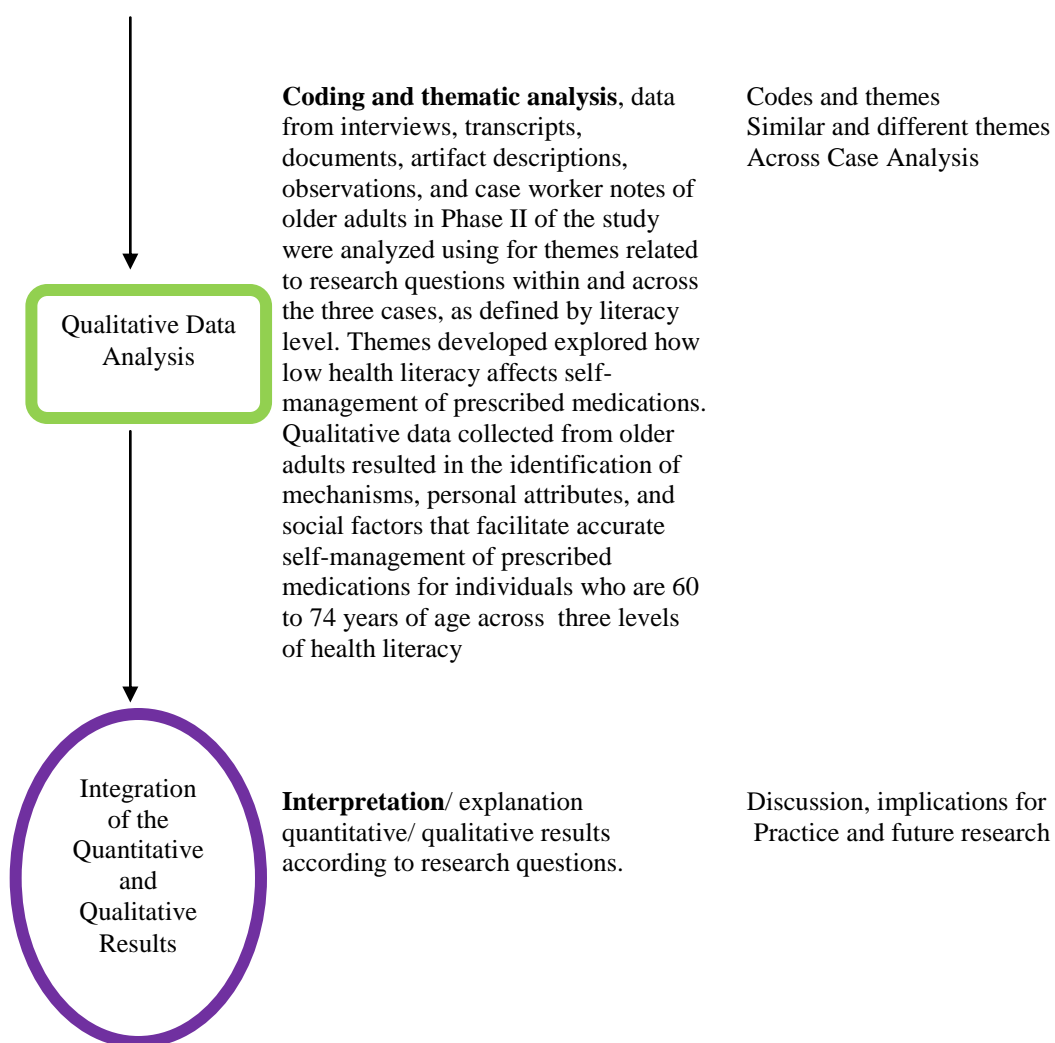
Implementation as reported by Creswell and Plano Clark (2007) represents the sequence of data collection and analysis in the study. Implementation can be used to carry out a study that is sequential in nature where the second phase (qualitative) is emphasized and connected to the results of the first phase (quantitative). The explanatory design-participant selection model using the maximal variation strategy was used to purposefully select participants for the qualitative phase of this study to comprehend how community dwelling older adults ages 60 to 74 self-manage five or more daily prescribed medications.

Integration of the sample provides a link between the quantitative and qualitative sampling designed to yield quality meta-inferences (Onwuegbuzie & Johnson, 2006). The better the sample integration, the more likely the study is to yield sound generalizations to other populations (Onwuegbuzie & Johnson, 2006). This study employed a qualitative multiple case study design in the second phase. Using sampling integration allows the researcher to transfer the case-study findings to similar settings (Lincoln & Guba, 1985). For this study, integration of the data was achieved through selecting the participants for Phase II (qualitative approach) from the population of community dwelling older adults as previously defined in Phase I (quantitative approach) of the study (Onwuegbuzie & Johnson, 2006). The quantitative and qualitative phases were connected at the intermediate-stage, while the results from two phases of the study were integrated when discussing the study meta-inferences. The study procedures as well as the design flow are visually represented in the diagram presented below in Figure 4.

Figure 4. Study Procedures and Study Design Flow







## Phase I Quantitative

### *Sampling*

Data collection was carried out in a rural town 60 miles south of Birmingham, Alabama. Located in south Talladega County, Sylacauga has a population of approximately 12,000 people. During the summer of 2010, quantitative data were collected from a convenience sample of community dwelling older adult volunteers over a four-day period from an accessible population. Convenience sampling is made up of people who are available, volunteer, or can be easily recruited (Johnson & Christensen, 2008). Johnson and Christensen (2008) define an accessible population as “research participants who are available for participation in the research” (p. 581). For this study, the convenience sample originated from seniors who were participants in a wellness program offered by a community resource center (accessible population). Results will be interpreted with reference to the sample and study community.

Sylacauga Alliance for Family Enhancement (SAFE) is the community resource center that provided organizational support for this study (see Appendix D). SAFE offers an educational and assistance program, known as the SenioRx Wellness program (SenioRx). SenioRx assists individuals who are 55 and older to access free or reduced-cost medications through programs provided by pharmaceutical companies. The program also provides information and classes to promote better health through four community resource centers (CRCs) and one assisted living facility (ALF) located within the Sylacauga area. The combined enrollment of all facilities (4 CRCs and the ALF) is approximately 200.

Of the 200 eligible participants for the study, 50 requested packets for participation in the quantitative phase which were provided by the researcher. Following a brief orientation meeting, 26 of 50 participants volunteered and completed Round One of the quantitative data collection. Each completed the DQ and the PMAR that had been given to them in the packet of information. During Round Two of the quantitative data collection, the TOFHLA was administered to all 26 individuals however, only 15 individuals were willing to take the test of health literacy. The next section describes instruments used for the quantitative data collection of the study.

### *Data Collection Tools*

Quantitative data collection for Phase I of the study was accomplished using three instruments: the Demographic Questionnaire (DQ) (Appendix A), the Personal Medication Administration Record (PMAR) (Appendix B), and the Test of Functional Health Literacy for Adults (TOFHLA)(Appendix C). Details of each are described below.

### *Demographic Questionnaire*

The Demographic Questionnaire provides characteristics of each participant via self-report. The DQ developed by the investigator for this study is comprised of nine objective items written at a 2.2 grade level as determined by the Flesch-Kincaid readability feature offered as part of *Microsoft Word*.

During the summer of 2008, the investigator composed a pilot focus group of nine community dwelling older adults (participants in programs at SAFE) and three staff

members from SAFE to participate in the development of the DQ. During a two-hour focus group discussion about DQ items conducted at SAFE, seniors suggested reordering items for ease of understanding. The approximate time to respond to the nine items of the DQ was 10 minutes. No changes were suggested to item content. Focus group participants indicated that the tool as revised was easy to read and understand.

For this dissertation study, the DQ as revised in 2008 was used as the primary tool to collect demographic data (age, gender, educational level, household composition marital status, employment, health insurance and annual income). Items of the DQ are compatible with records kept at SAFE for the SenioRx Wellness Program.

Because of the limited number of participants for this study, it was not possible to establish validity of the DQ using statistical methods (i.e., Cronbach's alpha). However, all of the data collected from the DQ were cross-checked for consistency using records kept at SAFE for the SenioRx Wellness Program. Case records are maintained in a manner to comply with federal regulations for the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

#### *Patient Medication Administration Record*

The Patient Medication Administration Record (PMAR) was used in this study to collect self-reported information about prescribed medication. The PMAR was adapted from the PMR developed by the *SOS Rx Coalition*. The PMAR presents items grouped in four sections: (a) My Personal Information (contains 10 questions about personal demographic data and number of ADEs during the past 12 months); (b) Physicians and Pharmacists (identifying information); (c) My Allergies (specifying all allergies); & (d)

Medication Record chart, which requires the respondent to identify by name all prescription medication, form (pill, liquid, patch, etc.), dosage, frequency and time of administration, whether to take on schedule or only as needed, beginning and ending dates, directions and reasons for use. For this study the researcher added a new item, “How many Adverse Drug Events did you experience in the last 12 months? This could be anything that made you afraid that you took your medication wrong.” In addition, the format was altered to large-print for easier reading. One shortcoming of the PMAR is lack of observational data about actual administration, which was addressed during in-home interviews (Phase II of the study).

Time to complete the PMAR varied across respondents according to the number of chronic conditions, prescribing physicians, and number of medications; the researcher did not solicit length of time to complete this form from respondents in this study. Using the information gathered during in-home visits for the qualitative phase of data collection the PMAR was used to validate accuracy or confirm errors.

The PMAR used for this study was adapted from the Personal Medication Record (PMR) originally designed by the *SOS Rx Coalition* of the National Consumers League (NCL) (2004). The NCL strives to make the outpatient use of prescription medications safer, especially for senior citizens. The *SOS Rx Coalition* initiative targets behavior change through education, promotes public policy for the creation of a clearinghouse of safe prescription practices, and encourages the use of a personal medication record to enhance health of seniors (Personal Communication, Rebecca Burkholder, NCL).



An expert panel made up of *SOS Rx Coalition* members was convened in 2003 by the NCL to develop a set of “inclusionary criteria” for the PMR. Members include AARP, National Association of Boards of Pharmacy, American Society of Health System Pharmacists, American Medical Association, and Centers for Medicare and Medicaid Services, among others. The NCL charged the group with the development and promotion of a PMR.

The minimum criteria suggested by the panel for the PMR includes a section to list prescriptions and over-the-counter medicines, as well as dietary supplements. The PMR template was disseminated to many consumer organizations (National Consumers League, 2004). The NCL released a statement in support of their PMR template on their website, which states “consumers should have a role in ensuring that a complete, accurate, and updated list of medications and supplements is available to all of their medical care providers so as to maximize therapeutic benefit and minimize the risk of adverse reactions.”

In 2007, the SOS Rx Senior Outpatient Medication Safety Coalition pledged to “increase dissemination of the PMR data elements developed by SOS Rx. We intend to focus dissemination of the PMR to high-risk populations – such as those who manage multiple medications, multiple chronic conditions, and low health literacy... we hope to promote consumer action to avoid errors.” (Personal Communication, Rebecca Burkholder, NCL).

The AARP is among the list of officially committed partners for the National Medication Adherence Campaign, a nationwide effort to engage consumers and health care providers with support from the Agency for Healthcare Research and Quality

(AHRQ). The AARP developed its version of a personal medication record known as, “My Personal Medication Record” in 2007 (Personal Communication, Rebecca Burkholder, NCL).

Multiple attempts were made to locate information regarding field testing results for the PMR by the NCL and or the AARP. Communications with the NCL revealed that field testing or validity and reliability had not been established using statistical tests by either the NCL or AARP. The NCL had the intent to field test the document however, limited funding prevented testing therefore, the PMR is based on expert panel opinion of what must be included in any PMR developed (Personal Communication, Rebecca Burkholder, Jurist Doctorate and Vice President of Health Policy for the NCL).

#### *Test of Functional Health Literacy in Adults*

The Test of Functional Health Literacy in Adults (TOFHLA) (Nurss, Parker, Williams & Baker, 2001) measures the ability of patients to perform such tasks as reading labels on prescription bottles, informed consent documents, instructions about diagnostic tests, instructions about how often to take medication, reminder notices for a doctor's appointment, and instructions to complete a health insurance form (Baker et al., 1999). The version used for this study has two sections: reading comprehension and numeracy. The reading comprehension test is a 50-item multiple choice exam which is given during a 12-minute time frame. The numeracy section is an interactive 17-item exam administered using prompts during a 10-minute time frame. The Functional Correlation of the TOFHLA Score as outlined below in Table 3 was developed by the

original authors of the instrument for use by others who administer the TOFHLA for research purposes.

Table 3

*Functional Correlation of TOFHLA Scores*

Level	TOFHLA score	Functional health literacy description
Inadequate functional health literacy	0-59	Unable to read and interpret health texts
Marginal functional health literacy	60-74	Has difficulty reading and interpreting health texts
Adequate functional health literacy	75-100	Can read and interpret most health texts

*Note.* Nurss, J., Parker, R., Baker, D., (1994). *Test of Functional Health Literacy in Adults* (Chapter 3, pg. 13). Peppercom Books and Press, Inc., Hartford, Missouri.

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The TOFHLA was administered to each participant who attended the planned data collection event. The TOFHLA is an instrument used to measure health literacy levels and categorize the community dwelling older adults (ages 60 to 74) who self-

manage five or more daily prescription medications and participate in programs offered by SAFE into one of three levels of health literacy: inadequate, marginal, or adequate (Baker, Williams, Parker, Gazmarian, & Nurss, 1999). The average time to complete both sections of the TOFHLA is 22 minutes (Parker et al., 1995).

Reliability of the TOFHLA has been calculated by both split-half and internal consistency measures using Equal Length Spearman-Brown and Cronbach's Alpha formulas, respectively (Nurss, Parker, Williams, & Baker, 2001). The calculated Cronbach's Alpha of TOFHLA is 0.98 (Nurss et al., 2001). Construct validity for this functional literacy test was reported by its authors for both the Reading Comprehension and Numeracy subtests (Nurss et al., 2001). For this dissertation, the researcher relied on the reported validity of the original study as there were too few participants to estimate validity for this study.

### Quantitative Data Collection

Quantitative data collection for Phase I of the study was accomplished in two rounds, and in two settings (each participant's home and the CRC or ALF). In Round One, 26 participants self-administered the DQ and the PMAR in their home. For Round Two of the quantitative data collection, 26 presented to take the TOFHLA; however, only 15 individuals from the group of 26 were willing to take the test of health literacy.

Two months prior to beginning data collection for Phase I of the study the researcher was invited to speak to each group of seniors at the CRCs and the ALF. During these site visits, the investigator: (a) solicited interest in the study among all participants of the SenioRx; (b) discussed the study purpose with potential participants;

(c) described risks and benefits of study enrollment; (d) educated seniors about the meaning of “adverse drug event”; and (f) reviewed study materials in the packet with the group. Before leaving each CRC or ALF, a question and answer session was conducted by the researcher to address issues of concern that were raised by the potential participants.

Seniors who requested a packet (n=50) were given one to take home with them, so that they had ample time to read over the materials and decide whether to participate in the quantitative data collection of the study. The packet of information contained an information sheet about the study. Participants were asked to complete: (a) a questionnaire disclosing demographic information (DQ) and (b) his or her personal medication record (PMAR). Additionally, they were reminded of the event one week in advance by phone or post card.

Many of the 200 older adults identified in the five settings did not meet the minimum criteria for participation in Phase I of the study because they were not between the ages of 60 to 74, and or were not prescribed five or more daily medications. In an attempt to be inclusive of all seniors who participate in the SenioRx at any of the five settings, screening for age or number of medications was not done prior to the quantitative data collection. Instead, all attendees were encouraged to participate in the quantitative data collection regardless of their age or number of prescribed medications. This gesture provided a more inclusive atmosphere within the groups that resulted in an increase in the number of participants. Some stated that they would participate if they had a friend with them during data collection.

Staff members from SAFE who are case workers for SenioRx scheduled the quantitative data collection at each CRC and the ALF, promoted attendance, and offered daily encouragement of participation leading up to the planned event. On the days of the planned special events, a total of 26 seniors brought the completed Demographic Questionnaire (DQ) and Personal Medication Administration Record (PMAR) with them when they arrived at their designated CRC or the ALF. A time span of 15 minutes was allowed between the time advertised for the special event (when seniors began to arrive) until the start of the assessment for health literacy (Test of Functional Health Literacy for Adults or TOFHLA). Escorted to a private area, participants were given a file folder (with an alpha-numeric id code) to hold the completed documents. The file had an index card attached to it with the same alpha-numeric code. Alpha-numeric numbers included the first letter of the name of the center (i.e., Center C “C”) followed by the number of one of those participating. For example, if three participants turned in the folder at the C CRC, alpha-numeric numbers located on the tabs of the folders and given out were “C1”, “C2” and “C3”. This coding procedure was done so that the researcher could find each participant’s information should they have any questions about his or her file.

Test takers were seated with an empty space on each side of them to provide privacy and ensure accuracy. Number 2 Pencils were available on the table. The reading comprehension portion of the TOFHLA was given out, face down along with a cover sheet for accuracy and credibility of the answers to the test. Questions were answered and seniors were asked not to speak to anyone during testing. Eleven of the participants refused to take the TOFHLA after their questions were answered or early during the reading comprehension portion of testing. The timer was set for 12 minutes and all were

instructed to turn their test over and begin. Three, two, and one minute warnings were announced so that all test takers would know how much time they had left. At the end of the 12 minutes, all test takers were asked to put their answered test into the folder, close it and again, place it in front of them on the desk. The researcher encouraged all to stand up, stretch, and utilize the facilities if needed prior to moving on to the numeracy portion of the test. Within three minutes, all were back and seated to begin the final part of the TOFHLA exam.

For the 17-item numeracy portion of the TOFHLA, a series of interactive prompts (given to each test taker and read by the proctor) are used for which the test taker responds to. These prompts are printed images, sealed with lamination so they can be used over and over. The prompts include: prescription vials, an appointment slip, and a chart describing eligibility for assistance from Medicare. The numeracy portion was distributed to the group, face down along with a laminated prompt sheet and cover sheet. Test takers were asked if they had any questions before beginning the numeracy section of the TOFHLA. After questions were answered the researcher reminded the group not to talk during the test and to answer questions as they were prompted. They were then instructed to turn their test over and the researcher (proctor) began with the first prompt.

Once the test began, the researcher read each prompt spaced evenly over a 10-minute time frame as the test takers recorded responses. Those having difficulty answering any question were encouraged to do the best they could and move on once the next question was read. At the end of the 10 minutes, test takers were asked to: (a) put their second section of the TOFHLA in the folder, (b) close the folder and leave it on the

desk and, (c) take the index card with the id code with them. For those who did not finish during the 10 minutes, they were asked to turn in what they had completed.

The completed TOFHLA exam was placed in a folder and returned to the researcher. Each participant received an index card with the alpha-numeric code that was also noted on the tab of the file folder. Once all data was returned to the researcher, participants enjoyed the incentives offered. Files were kept in a secure lock box for transportation back to Birmingham, Alabama. Upon arrival back in Birmingham, the researcher scored each test using the Functional Correlation of TOFHLA as presented in Table 3.

Upon completion of all quantitative data collection, all community dwelling older adults (ages 60 to 74) from Phase I of the study (n=50) who met the inclusionary criteria for Phase II of the study (N=15) were invited to SAFE for an annual vision screening. All 15 participants met the minimum criteria for accurate vision as determined by the SenioRx Medication Wellness Program staff at SAFE who used the Snellen Eye Chart for testing.

### Quantitative Data Analysis

Descriptive research is defined by Johnson and Christensen (2008) as “research focused on providing an accurate description or picture of the status or characteristics of a situation or phenomenon” (p.585). Descriptive analysis of the quantitative data (DQ, PMAR and TOFHLA) using the 12.0 student version of the Statistical Package for the Social Sciences (SPSS) provided descriptive statistics for Phase I of the study.



Descriptive statistics is defined by Johnson and Christensen (2008) as “statistics that focus on describing, summarizing, or explaining data” (p. 585). For this study, the descriptive findings for the mean, median, mode, range, and percentages were used to describe, summarize, and explain the data from Phase I and to select participants for the qualitative phase of data collection via purposive sample selection using the maximal variation strategy.

### Phase II Qualitative

For the qualitative phase of the study, purposive sampling using the maximal variation strategy was used to select participants for Phase II of the study. Incorporating the maximal variation strategy with purposive sampling resulted in three distinct cases based on health literacy with representation of a variety of participants within each case to ensure every type of participant was represented. Within Chapter Four is a detailed explanation of how cases were composed.

### *Multiple Case Study Design*

Yin (2003) defines case study research as “an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident” (p.13). A case study design can be one individual case or multiple cases that are within a setting or context (a bounded system) with a finite number of participants that seeks to answer a key question (Stake, 1995). Data collection pulls from multiple sources of data. The reporting of the

data provides a description of the cases and the themes that developed about the cases (Stake 1995; Yin, 2003).

There are three types of case study design; single instrumental, intrinsic, and collective or multiple instrumental (Stake, 1995). For this study, the collective design was useful to examine the potential of adverse drug events from the practice of polypharmacy. This design allowed for the selection of multiple cases to explore potential threats to seniors who are prescribed five or more daily prescribed medications. Additionally, case studies allow for the selection of cases that show different perspectives through maximal variation sampling.

Multiple forms of data collection are used for case study design to develop an in-depth understanding of the case(s) (Stake, 1995; Yin, 2003). Interviews, observation, documents from SAFE, prescription bottle labels and artifact information were all used in data collection for this phase of the study. A detailed description of the cases and common themes in the cases are described in Chapter 4 though within-case analysis followed by a cross-case analysis in a prose summary (Creswell, 2002).

### *Sampling*

Jones et al., (2006) note that in case study methodology, sampling occurs on two levels. The first level involves selection of the case followed by the second level or selection of the participants for the case (Merriam, 1998). Samples are drawn that reflect “an emphasis on information-rich cases that elicit an in-depth understanding of a particular phenomenon” (Jones et al., 2006, p. 65). Purposive sampling selects

participants with a specific purpose in mind (Creswell, Plano Clark, Gutmann, & Hanson, 2003). Purposive sampling addresses particular needs related to the research questions in a study and focuses on the depth of understanding that each case can provide to the study (Teddlie & Tashakkori, 2009).

The explanatory design-participant selection model using the maximal variation strategy was used to purposefully select participants for the qualitative phase of this study to comprehend how community dwelling older adults ages 60 to 74 self-manage five or more daily prescribed medications? Additionally, social support services which impact self-management of prescribed medications were explored as well as whether participants of this study experienced adverse drug events related to polypharmacy practices within the past 12 months.

Purposive sampling allows the researcher to specify the characteristics of the population of interest and locates individuals with those characteristics (Johnson & Christensen, 2008). Incorporating the maximal variation strategy with purposive sampling resulted in three distinct cases based on health literacy with representation of a variety of participants within each case to ensure every type of participant was represented (Johnson & Christensen, 2008). Johnson and Christensen define maximal variation strategy as “purposively selecting a wide range of cases” (p. 592).

After the TOFHLA was scored, participants were grouped based on the three levels of health literacy. Using the PMAR, each participant’s TOFHLA score was matched up with his or her number of prescribed medications. The final portion of data selection for the quantitative data analysis came from the DQ. Variables selected for testing to provide information for the purposive sampling included age, gender, levels of

education, and score on TOFHLA. These variables were chosen because of their relevance to the study research questions (Stommel & Wills, 2004).

To facilitate the purposive sampling using the maximal variation strategy for selection of the cases for the qualitative phase of the study, the quantitative data analysis included testing for range, ranking, and outliers. The range analysis provided information about the difference between the highest and lowest numbers, and the ranking showed the ordering of responses in descending order (Johnson & Christensen, 2008). Testing for outliers provided information about any participant's data that was atypical of the other numbers in the distribution (Johnson & Christensen, 2008).

Missing data from the DQ were found in many of the charts (salary, insurance coverage, and household composition), therefore, that information was not used for SPSS analysis. Additionally, if any one question was answered by all participants the same way, it was noted and set aside for further evaluation during Phase II (qualitative) data collection; examples included questions about adverse drug events and employment.

For the qualitative phase of a MM study, Schumacher (1993) addresses the need and importance for the sample to meet a common set of criteria. For the qualitative phase of this study the sample was selected from seniors who took part in the quantitative phase of the study. All were English-speaking, community dwelling older adults (ages 60 to 74) across three levels of health literacy that self-manage five or more daily prescription medications and participate in programs offered by SAFE.

The qualitative sample was purposefully selected using the maximal variation strategy with consideration as noted. The most important variable for the sample selection was health literacy scores and levels as determined by the TOFHLA. Health

literacy categories of inadequate, marginal, and adequate are the labels of the three cases. Following health literacy scores, educational levels were considered in order to estimate individuals' perceived ability to correctly self-manage prescribed medications. The third most important variable considered was the age of participants. Individuals who are less than 60 years of age are less likely to be prescribed 5 or more daily medications. Older adults who are 74 years of age or younger are less likely to have cognitive function decline. Considered next were the number of daily prescribed medications. This number was used both to determine eligibility for the study and to explore risk for adverse drug events. Lastly, gender and marital status were incorporated into the study for selection purposes to have a varied sample. A *Microsoft Excel Spreadsheet* that includes all participants from Phase I who completed the quantitative data collection was used to enter the data for comparison and sample selection (Table 4).

Table 4

*Characteristics Used for Purposeful Selection Using the Maximal Variation Strategy  
for Phase II of the Study*

Alpha numeric ID	TOFHLA category	Highest grade completed	Age	Number daily Rx medications	Gender	Married
1S	Adequate/75	12	70	15	Female	No
4M	Adequate/77	12	71	12	Male	No
6O	Adequate/81	10	72	9	Female	Yes
6C	Marginal/65	12	61	12	Female	No
5S	Marginal/68	12	68	10	Male	Yes
1O	Marginal/71	12	74	9	Female	Yes
4O	Inadequate/37	8	72	11	Female	Yes
25MV	Inadequate/42	11	72	11	Female	Yes
1C	Inadequate/50	10	71	10	Female	No
2MV	Inadequate/53	10	74	10	Female	Yes
14MV	Inadequate/58	9	74	12	Female	No
3MC	Inadequate/59	9	73	11	Female	No
2C	Inadequate/59	12	73	10	Female	No
1M	Inadequate/59	12	73	12	Female	Yes

Upon completion of all data collection and analysis for Phase I of the study, the data were stratified by three health literacy levels - adequate, marginal and inadequate -

to establish cases one, two, and three. With only 15 total participants to complete all data collection from Phase I, the results of stratification by health literacy levels were limiting. A total of three participants with adequate health literacy were grouped for case one and likewise three participants with marginal health literacy were grouped for case two. Case one and two did not have enough participants to purposively select individuals for each case respectively. However, in spite of that finding, the cases do show variation in number of medications prescribed, gender and marital status.

Case One health literacy scores were 75, 77, and 81 with one participant finishing the 10<sup>th</sup> grade and two graduating from high school. The ages were 70, 71 and 72; numbers of daily prescribed medications were 9, 12, and 15; there were two females and one male; one participant was married and two were not. Case Two health literacy scores were 65, 68, and 71. Ages were 61, 68 and 74; numbers of daily prescribed medications were 9, 10 and 12; two participants were female and one was male, and two were married while one was single.

For Case Three (to represent inadequate health literacy) the remaining nine participants' data were reviewed for purposeful selection using the maximal variation strategy. Health literacy scores identified 6 different scores (37, 42, 50, 53, 58 and 59). Participants selected to progress for further review represented the one with the lowest score, the three with the highest score, and the two mid-ranking scores of 50 and 53. The researcher wanted all three cases for the study to be equal in size thus, the need for elimination of some of the participants. The participants who scored at 42 and 58 were not considered for progression because they fall into the midrange between the lowest

and the middle scores and the highest and the middle scores therefore they did not add to the value for distinction using the maximal variation strategy.

The remaining seven participants were reviewed for the level of education or highest grade completed representing grades 8, 10, and 12. One participant scored 37 on the TOFHLA and had the lowest level of education (8<sup>th</sup> grade). Subsequently she was earmarked to be the likely participant for Case Three to represent the lower extreme for the case. Additionally, of the three who scored 59 on the TOFHLA, the reported level of education completed was grades 10, 12, and 12. Employing the maximal variation strategy, the selection progressed to choose between the two who completed the 12<sup>th</sup> grade and thereby eliminating the one who scored 59 and completed the 10<sup>th</sup> grade. Both participants who scored 59 and finished the 12<sup>th</sup> grade were 72 years old. The number of daily prescription medications for the two were ten and twelve and both were female. The information about the number of daily prescribed medications lead the researcher to earmark the participant who scored 59, completed the 12<sup>th</sup> grade and who was prescribed 12 daily prescription medications for selection for Case Three.

At this point the researcher had a participant earmarked for further review to represent the upper and lower variations for the inadequate health literacy know as Case Three. At this point the focus shifted to the two participants who scored in the middle of the range of TOFHLA scores. Table 4 reveals that these two were similar in several categories; both were female, neither were married; they were only two years apart in age. The most compelling reason for selection of one instead of the other were: (a) one completed the 10<sup>th</sup> grade which placed her in the mid-range of educational level (10<sup>th</sup>



grade), and (b) she was 72 years old which puts her in the midrange of the ages represented in Case Three.

It is important to note that multiple missing data were found when recording data from the DQ during analysis of the quantitative data. Thus, the missing variables /characteristics; (a) household composition, (b) income, and (c) public or private insurance were not used for purposive selection of the qualitative sample. Additionally, all respondents answered the “yes” to the question from the DQ “Do you take your daily prescribed medications the way you are supposed to every day?” and all answered “no” to the DQ question “Are you employed.”

Data collected where all respondents answered “yes” or “no” to a single question were eliminated for the purposeful selection using the maximal variation strategy for sample selection for Phase II of the study. The participants selected for case-study analysis of the purposive sample selection using the maximal variation strategy are represented in Table 5.

Table 5

*Qualitative Sample for Phase II. Representing Three Distinct Cases: Adequate, Marginal, and Inadequate Levels of Health Literacy as Measured by the TOFHLA*

Alpha numeric ID	Category/ numeric	Highest grade completed	Age	Number daily Rx medication	Gender	Married
1S	Adequate/75	12	70	15	Female	No
4M	Adequate/77	12	71	12	Male	No
6O	Adequate/81	10	72	9	Female	Yes
6C	Marginal/65	12	61	12	Female	No
5S	Marginal/68	12	68	10	Male	Yes
1O	Marginal/71	12	74	9	Female	Yes
4O	Inadequate/37	8	72	11	Female	Yes
2MV	Inadequate/53	10	74	10	Female	Yes
1M	Inadequate/59	12	73	12	Female	Yes

#### Data Collection Tools

Data collection for the qualitative phase of the study was accomplished using multiple sources. A focus group was convened during the summer of 2008 with participants of the SenioRx Wellness Program at SAFE. Group discussion enabled the researcher to improve the Checklist, Interview and Observational Protocol (IOP) for later

use to guide the in-home interviews for this study. Additionally, a Medication Administration Self-Efficacy Scale (MASES) was utilized and a thorough review of the SenioRx program charts for each participant selected for the qualitative data collection was reviewed in the presence of the Sylacauga Alliance for Family Enhancement case-worker. All data collection tools are described below.

### *Checklist(s)*

In collaboration with the Executive Director of SAFE, two checklists were developed. One was for use during the home visit and the other for SenioRx Wellness chart review. The checklists provided the researcher with tools that could be used during the home visit to make certain all home visits were comparable as well as during SenioRx Wellness chart review. Items on the checklists pertain to the date, time, length of the interview, identity of the interviewer/transcriber, identity of SAFE caseworkers/observer on hand during the interview, and setting. The checklists can be found in Appendices E and H.

### *Interview and Observational Protocol*

Qualitative data collection should remain unstructured and contain open-ended questions (Creswell, 2002). A pilot focus group of nine community dwelling older adults (participants in programs at SAFE) and three staff members from SAFE were invited to participate in the development of the IOP. The community dwelling older adults had been tested for health literacy levels using the TOFHLA. Composition of the focus group represented older adults ages 60 to 74 across three levels of health literacy, who self-

managed five or more daily prescription medications and participated in programs offered by the SAFE. SAFE caseworkers observed the focus group and provided input based on their experience with the population.

During a two-hour focus group discussion on the subject of IOP items, seniors suggested minor changes in wording. Seniors wanted multisyllabic words translated to simple words using synonyms so that the document would be easier to understand. The IOP was revised considering input from the focus group and SAFE caseworkers. The final version resulted in an IOP written at a third grade reading level for ease of understanding. During a return visit to meet with the focus group two weeks after the initial meeting, participants indicated that the tool as revised was easy to understand.

The Interview and Observational Protocol (IOP) (Appendix F) used for the study contains eleven items, the most of which contain multiple open-ended questions and probes to guide the data collection. Using the IOP, participants are quizzed about how they self-administer multiple medications on a daily basis and utilize the health care system.

Items one and two contain questions used to collect identical information solicited on the Personal Medication Administration Record (PMAR). Sample questions from items one and two are: “Tell me about the medications you use on a daily basis;” “How do you take them?” “Why do you take them?” and so forth. Other information the IOP seeks to ascertain relate to: (a) benefits from the medications they take, (b) information provided via visits with physician or health care provider, (c) number of health care providers/ pharmacists used regularly, (d) auxiliary services prescribed such as physical

therapy, (d) community agencies or programs used on a regular basis for assistance with medication adherence, and (e) concerns/worries about medical regimen.

Observations/interviews were conducted focusing on the central question for the qualitative data collection, “How do community dwelling older adults between the ages of 60 to 74 self-manage five or more daily prescribed medication?” Field notes included words and actions recorded on a note pad both by the researcher and the observer case manager from the SenioRx program. Additionally there is a section for descriptive notes, observational notes and comments.

Because of the limited number of participants for this study and the preliminary focus group, it was not possible to establish validity of the IOP. During this dissertation study, all individuals who participated in Phase II of the study (qualitative) were asked if they understood all questions from the IOP as presented to them. All concurred that it was easy to understand the questions.

#### *Medication Administration Self-Efficacy Scale*

Medication self-efficacy was determined using the Medication Adherence Self-Efficacy Scale (MASES) (see Appendix G). Self-efficacy describes the confidence level of each participant to successfully manage a medication regimen (Gregson et al., 2001). Bandura (1985) defined self-efficacy as “an individual’s personal belief regarding their capabilities to carry out a specific task in order to achieve a desired outcome” (p. 1176).

Developed by Ogedegbe, Mancuso, Allegrante, and Charlson (2003), the MASES retained 26 items in the final version of a self-efficacy scale after determining item-to-total correlation and Cronbach’s alpha coefficients, and after discussion of

clinical significance. Researchers for the MASES study set the threshold for the item-to-total correlation coefficient as 0.5. A subset of participants completed the scale on two occasions. Items achieving both the item-to-total correlation coefficient  $> 0.5$  and kappa statistic  $> 0.4$  were retained. Researchers determined that five additional items had clinical or practical relevance for medication adherence. These items assessed cost of medications, side effects, and frequency of dosing. The Cronbach's alpha coefficient for the final 26-item Medication Adherence Self-Efficacy Scale was 0.95. Researchers concluded that the scale is useful to identify patients' low self-efficacy for adherence to prescription medications. Since its development, the MASES has been widely used by other researchers (Veazie & Cai, 2005; Makoul, & Clayman, 2006; Schroeder, Fahey, Hay, Montgomery, & Peters, 2006; Zeller, Schroeder, & Peters, 2008; Krousel-Wood, Muntner, Islam, Morisky, & Webber, 2009; Gozum, & Hacıhasanoglu, 2009; Ogedegbe, et al., 2007; Berna, et al., 2008; & Johnson, Mackinnon, Kong, & Stewart, 2006).

#### *SenioRx Wellness Program Chart Review*

Each participant for this study was part of the *SenioRx Wellness Program* (SenioRx) offered at SAFE. Upon conclusion of all data collection during home visits, the researcher and the caseworker met at SAFE to review the SenioRx charts for each participant who had participated in a home visit. The purpose of the review was to gain insight about how community dwelling older adults (ages 60 to 74) across three levels of health literacy perceive, respond to, and report health risks related to ADEs. A comprehensive review of the records was helpful to the researcher who sought to identify

risks for and occurrences of ADEs and accuracy of the information collected during the home visit. The types of medications prescribed and a review of records from past history of medication management were of interest both to the researcher and to the SAFE Executive Director. For instance, some participants in the interview revealed unsafe use of OTC medications and herbal supplements. The researcher developed a checklist that guided interviews of SAFE caseworkers (Appendix H) which is discussed in more detail later in this section.

### Qualitative Data Collection

For Phase II of the study, SAFE caseworkers called each participant chosen to continue in the study to explain the qualitative phase of the study and invite them to participate. During the conversation, information about incentives offered for participation was discussed. All invitees acknowledged interest and agreed to participate in Phase II data collection. The SAFE caseworker(s) arranged the meeting times and coordinated all dates for the home visits.

Home visits were planned for August and September 2010. Each participant was visited one time. The visit ranged from 30 to 45 minutes in length. Prior to data collection, an informed consent document, approved by the IRB was administered to each participant describing the study purpose, types and uses of data, risks and benefits (Appendix I). A SAFE case worker accompanied the researcher to each home visit to observe the interview process.

During home visits data collection began with interviews facilitated by the Interview and Observational Protocol (IOP). In-depth interviews using open-ended

questions from the IOP allowed the researcher to identify self-recorded barriers and facilitators of self-management of medications. During the analysis of the data the barriers and facilitators were aligned as they relate to the levels of the SEM (Creswell & Plano Clark, 2007). Self-care behavior, trust in health care providers, perceived levels of support from the community and organizations, and satisfaction with medication self-administration were discussed. Participants were allowed to review prescription bottles in the home. Family members were discouraged from joining the interview/discussion; the purpose of which was to avoid “helping” participants when answering questions and explanation/demonstration of how medications were self-administered.

Participants were asked to identify the name of each prescribed medication and prescribing physician along with specific information about why, how and when each medication was taken. Participants explained his or her understanding of why they were prescribed the medication, how it is taken on a daily basis, and how they store the prescribed medication.

Observational data collected during home visits provided additional information outside of the key interview questions. Non-specific types of information were collected regarding: (a) the accuracy of the self-reported information from Phase I; (b) home living conditions; and (c) the community in which participants live. Home visits provided an avenue for collection of qualitative data to compare self-reported practices of medication knowledge with observed medication self-administration practices. Other information ascertained during home visits were older adults’ knowledge, attitudes, and beliefs about medication adherence. Each participant was assessed for his or her self-efficacy for medication administration using the MASES.



To summarize, home visits provided the time for an interview and the opportunity to observe and compare self-reported information about self-administration of medication with observations of actual practices within the home to identify accuracy or inconsistencies. Occurrence of adverse drug events and the identification of barriers and facilitators for self-management of medications were explored as they relate to levels of the SEM (Creswell & Plano Clark, 2007). Additionally, the Checklist and IOP were reviewed to make certain all required items had been covered during the interview and observation time. Prior to leaving each visit the information recorded was read back to the participant to make certain the information had been recorded accurately. Results of this process of validation will be discussed in more detail in Chapter 4.

Following each interview, the participant was presented with the promised incentive for participation in the study (\$25.00). All participants were extremely appreciative of the payment. After leaving each home, time was allotted to return to SAFE to discuss recorded information with the SAFE caseworker that was present during the interview and to thoroughly review the SenioRx chart for each participant.

#### *Review of SAFE SenioRx Wellness Program Charts*

A thorough review of participants' charts for the SenioRx Wellness Program (SenioRx) was conducted following the home visits. SAFE caseworkers were available to answer questions during the review. The purpose of the review was to gain insight about how community dwelling older adults (ages 60 to 74) across three levels of health literacy perceive, respond to, and report health risks related to ADEs. A comprehensive review of the records was helpful to the researcher who sought to identify risks for and

occurrences of ADEs and accuracy of the information collected during the home visit. The types of medications prescribed and a review of records from past history of medication management was of interest both to the researcher and to the SAFE Executive Director. For instance, some participants in the interview revealed unsafe use of OTC medications and herbal supplements. The researcher developed a checklist that guided interviews of SAFE caseworkers (Appendix H). Sample items include:

1. What differences did you note between participant's responses to the PMAR and SAFE case records about self-administration of medication?
2. Did the participant accurately report ADEs based on your knowledge as a caseworker?

Discussions helped the researcher to identify how individual caseworkers respond to potential risks for ADEs, verify accuracy of all daily prescribed medications and identify inconsistencies for each participant.

### Qualitative Data Analysis

All qualitative research studies are unique and thus demand unique strategies for analysis (Creswell, 2009). Qualitative data analysis consists of identifying, coding, and categorizing patterns found in the data (Miller, 2000). The clarity and applicability of the findings, however, depend on the analytic intellect of the researcher (Byrne, 2001). This dependence on the human factor can be the greatest strength or the greatest weakness of a qualitative research study. It is incumbent on the researcher to report and document his or her analytic processes and procedures fully and truthfully so others may evaluate the credibility of the researcher and his or her findings (Lincoln & Guba, 1985).

Hatch (2002) describes the process of coding in terms of the goals of the analysis. For example, in typological analysis the author suggests marking entries within the transcripts related to the typology of interest to identify patterns, relationships and themes. Secondly, the researcher should code entries in the text according to the established patterns, relationships and themes. Utilizing the typological approach, the transcriptions were coded resulting in the identification of ten codes, which were later categorized into three overall themes. This process was selected based on the fact that this kind of coding is defined as the “most accessible” for new researchers and is generally done for the purpose of understanding the different ways in which people describe or discuss a particular topic (Morse, 2002b). The goal of this process is to find patterns within a framework or create a deeper understanding of a specific topic area. The idea as described by Hatch (2002) is to bring all these ideas on the same topic together in one place, aligned with the goals of this project. Chapter Four provides a table that highlights the themes and the corresponding codes from which they were developed.

To prepare for analysis of the data, it must first be organized. Creswell (2009) suggests the development of a matrix or table of sources that can be used to organize the data followed by the organization of the material by the type of information. For this study, the researcher began by organizing all the data collected from different qualitative sources. A matrix was developed to organize the data and to provide an overview of the types of data (interviews, observations, and document analysis). Folders using alpha-numeric codes for each participant were useful and helped keep all the data for each participant together.

Naturalistic generalization provides a practical application in a way that others feel the experience may have happened to them or represents perceived experiences to be similar. This study utilizes Stake's (1995) concept for naturalistic generalizations to analyze and report the findings. Stake suggests that individuals learn from generalizations made during daily experiences and interactions.

Data from interviews, observations, and SAFE SenioRx record reviews of each participant were analyzed for themes related to the accuracy of self-administration of prescription medication, support for the individuals of the study in consideration of the SEM, resources available within the community for each participant and issues related to medication adherence. Within and across case analysis of the qualitative data revealed similarities and differences within each case and across the three different levels of health literacy.

After developing the themes, the researcher used the information to develop "rich and thick" description of the findings of the study. Creswell (2002) stated that description needs to be detailed so that the reader can "see" the person or environment. Using vivid and accurate description, the researcher described the home environment for each participant specifically as it relates to self-administration of prescribed medications (example: storage, safety, and accessibility). Using an approach outlined by Teddlie and Tashakkori (1998), categories and subcategories of themes emerged to provide a more complex understanding of the study.

### Establishing Credibility

There are many perspectives on how qualitative research is deemed to have credibility (Creswell, 2009; Onwuegbuzie & Johnson, 2006; Teddlie & Tashakkori, 2009). Research scientists often look for qualitative equivalents that parallel traditional quantitative approaches to validation. Most qualitative researchers support the notion that validation is important for qualitative research. This study utilized a number of verification strategies including triangulation, inter-coder agreement, member checking and rich thick description.

#### *Triangulation*

Triangulation (Lincoln & Guba, 1985) was achieved by summarizing data collected using different methods along with verification of self-reported information during home visits and interviews. Participants in this study had a SenioRx record kept at SAFE used to monitor individual progress. The record contains valuable information regarding health history, prescribed and OTC medications, and medical regimes. Caseworkers for each participant have access to the information. Reviewing case history using existing documents and caseworker discussion was meaningful to verify self-administration of prescribed medications. Two of three caseworkers have been working with SAFE since the inception of the SenioRx and are very familiar with clients' medical histories.

During the SenioRx record review, data collected from the quantitative PMAR tool were compared to data collected by the researcher during the qualitative phase of the study. Afterwards, the researcher compared data gathered during Phases I & II with

medical records maintained by the SAFE SenioRx to identify similarities and differences. The researcher discussed with SAFE case workers a summary of data, particularly risks of ADEs among older adult participants.

### *Inter-coder Agreement*

Inter-coder agreement (Creswell, 2009) was used to determine the level of concurrence between notes taken by the SAFE staff member during observations and the researcher during the home interview. Comparison of themes that emerged during the qualitative analysis were discussed with the caseworker from SAFE. There was 100% agreement between the two as calculated using the total number of themes divided by those agreed upon between the researcher and the caseworker. The researcher utilized this type of validation to establish verification for what each perceived as the major themes as it relates to established codes.

### *Member Checking*

Lincoln and Guba (1985) suggest member checking or participant review to validate that those closest to the situation agree with the findings and interpretations of the researcher. This method entails recruiting someone close to the study (for this study it was each participant) to review accuracy of data and interpretations and verify similar conclusions.

Member checking was accomplished through verification of recorded information with SAFE caseworkers who accompanied the researcher during each home visit. Errors and omissions were noted and reviewed further for analysis and findings. At the end of

each interview, transcripts from each interview were read back to interviewees to ensure that the information was recorded accurately and in the appropriate context. Additionally, staff from SAFE who accompanied the investigator during participant interviews provided the researcher with an opportunity to discuss interpretations and clarify questions related to the individual interviews. This process was extremely useful in guiding the analysis.

### *Thick Rich Descriptions*

Using thick rich descriptions (Creswell, 2009; Onwuegbuzie & Johnson, 2006) from the collected data, findings of the qualitative phase of the study are detailed in Chapter 4. Analysis of the findings from the interview through a narrative provides the reader with a firsthand account of the environment in which community dwelling older adults (ages 60 to 74) across three levels of health literacy self-manage five or more daily prescription medications.

### Legitimation

Onwuegbuzie and Johnson (2006) developed the term *legitimation* to describe validity in mixed methods research. By definition, legitimation is a dynamic process of evaluation to demonstrate the quality of inference in mixed methods research (Onwuegbuzie & Johnson). Teddlie and Tashakkori (2009) noted that legitimation of mixed methods research allows the researcher to make inferences that are dependable, transferable, credible, trustworthy and can be verified.

It is essential to establish legitimation when interpreting results of a sequential explanatory study prior to generalizing the data. Onwuegbuzie and Johnson (2006)

developed a classification system of nine different legitimation types used for mixed methods research: sample integration, inside-outside, weakness minimization, sequential legitimation, conversion legitimation, paradigmatic mixing, commensurability, multiple validities, and political. This study incorporated five types of legitimation into this research study: sequential, inside-outside, weakness minimization, paradigmatic mixing and multiple validities.

### *Sequential*

The researcher utilized sequential legitimation, which describes the extent to which a researcher has minimized threats to legitimation related to the order or sequence of each research approach, quantitative and qualitative. It is possible that changing the sequence could yield different results. To avoid problems with this type of legitimation, the researcher designed this dissertation study with multiple phases, reversing the sequence of quantitative and qualitative approaches several times and examining the outcomes of each phase (Teddlie and Tashakkori, 2009).

A sequential mixed research design was used for this study. Quantitative data collection occurred in Phase I of the study through completion of the DQ and PMAR and administration of the TOFHLA which yielded health literacy scores for three distinct levels (inadequate, marginal, and adequate). Using the maximal variation strategy, scores on the quantitative assessment of the TOFHLA and variables from the DQ of age, educational level (highest grade completed), number of daily prescribed medications, gender and marital status were used to classify into three cases community dwelling older



adults (ages 60 to 74) across three levels of health literacy, who self-manage five or more daily prescription medications and participate in programs offered by SAFE.

The sequential explanatory design used in this study was expected to produce meta-inferences to help explain similarities and differences in self-management of prescription medication among the cases, as defined by three levels of health literacy. These inferences would be more difficult if all participants in the qualitative or second phase of the study represented a single case drawn by random sampling. Therefore, all participants selected for the qualitative phase of the study were part of the quantitative phase of the study. The follow-up, in-depth qualitative phase builds upon what was found during data analysis from the quantitative phase of the study. Failure to use the same individuals for this study would have limited the ability to draw conclusions for meta-inferences. That being said, the number of participants limited the meta-inferences as described in Chapter One.

### *Inside-Outside*

This type of legitimation refers to the degree to which the researcher accurately presents views of insiders and observers to describe and explain phenomena of interest and interpret data. The qualitative (Phase II) component of this study focused on the ability of the researcher to maintain objectivity which can be compromised if any member of the research team becomes too involved with the participants in the study. Soliciting others to review how the researcher conceptualized interrelationships of data and his or her interpretation of results is one approach that can be used to minimize this threat to legitimation.

### *Weakness Minimization*

Weakness minimization is the extent to which the weakness from one approach (quantitative or qualitative) is compensated by the strengths from the other approach. Mixed methods research can maximize this concept through a study designed to combine quantitative and qualitative methods. It is important that the researcher carefully assesses the extent of weaknesses from one approach and estimate how each weakness may be compensated by the strengths from the other approach. The researcher should utilize the knowledge about the weaknesses and strengths when combining, weighting, and interpreting the results of the study.

For example, weaknesses of a quantitative approach to determine ADEs among community dwelling older adults include recall bias and providing the socially desirable responses when self-reporting past health behavior in an artificial setting (i.e. community resource center). The addition of a qualitative approach enables the researcher to explain how and when medication errors occur through interaction with the participant in an authentic or home setting. This yields richer explanation of why community dwelling older adults may become confused when self-managing prescribed medications.

### *Paradigmatic Mixing*

Paradigmatic mixing legitimation describes how the investigator acknowledges personal beliefs that underlie quantitative and qualitative approaches and blends these into the research design and analysis of data. Combining quantitative and qualitative approaches can be difficult due to the nature of the two forms of data. Quantitative

methods have been used for scientific research for several centuries. These methods include strict guidelines for random selection of participants, experimental control, and replication of results after data analysis (Creswell, 2009).

By contrast, qualitative data collection occurs in the field or natural setting and analysis is subject to bias unless the research team adheres to the protocol developed for the study. To avoid problems with paradigmatic mixing, the researcher must guard against personal bias due to preconceived expectations. The mixed methods researcher should consider quantitative and qualitative approaches as complementary, rather than as opposing approaches. The researcher must continually re-evaluate how data from each approach is interpreted in comparison to the other (Creswell, 2009; Onwuegbuzie & Johnson, 2006)

As an example, in this study the researcher convened the individual groups of seniors at each of the four community resource centers and the assisted living facility used in this study for data collection. Prior to the study, the researcher explained determinants of ADEs to each of the groups and allowed for a question and answer session. Additionally, prior to quantitative data collection, the information about what constitutes an ADE (as outlined by the literature in Chapter Two of this study) was described to each participant. Finally, prior to qualitative data collection during home visits the same information was emphasized.

During thematic analysis of this study, themes of participants' understanding were explored. Quantitative data were shared with a small number of community dwelling older adults during a structured interview for insight into interpretation for this study.

When forming meta-inferences, the researcher found that he or she should evaluate how the perceptions of quantitative and qualitative approaches could be considered individually and also examined as complementary and compatible. Legitimation comes from the researcher making explicit assumptions and then designing and conducting research consistent with the stated assumptions. For example, the researcher for this study assumes that community dwelling older adults (ages 60 to 74) across three levels of health literacy who self-manage five or more daily prescription medications and participate in programs offered by SAFE experience difficulty identifying generic drugs that appear different from the same previously purchased medications. This can be problematic for community dwelling older adults, especially since pharmacies contract with different companies to purchase generic medications seeking the lowest price. The color and shape of medications may differ with each refill of the prescription medication depending on supplier. It is important to educate community dwelling older adults to understand why the same medication may appear different upon refill. Patients should be taught to rely on the label of the bottle and name of the medication, rather than its appearance.

Onwuegbuzie and Johnson (2006) suggested separately considering data from quantitative and qualitative approaches, and then combining the two forms of data to produce a complete understanding of the results. The researcher for this study reviewed how two distinct and complementary methods yielded a complete understanding of the phenomenon of interest, i.e. accurate self-management of five or more prescription medications among community dwelling older adults.

For example, the quantitative phase provided the investigator with a self-reported PMAR outlining the daily prescribed medications of each participant. During the qualitative phase of the study, the investigator was allowed to review all prescribed medications while conducting the in-depth interviews in seniors' homes. Comparisons between self-report information to the actual medication bottle labels revealed the level of understanding for each prescribed medication and exposed inaccuracies.

### *Multiple Validities*

This type of legitimization is pertinent to every mixed methods research study. Multiple validities refer to the degree to which all of the pertinent validities (quantitative, qualitative, and mixed) are addressed and resolved successfully. Data for Phase I of the study were collected in a group setting with adequate spacing between participants during the TOFHLA administration so participants answer truthfully to the best of their ability. Within the qualitative component, cases were selected using maximal variation to represent three literacy levels. Minimal bias is important when interpreting thick, rich descriptions of barriers to and facilitators of medication self-management among community dwelling older adults. During integration of the quantitative and qualitative data, the researcher draws meta-inferences relevant to the larger population of interest (Onwuegbuzie & Johnson, 2006).

### Ethical Considerations

Over the past 50 years, researchers conducting human experimentation have sought to protect individual participants and vulnerable populations (Weijer & Emanuel,

2000). Emanuel, Wendler, and Grady (2000) proposed seven requirements to systematically evaluate the ethics of research that have merit for this study: (a) value, which means enhancements of knowledge must be derived from the research; (b) scientific validity, a rigorous research design and methodology; (c) participant selection according to the scientific objectives; (d) favorable risk-benefit ratio to maximize the potential benefits to individuals and knowledge gained for society and minimize risks to individual participants; (e) independent review by unaffiliated individuals who will approve, modify, or terminate the study protocol; (f) active informed consent for voluntary participation; and (g) respect for enrolled subjects to protect their privacy and provide the opportunity to withdraw at any time without prejudice, and monitor their well-being throughout the study.

Value for this study was determined when researching areas of the literature. Failure to find pertinent studies in the current body of knowledge related to health literacy and self-administration of daily prescription medications and how often adverse drug events occur established the need for more scientific research in this area. Additionally, DeWalt, et al. (2004) suggested future researchers should examine factors that mediate the relationship between literacy and health outcomes of older adults such as polypharmacy and ADEs leading to medical treatment. Additionally, the mixed methods approach sequential explanatory design was used to understand the perceptions and experiences of older adults who are prescribed five or more daily medications (Creswell, 2009). The outcomes of this study provide an understanding of the barriers and facilitators for accurate medication self-administration among community dwelling older adults.

Participant selection was carried out using scientific principles. The elderly, especially those 75 years or older, are recognized as a vulnerable population for participation in human subjects research due to decreased cognitive function (Aday, 1994; Brown & Park, 2003). Participants invited to join the study ranged between the ages of 60 to 74. Adults older than 74 years of age were excluded from the study to minimize inherent problems of non-adherence to medication self-management such as cognitive decline (Brown & Park, 2003).

A favorable risk-benefit ratio was established to maximize the potential benefits to individuals and knowledge gained for society and minimize risks to individual participants. The risk for participating in this study was no more than one would experience during normal daily activities. The benefits from the study include added literature to the current body of knowledge in addition to continuation of the study using a larger sample population so that more thorough meta-inferences may be made.

An independent review by unaffiliated individuals who have the authority to approve, modify, or terminate the study protocol was established via the Institutional Review Board (IRB) at the University of Alabama at Birmingham (UAB). IRB approval was obtained for this research study in February of 2009 (see Appendix I). The research team for this project followed the code of professional conduct as specified by the UAB Office of the IRB.

Active informed consent for voluntary participation was established for this study. The researcher for this project followed the code of professional conduct as specified by the UAB Office of the IRB. For Phase I of the study, potential participants received an invitation/informational letter) (see Appendix J) explaining the study. Informed consent

was implied when the self-reported documents were returned by each participant. For Phase II of the study, an Informed Consent document was mailed to participants prior to data collection for his or her review. On the day of the home visit, the researcher read the Informed Consent document to each participant and asked if he or she had any questions. Following a question and answer period during the home visit, the Informed Consent was signed by each participant (Appendix K). A copy was given to each participant so that they would have the information should they choose to withdraw from the study or have the need to ask further questions.

Respect for enrolled subjects to protect their privacy, providing the opportunity to withdraw at any time without prejudice, and monitoring their well-being throughout the study was established in several ways. Health literacy is the ability to comprehend written and oral health information, apply knowledge for self-care, and interpret numbers. It is likely that those with below-average reading and numeracy skills may feel uncomfortable during a health literacy assessment. The researcher ensured privacy during the TOFHLA assessment by spacing the participants so that the person next to each one could not see the other's assessment. The Informed Consent process provided each participant with information about how to withdraw without prejudice from the study should they choose to do so. The anonymity of each participant was given high priority and as such, each participant was assigned an identifying label such as C1 (for the first participant at Childersburg Senior Center) to protect his or her privacy. Identifying information was not collected during either phase of the study or during chart review. All data was stored on a secure computer drive with password protection. Access was granted only to the researcher directly involved in the project. No information was stored on a laptop.



The above seven requirements incorporate ethical principles for health-related research (i.e., respect for autonomy, beneficence, and non-maleficence). In addition, the researcher practiced distributive or social justice through equal allocation of risks and benefits. This means that community dwelling older adults (ages 60 to 74) across three levels of health literacy who self-manage five or more daily prescription medications and participate in programs offered by SAFE were all invited to enroll in the study, regardless of race/ethnicity, religious practices, gender, chronic health condition, or socioeconomic status (Soskolne, 1997).

#### Role of the Researcher

The researcher for this project was a graduate student at the University of Alabama at Birmingham, a former resident of the community where SAFE is located, and has experience working with community dwelling older adults and SAFE staff members. In addition, this researcher collected all of the data and provided the findings to the Executive Director at SAFE at the conclusion of the study. The researcher has worked with populations experiencing health disparities; therefore, she was comfortable working with this group. She identified possible personal experiences that could contribute to bias when collecting and analyzing the data through utilization of bracketing.

The researcher has conducted two prior research projects on the topic of health literacy with different populations who utilize SAFE services. Prior to data collection a review of potential participants allowed the researcher to determine if there were any individuals known personally to her. Additionally, a comprehensive review of potential participants was compared to the focus group initiated in 2008 to develop some of the

tools used for data collection. Participants of the focus group were eliminated as possible participants for this study.

Potential biases associated with a mixed methods design relate to representation, data integration, and legitimation of the study (Onwuegbuzie & Johnson, 2006).

Overcoming the challenge of misrepresentation requires a trained investigator who can suspend personal beliefs and biases while exploring lived experiences of another person (Onwuegbuzie & Johnson, 2006). The investigator for this study made logical inferences, while minimizing preconceptions about the focal health issue. Case-worker interviews and parallel observations during home visits increased the strength of this study.

Mixed methods research does not require agreement of data gathered through different approaches, quantitative and qualitative. It is necessary to maintain focus on the primary research questions when analyzing and interpreting data. The researcher discussed with the dissertation committee potential biases during data analysis and integration. In Chapter 4 the researcher informs the reader of any potential effect of researcher bias on inferences drawn from the data. The combination of systematic quantitative data collection with in-depth qualitative observation and data interpretation yielded an accurate and thorough understanding of the phenomenon of interest, determinants of self-administration of daily prescribed medication that have the potential to cause adverse drug effects among a sample of community dwelling older adults with knowledge (Stewart, Makwarimba, Barnfather, Letourneau, & Neufeld, 2008).

### Summary

Descriptions of the mixed methods used for the quantitative and qualitative phases of the study were presented in this chapter. The rationale for why the researcher chose this design including consideration of advantages and disadvantages is specified; including priority, implementation and integration of the quantitative and qualitative data are discussed. An overview of how the samples were chosen and data collection tools are described. Data analyses for both phases of the study are described.

Additionally, the researcher covered how credibility was established through triangulation, inter-coder agreement and member checking. Thick rich descriptions are used to enlighten the reader. Legitimation used during the study was described at length in this chapter to provide insight to the reader of how validity was established. Ethical considerations were covered including the role of the researcher.

## CHAPTER FOUR

### RESULTS OF THE STUDY

Results for both phases of this study are presented in this chapter. The quantitative results from Phase I are presented followed by the findings of the qualitative Phase II of the study. For the qualitative phase, the findings of analysis within and across three cases are described.

#### Phase I Quantitative Analysis

The primary purpose of the quantitative data collection and analysis of this study was to determine which participants would be eligible to progress to the qualitative phase of the study. Demographic characteristics for those who participated in the quantitative data collection are presented in this section (Table 6). Additionally, the data collected from Phase I of the study was used to select individuals for subsequent interviews conducted in participants' residences. Research questions are answered for Phase I of the study throughout this section.

#### Descriptive Statistics

The quantitative data from Phase I: (a) Demographic Questionnaire (DQ), (b) Personal Medication Administration Record (PMAR), and (c) scores for the Test of Functional Health Literacy in Adults (TOFHLA), were analyzed using the 12.0 student

version of the Statistical Package for the Social Sciences (SPSS). The analysis provided descriptive statistics, frequencies, and percentages for the demographic data, as well as the mean, median and range for continuous data. Demographic characteristics were used to narrow the sample through the purposeful selection using the maximal variation strategy (n=15) which subsequently became the sample for qualitative Phase II of this study.

### Research Questions and Results

*Research Question 1* What are the characteristics (gender, age, educational level, composition of household, marital status, employment, type(s) of health insurance and annual income) of community dwelling older adults who participated in programs offered by SAFE and took part in this study?

Thirteen of the participants (87%) were female and two participants (13%) were male. To meet the age requirement for consideration of Phase II of the study respondents were required to be at or between the ages of 60 to 74 years old at the time of the study. One older adult (7%) was 61 years old and one older adult (7%) was 68 years old. The remaining 13 older adult participants (86%) reported that they were at or between the ages of 70 to 74. Additionally, the mean age was 71.27 years and the median age was 72 years old. In reference to the question about the highest grade completed in school; seven older adults (47%) reported that they had not graduated from high school with the remaining eight (53%) responding that they completed the 12<sup>th</sup> grade in high school. The mean average of grades complete in school was 10.86 years in school which meant that the average grade completed was close to the 11<sup>th</sup> grade. Nine respondents did not

answer the question of “How many individuals did each participant care for within his or her home?” (household composition); four participants (27%) answered that they took care of one person within the home that he or she resided, and two participants (13%) answered that they took care of two other persons within the home that he or she resided. Regarding marital status; eight participants (53%) responded affirmatively indicating they were married at the time of the data collection and seven participants (47%) reported that they were not married at the time of the data collection. When questioned about employment status, all 15 respondents (100%) reported that they were unemployed at the time of the data collection. When answering questions about health insurance; ten participants (67%) reported they had private insurance at the time of the data collection with five participants (33%) failing to answer the question (missing data). Twelve participants (80%) reported they had public insurance at the time of the data collection and one participant (7%) reported they did not have public insurance at the time of the data collection, and two participants (13%) failed to respond this question. Regarding annual income, nine participants (60%) reported they made less than \$15,000 during the year for which the data were collected for this study, four participants (27%) reported they made between \$15,000 and \$25,000 during the year for which the data were collected and two participants (13%) did not respond to the question (missing data). Results of the characteristics of the sample are presented in Table 6 below.

Table 6

*Descriptive Findings from Quantitative Analysis of the Demographic Questionnaire*

Characteristics	Frequency (n=15)	%	Mean	Median	Range
<b>Gender</b>					
Female	13	87%			
Male	2	13%			
<b>Age</b>					
			71.27	72	13
60-65	1	7%			
66-69	1	7%			
70-74	13	86%			
<b>Highest Grade Completed</b>					
			10.86	12	5
8 <sup>th</sup> grade in junior high	1	7%			
9 <sup>th</sup> grade in high school	2	13%			
10 <sup>th</sup> grade in high school	3	20%			
11 <sup>th</sup> grade in high school	1	7%			
12 <sup>th</sup> grade in high school	8	53%			
<b>Number of individuals that live with you/ you care for (household composition)</b>					
1 person	4	27%			
2 people	2	13%			
Missing	9	60%			

Characteristics	Frequency (n=15)	%	Mean	Median	Range
Are you Married?					
Yes	8	53%			
No	7	47%			
Are you Employed?					
No	15	100%			
Yes	0	0%			
Do you have Private Insurance?					
Yes	10	67%			
No	0	0%			
Missing	5	33%			
Do you have Public Insurance?					
Yes	12	80%			
No	1	7%			
Missing	2	13%			
Annual Income					
Less than \$15,000 year	9	60%			
\$15,000 to \$25,000 year	4	27%			
Missing	2	13%			



*Research Question 2* What level of health literacy do community dwelling older adults who participated in programs offered by SAFE and are prescribed five or more daily prescription medications score within, as measured by the TOFHLA?

The majority of the sample demonstrated inadequate health literacy as shown in Table 7. Nine participants (60%), scored within the level of inadequate health literacy, three participants (20%) scored at the level of marginal health literacy and three persons (20%) demonstrated adequate health literacy as measured by the TOFHLA. The mean score from the results of the TOFHLA was at the lowest limit of the marginal level of health literacy (60.53) and the median score was at the highest level of the level of inadequate health literacy (59) which indicates that the overall sample demonstrated very poor health literacy.

Table 7

*Scores of the Test of Functional Health Literacy in Adults*

Levels/scale	Frequency (n=15)	%	Mean score	Median scores	Range of scores
TOFHLA			60.53	59	44
Inadequate (75-100)	9	60%			
Marginal (60-74)	3	20%			
Adequate (0-59)	3	20%			

*Research Question 3* How many daily prescribed medications do participants from this study take?

In order to be eligible for participation in this study, older adults at the age of or between the ages of 60 to 74 were screened for how many daily prescribed medications he or she took as prescribed. All reported that they took the minimum number of daily prescribed medications required (five) for participation in the study. Fourteen of the 15 participants recorded that they took all of their medications as prescribed. Additionally, the data revealed that all took at least five or more daily prescribed medications with the average number of daily prescribed medications being 10 with a range of 15 meaning that one or more participants took up to 15 daily medications.

*Research Question 4* How frequently are community dwelling older adults ages 60 to 74, who are prescribed five or more daily medications and participate in programs, offered by SAFE experience adverse drug events as self-reported on the PMAR?

All participants (100%) reported zero adverse drug events over the past 12 months.

#### *Summary of Phase One Findings*

To summarize, a “snapshot” of the quantitative sample population of this study (n=15) is described as being primarily female between the ages of 60-74 but with most falling between the ages of 70 to 74 years. The majority of the sample completed a high school education, was unemployed at the time of the data collection and had some type of health insurance. Of those reporting their annual salary, most could be categorized as making less than \$15,000 annually. Even though most of the sample did graduate from

high school, most scored at the inadequate level of health literacy meaning that they have difficulty understanding the most basic of instructions for their health care.

After all quantitative data were analyzed the sample was stratified by health literacy level so that participants could be selected for the qualitative phase of the study. The investigator narrowed the pool of community dwelling older adults from  $n=15$  (Phase I of the study) to  $n=9$  for the follow-up in-depth qualitative phase of the study (Phase II). Subsequently, all participants were grouped into one of three cases known as; Case One: Adequate Health Literacy ( $n=3$ ), Case Two: Marginal Health Literacy ( $n=3$ ), and Case Three: Inadequate Health Literacy ( $n=3$ ).

### Phase II Qualitative Analysis

The purpose of this section is to describe the qualitative findings that help to answer the central question of the study “How do community-dwelling older adults (ages 60 to 74) who participate in programs offered by the Sylacauga Alliance for Family Enhancement (SAFE) and across three levels of health literacy self-manage five or more daily prescription medications?” Also of interest is how often the participants experienced ADEs during the previous 12 months. The qualitative results are presented from the data collected during in-home interviews with participants, caseworker interviews at SAFE, review of SenioRx Wellness Program files, and related artifacts.

### Context

In order to understand how the participants in this study are similar or different from the population at large in Alabama, it is important to understand the level(s) of

literacy for residents across Alabama. Reder compiled a report (as cited in Matthews and Sewell, 2002), about the levels of literacy for each state in the U.S. He reported that 57% of residents in Alabama scored at the lowest literacy levels of 1 or 2 as calculated by the National Adult Literacy Survey (1993). Individuals scoring at literacy level 1 include those who are functionally illiterate, who cannot read above the 5<sup>th</sup> grade level, and have difficulty with the simplest calculations. Those scoring at level 2 can (a) read and understand basic information through simple prose text in documents, (b) follow simple basic written instructions, and (c) are able to perform easy mathematical operations when the arithmetic operation is specified and easily understood. More recent information, reported by the National Assessment for Adult Literacy (2003) found little to no improvement in literacy across the nation. Specific data were not available by city or town.

The most recent U.S. Census report of demographics for the study population was completed in 2010; approximately 13,040 residents live within the city limits and surrounding area of Sylacauga, Alabama. Individuals between the ages of 60 to 74 represented 15% of the population in 2000 with two-thirds of those being female. The subset of questions reported on small cities in 2000 was not available for the older population in 2011 (United States Census Bureau, *It's In Our Hands*, 2010; U. S. Census Bureau, *American Fact Finder*, 2000).

### *Setting*

The setting for this study was a community resource center located in Sylacauga, Alabama in a town of 13,040 residents located one hour southeast of Birmingham. All

data collection was conducted during the summer of 2010. Before and after in-home visits to study participants, the researcher met with caseworkers and the executive director of the resource center. The purpose was to understand how the organization provides supportive services to the aging population. SAFE is a community-based nonprofit organization whose purpose is to provide meaningful opportunities for families, to contribute to the growth of the community and to serve others while promoting community cohesion. SAFE is designated as an Aging & Disability Resource Center (ADRC) and offers the SenioRx Wellness Medication Program (SenioRx) to approximately 200 residents in the area, all of whom were invited to participate in this study.

The SenioRx assists individuals who are 55 years and older with access to free or reduced cost medication through programs provided by pharmaceutical companies. The program also provides application and enrollment assistance to Medicare recipients who wish to participate in the Part D prescription benefit. In addition, classes promoting personal health and wellness behaviors are offered to seniors.

During the time spent at SAFE, the staff shared with the researcher the many opportunities available for seniors in the community who seek assistance. These include: literacy classes, workshops to enhance computer skills, classes to better understand how to manage personal finances, and services and classes to help residents self-manage their medications (SenioRx).

SAFE is housed in an old building which at one time was the U.S. Post Office and utility department for this small community. Built in the 1940s, the fragmentation of the building showed signs of having been added on to several times over the years. It was at

this location that information was gathered from caseworkers regarding participants' involvement in the SenioRx Wellness program. SAFE caseworkers provided a private comfortable environment so that the researcher could review all of the files of each participant for this study before and after completing home visits and interviews.

For the planned home visits, the SAFE Executive Director suggested that a caseworker accompany the researcher. This was particularly helpful since the residents trust their caseworkers. The Executive Director stated that she believed study participants, "would be more likely to provide honest answers to the researcher's questions if their assigned caseworker was present."

Following a thorough review of each participant's file, the researcher and the SAFE caseworker began the qualitative data collection according to a schedule established by SAFE caseworkers for each participant of this study. The following sections of Chapter Four describe the three distinct cases composed of three participants who represent the levels of health literacy: adequate, marginal, and inadequate. Following the case description, the three cases are compared for similarities and differences.

#### *Case One: Adequate Health Literacy*

Persons with adequate health literacy are able to read, process, and incorporate knowledge into their decision-making. Within a managed health care environment, providers do not always have time to explain self-care instructions to patients. Patients are expected to participate in their health care by making informed decisions. Even patients who are capable of reading and assimilating large amounts of information can be overwhelmed by medical jargon and the amount of information they receive during a health care encounter (Davis et al., 2006).

Case One is represented by three individuals selected from Phase I of the study who scored at the adequate level of health literacy and who participated in the SenioRx program at SAFE. Case One health literacy scores on the Test of Functional Health Literacy in Adults (TOFHLA) were 75, 77 and 81. Scores indicating an adequate level of health literacy range from 75 to 100. All of the participants for Case One scored in the low range of this classification. Participants for Case One are described below with their names changed to protect their identity. All information was document at the time of the data collection to reduce the likelihood of researcher recall error. Participants' characteristics are presented as they were at the time of the data collection for this study.

### *Participants*

#### *Mrs. D*

Mrs. D, a 70-year old white female with a high school education, scored 75 on the TOFHLA. She is now retired with excellent benefits from her many years of service as a county employee. Mrs. D is a widow who lives alone in a private home with comfortable furnishings. At the time of the visit her home was neat, clean, and had acreage surrounding the home. Even though she is independent and lives alone, her family lives nearby. Her daughter and granddaughter stopped by during the time the researcher and SAFE caseworker were at her home for the qualitative interview. Mrs. D was well spoken and had a good understanding of her health care needs and the medications prescribed for her.

Mrs. D reported that she saw three physicians and one nurse practitioner for her health care needs. One physician provided annual follow-up care for breast cancer; the

other provided glaucoma treatment. At the time of the interview, she was prescribed seven medications. She also took eight supplements daily that she has discussed with her primary health care providers.

Mrs. D, a participant in the SenioRx program offered by SAFE, had not utilized the program for assistance in purchasing her medications. She stated, “I have excellent insurance as part of my benefits package from my retirement.” The SAFE caseworker confirmed that she had worked with Mrs. D to inform her of all of the possibilities that were available to her. Mrs. D acknowledged she did not need or choose to seek financial assistance for medications. Mrs. D did confirm that she “enjoys” the educational programs offered by the SenioRx program.

*Mr. J*

Mr. J, a 71-year old white male high school graduate, scored 77 on the TOFHLA. He was classified as disabled several years ago and receives two forms of health insurance benefits (Medicare and Blue Cross Blue Shield of Alabama). Unmarried, he resides alone in a private room in a senior living center. His home environment was very small, clean but cluttered and his furnishings were comfortable. He had an oxygen tank and stated, “I get oxygen therapy and use an electric wheelchair.” He noted, “I have many close friends who also reside at the senior living center.” Mr. J stated, “friends come by to check on me and they are always willing to help me.” Additionally, he receives home visits “once a month from a hospice agency because I am on oxygen treatment,” he said. Mr. J was well-spoken and had a good understanding of his health care needs and the medications prescribed for him.



Mr. J reported that he used six physicians for his health care. He noted “I see one for cardiovascular care, one for my diabetes, one podiatrist that works on my feet, a pulmonologist, a GI doc, and the other one is my primary health care provider.” At the time of the interview, he was prescribed 15 medications.

Mr. J, a participant in the SenioRx program, offered by SAFE reported “I utilize the program for assistance to purchase my medications and also get visits from a SAFE caseworker who discusses all of my medications with me.” Mr. J praised the caseworkers from SAFE and said, “I don’t know how I would manage without their help, they are so wonderful to me and make sure I take my meds as I am supposed to (do).” The caseworker reported, “Mr. J is compliant with all of the instructions given to him even though he has a complicated health care plan.” Because he has multiple chronic conditions, she acknowledged that SAFE caseworkers keep a close watch on him.

*Mrs. B*

Mrs. B, a 72-year old white female and retired widow, completed the 10<sup>th</sup> grade in high school and scored 81 on the TOFHLA. Her home was a private residence that was neat and clean. Additionally, her friend worked at SAFE as a volunteer caseworker and Mrs. B stated, “my family all live close by.” Mrs. B stated she felt “especially comfortable using SAFE for my medication needs.”

Mrs. B was well-spoken and had a good understanding of her health care needs and the medications prescribed for her. She reported that she saw three physicians for her health care needs. When explaining who the physicians were, Mrs. B said, “one of the doctors is for my heart, another is an ear, nose and throat specialist and then you have my primary health care provider.” At the time of the interview, she was prescribed five

medications. Mrs. B is a participant in the SAFE SenioRx program and utilizes the program for financial assistance. She has attended educational programs as previously described and offered by SAFE. Mrs. B. said, “I just love all the girls at SAFE; they do so much for me!” The SAFE caseworker disclosed that Mrs. B calls frequently. SAFE caseworkers are very familiar with her needs and “we all make sure we check in with her as often as we can.” When going over the files at SAFE, it seemed as if everyone at SAFE knew Mrs. B very well and each shared individual accounts of time spent with her in her home.

### *Themes*

Three themes emerged during analysis of data gleaned from participant interviews, observations, medication records, related artifacts and SAFE caseworker files. The themes were as follows: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the synthesis of the data collected themes were developed and explored for mechanisms such as, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for participants in Phase II of this dissertation study.

### *Accuracy of Self-Administration of Prescribed Medications*

The accuracy of self-administration of prescription medications for each participant of Case One was revealed through examination of several sources. Data collected during Phase I using the Personal Medication Administration Record (PMAR)

was examined prior to and during each home visit. During home visits, participants' verbal explanations were recorded and compared to information gathered from the PMAR. Notes taken by the SAFE caseworker during the interview were also reviewed. These records were compared to SenioRx Wellness program files to determine the accuracy of self-administration for each participant.

After obtaining informed consent during in-home visits, each participant displayed to the researcher and SAFE caseworker all of the medications/bottles prescribed by his or her health care provider. Discussion with each participant revealed: (a) recognition of the name of each medication, route of administration (i.e. pill, liquid, patch), and dosage; (b) medication purpose; (c) time and frequency of administration; (d) beginning and ending dates of treatment; (e) name of the prescriber; and (f) occurrence of adverse drug events during the 12 previous months leading up to the study.

As participants of Case One were reciting all of the aforementioned information, the researcher compared accuracy of written information recorded on the PMAR. The investigator noted accuracy of written and oral information as provided by participants. In addition, the assigned SAFE caseworker took detailed notes, permitting further comparison to SAFE SenioRx files. Results revealed that each participant from Case One accurately identified all aspects of his or her prescription medication. Comparisons of information from the PMAR to what was found in the home, as well as the participant's account of each medication, the SAFE caseworkers' notes and SenioRx files indicated no errors of understanding. Mr. J was eager to show the researcher his medications and he stated, "with all that stuff, it's a wonder I am still alive." Mrs. B, who uses the least amount of medication, reported, "I don't take much but wish I could come off all of them

(medications)” and Mrs. D was proud to tell us about her record keeping. She showed us her “pill box” where she stored her medication for 30 days so she would “not get them mixed up.” To summarize, participants from Case One demonstrated 100% accuracy when self-reporting the prescription medications used by each participant both on the PMAR and during the qualitative data collection for Phase II of the study. The three participants similarly stated that they take their medicine the way they are supposed to (do).

The investigator, who is a nurse practitioner, took time to question each participant about every medication prescribed during each home visit. The purpose of this exercise was to determine his or her understanding of medication self-administration. Those with questions about their medication (for instance how supplements may interact with prescriptions) received practical information to understand potential health threats. All participants stated they were “very appreciative” of the time spent with them to better understand how to take medications.

### *Issues Related to Prescription Medication Adherence*

Data collection for Case One participants exposed several issues that affect accurate self-management of prescribed medications. These issues are further discussed below as emergent sub-themes.

*Lack of communication.* Two of the three participants expressed concern with lack of patient-provider communication. Specifically, participants stated that their health care provider (physician) does not take time to explain reasons why medications are prescribed. Both participants who expressed this concern also indicated that their

physicians did not devote enough time with them. For example, Mrs. D stated that “my doctor spends very little time with me to tell me about my health care needs.”

Additionally, Mrs. D observed that her physician, “only spends a few minutes with me during each office visit,” but further explained that often she had to discuss her health care needs with the nurse practitioner because her physician was too busy to see her. She said, “I rarely see the doctor but his nurse practitioner spends a lot of time with me to make sure I understand everything about any medicines he prescribes for me. The nurse practitioner spends time with me to explain about any supplements I take and how they can interact with my prescription medications.” Mrs. B felt similarly, “My doctor doesn’t spend much time with me, usually 2 or 3 minutes.” On the other hand, Mr. J was very pleased with the patient-provider communication between him and his doctor and stated, “Dr. B spends as much time with me as I want him to (do).”

When reviewing the PMAR and other related artifacts, the researcher questioned all participants about the patient-provider communication in terms of his or her understanding of the health care information given to each. They all commented that often they did not understand the medical terms. Mrs. B stated, “some of the things they tell me are over my head and I hate to ask them questions when they act like I should understand.” Following the interview, the SAFE caseworker confirmed that the calls she often receives from study participants are related to questions about what they were told during a visit to the health care provider.

*Generic substitutions for prescribed medications.* The participants of Case One stated that they have issues in recognizing prescribed generic medications when the color and shape change from month to month. They reported that they sometimes have been

confused by a change in the color or shape of medications that they had been taking for a lengthy time period. Mrs. D said, “I just wish they would leave it the same shape and color each month” and Mr. J stated, “I get confused sometimes with how the generics look but the caseworker helps me keep them straight.” In spite of their lack of knowledge regarding generic medication appearance, each praised their pharmacy because the pharmacist spent the appropriate time to explain when there were changes. Mrs. B affirmed, “my pharmacist goes over all new medications with me and alerts me to any changes of the color and shape just for the two I take that are generic.” Mrs. D echoed Mrs. B by stating, “my pharmacist is so good to me and takes as much time as I need for him to explain about my medications, especially if they change the way they look.” Additionally all participants in Case One stated that they retain leaflets and handouts stapled to their prescription envelopes to review as needed.

*Financial concerns.* Concerns of the participants in Case One included future health care costs. Two of the three participants verbalized that at the present; they do not have a problem paying for medications, but do worry that in the future finances could prohibit them from getting all the prescribed medication they might need.” Mr. J said, “What if the SAFE program goes away? I don’t know if I could afford to get all the medication prescribed for me.” Mrs. D stated, “I worry about all this health care reform and feel anxious about how it will impact me financially in the future.”

Participants for Case One expressed “anxiety” over the cost of prescribed medications. Additionally, Mr. J and Mrs. B both praised the caseworkers at SAFE for making sure “I have what I need.” It is important to note that these three individuals all stated that they are able to “ask family to help out” with the costs of prescription

medications but have not had to ask them for help up to this point (at the time of the interview). With assistance offered by SAFE and family members, these older adults should be able to continue the prescribed medications important to sustain their health.

*Transportation.* All participants from Case One had the ability to visit their health care provider and pharmacy for prescribed medications, but they did worry about the possibility of decreased independence in the future. One participant owns a car and still drives without difficulty. Mrs. D stated, “I don’t have any trouble getting out and about. I drive when I want to and where ever I need to in order to get what I need or want.” Another participant (Mr. J) stated he has friends and family who help out when the need arises to see the health care provider and or to go to the pharmacy to pick up prescribed medications. He stated, “my friends around town are great and call me often. If I need something or need to go somewhere, they are always happy to help me. If they are not available and I need to go somewhere, I call my son or another family member.” The last participant of Case One (Mrs. B) drives, but worries that she may not always be able to drive and self-manage medications without help from others. She stated, “it gets harder for me all the time (to drive). I quit driving at night a few years ago because I can’t see good.”

Regarding transportation to pick up medication, the pharmacy(s) they use provides a service for the community; they will deliver any medications prescribed for their customers. This information supports the statement of the SAFE caseworker, “many of the pharmacies in the community go out of their way to help their customers, many of who are our clients at SAFE.” Additionally, each community resource center has a van that picks seniors up to travel to programs offered via SAFE at each (CRC)

location. Transportation vouchers are also available at some of the community support programs to pay for a taxi when needed.

*Side effects.* Listed as a concern by the participants in Case One; side effects as reported to the researcher were mild and non-threatening. Mrs. D said, “I worry I might have side effects from the prescriptions my doctor wants me to take.” During the interview, when questioned about adverse drug events experienced over the past 12 months (leading up to this study), two of the three participants reported what they thought were adverse drug events (ADEs). In reality, all ADEs they each verbalized were actually not ADEs but were instead a side effect common to the administration of the medications they were taking. Additionally, each participant in Case One had recorded on his or her PMAR “none” to the questions that asked, “How many adverse drug events did you have during the 12 months preceding today?” The PMAR was given to all participants immediately following the presentation at each CRC regarding what constitutes an adverse drug event prior to beginning Phase I.

During Phase II of the qualitative data collection and during the in-home interview, participants were again asked “how many adverse drug events did you have during the previous 12 months?” The participants named several accounts for which they believed were adverse drug events. Once they completed their list recalling perceived ADEs, the researcher questioned them about when such ADEs occurred. All participants gave accounts for these episodes and when comparing the episodes to the period from which they took a certain drug, it was noted that these episodes were actually side effects that were commonly listed by the manufacturer for that particular drug.



For example, Mrs. D takes NEXIUM which is approved by the U.S. Federal Drug Administration (FDA) for relief of heartburn and acid reflux. One of the common side effects is the development of a headache. Mrs. D complained that she “worries about getting a headache” and reported to the researcher that she had several ADEs after taking NEXIUM.

Upon completion of the interview, the researcher for this study took the time to go over all medications prescribed for each of the participants of this study. During this informational session, the researcher (who is a nurse practitioner) covered all potential side effects of each medication. When finishing the informational session with Mrs. D the researcher again asked her, “Did you experience any ADEs during the 12 months prior to this meeting?” to which she replied “No.”

*Self-efficacy.* Self-efficacy as defined by Bandura (1985) describes an individual’s beliefs about their capabilities to perform a specific action or behavior. Self-efficacy allows patients to exercise influence over events that affect his/her life when they feel empowered to self-advocate and make decisions for themselves.

It was clear when discussing with the participants in this case that they had very strong feelings about his or her ability to self-manage medications prescribed for them. During the home interview, Mrs. D stated, “I know how to take my drugs and feel very confident that I know what to do and when” and “I know they don’t like for me to take all the supplements I take but I have read about them and know what I am doing; the supplements make me feel better.” Using the open-ended questions on the Medication Administration Self-Efficacy Scale (MASES) participants of Case One of this study were encouraged to elaborate on questions asked of them during the interview when

completing the MASES. All three scored between a 2 and 3 on the MASES indicating that they all demonstrated a high level of self-efficacy in the area of confidence to properly self-administer their prescription medications. The MASES scoring procedure is described in Chapter Three.

As cited in Chapter Two of this study, researchers concluded that the MASES is useful to identify patients' low self-efficacy for adherence to prescription medications. The MASES results for the individuals in Case One may be one explanation of why they do not report any ADEs even though they are all in a high risk group for ADEs. More will be covered about this finding in Case Two and Three and will be compared during cross-case analysis.

### *Support System Resources*

Resources within the community are a very important part of the SenioRx program. The participants of Case One reported various types of support that they all receive via SAFE which are listed as emergent sub-themes below.

*Community resource centers.* The community resource centers (CRCs) were an integral part of the SenioRx program. The CRCs are the venues where residents of the community who are SenioRx participants gather for daily balanced hot meals as well as educational programs presented during lunch. Educational sessions feature content about nutrition, prescription medications, and diagnoses such as heart disease with a focus on prevention. Transportation is available for any resident who does not have a car or a family member to transport them to and from the CRC. Mr. J, who lived in the senior living facility, had a slightly different situation. He explained, "All I have to do is wheel myself across the hall!"

The participants from Case One were very enthusiastic about their experiences when at the CRC. Each of them shared various stories with the researcher about personal feelings, experiences and their time spent at the CRC. For example, Mrs. B enjoyed the experience of going to the center every week day. She stated, "Going to the community center is my favorite part of the day; I look forward to the van picking me up every morning." The other two participants liked the case workers at the CRC and enjoyed learning new things. Mrs. D stated "I love my case worker from SAFE and enjoy going to the community center to learn new things about medicines and my nutrition." Mr. J stated, "Having the programs presented by SAFE has helped me to stay in touch with them (SAFE caseworkers) and it provides me with a chance to see my caseworker often." Participants also mentioned SAFE caseworker, the primary caseworker for the SenioRx program. They said that she was like one of their family and indicated that they felt comfortable going to her or any of the other SAFE caseworkers if they had any problems with their medications which could also promote his or her self-efficacy. Mrs. D noted, Miss S is my caseworker and has been for a while." Mrs. B was particularly ready to share her feelings about the caseworkers, "they are all so nice."

*Health care providers.* Participants of this case thought that physicians generally did not spend enough time with them. Two of the three reported that the physician was in the room with them five minutes or less during any check-up they had during the previous 12 months however the nurses from each office were available for their questions or concerns. Mrs. D verbalized, "Dr. S does not spend but 5 or so minutes with me but he makes sure the nurse does all the explaining." Mrs. B said, "He (the physician) is in and out pretty quick but I know how busy he is." Even though they felt this way,

they reported “good relationships with the nurses” for each physician. Mrs. D stated, “the nurse practitioner who works for Dr. S spends about 30 minutes with me every time I go; she goes over all of my meds and also preaches to me about all the supplements I take.” Mrs. B stated that the nurse for her physician “steps in to make sure I have adequate information about my health care regimen as well as any prescription medications I take.” Additionally these two women voiced their belief that if they really needed to speak to the physician longer then “the physician would make time for them as patients.” Participants agreed they felt comfortable speaking with the nurse and never hesitated to call his or her doctor’s office (or nurse) should a concern or question arise once they returned home. Mrs. D said, “I know I can call the nurse practitioner at anytime but I don’t really need to because she spends so much time with me while I am at the office.” Mrs. B reported, “The nurse is easier to get in touch with but I rarely call.” This situation (being able to call the nurse when needed) made the participants in Case One feel good about whom they had chosen as their health care provider.

*Pharmacy.* The participants also listed pharmacies as an important resource for their accurate self-administration of daily prescribed medications. The SenioRx works in concert with various agencies within the community to ensure participants are receiving the information they need to properly self-manage prescription medication. One of the caseworkers at SAFE stated “caseworkers for the SenioRx program met with all of the pharmacies in the area (when beginning to implement the program) to provide valuable information about how the SenioRx program should be implemented.” This age group utilizes generic medications whenever possible (to save money), therefore it was important for the pharmacists to be willing to spend extra time with their customers. Mr.

J reported, “My pharmacist always makes sure to tell me if there is a change in my medications such as size, shape, and color. When the doctor prescribes a new medicine for me, my pharmacist always makes sure I understand why I am supposed to take it, the dosage, and any side effects I should pay attention to.” Mrs. D noted, “my pharmacist is good to tell me about my medications when I get something new; and I keep all those handouts they staple to the envelopes.” Mrs. B echoed what both Mr. J and Mrs. D stated when speaking about her experience with her pharmacy stating, “my pharmacist always goes over any changes in my medicine, especially if they (pharmaceutical companies) change the color or shape.” Pharmacist and pharmacies within the community where the SenioRx program is utilized were mentioned by all of the participants. Each participant was very complementary of the customer service they receive from the pharmacy used for purchasing all of his or her prescription medications.

*Insurance Companies.* Health insurance also plays an important role in the self-management of prescribed medications for each participant in Case One of the study. The caseworkers for the SenioRx program counsels each senior in the program to explain the benefits offered for them through the insurance company of their choice; how they can maximize coverage, as well as how they can save money through various programs offered by each insurance company. Mrs. D praised her insurance coverage from Blue Cross and Blue Shield of Alabama (BCBS) stating, “They are the best (in Alabama) and I am so happy that I have them as part of my retirement benefits.” Mr. J who also uses BCBS stated, “if it weren’t for BCBS I would not be alive right now, they are wonderful to make sure I have everything I need for my medicines, oxygen, and equipment.” Mrs. B, who is on Medicare and Part D, uses the least amount of medicine (five prescribed

daily medications). She did not comment on her insurance other than to say she felt like she is “fortunate to have Medicare.” The participants expressed their concern regarding what might happen to their health care and insurance in the future with the recent health care reform bill.

*Hospital.* Within the community where SAFE operates, the hospital collaborates with the SenioRx program caseworkers to offer educational programs to individuals within the community. Mrs. B stated that she “enjoyed going to the programs offered at the hospital about how to use your medicines” going on “I like it that our local hospital cares about keeping us well.”

Several of the nurses in the community work for the hospital and volunteer for the SenioRx program which allows for continuity of care in the eyes of the participants for this study. The other two participants for Case One of this study did not list the hospital as a resource they find helpful (regarding their medication self-management); however, others in Cases Two and Three did mention the hospital.

*Friends and family.* Case One participants listed “family and friends” as an important resource for them to self-manage his or her prescribed medications. All three participants noted that without family and friends to assist them with transportation, finances, and understanding of his or her prescribed medications they might not be as successful with self-management of the medications prescribed for them. Mrs. D, for instance, shared her belief that she was totally self-sustaining but given circumstances that required assistance, she expressed that she could call her daughter for help; “I don’t need any help from anyone because I know what I am doing, I read a lot and ask a lot of questions when I am with the nurse practitioner I feel really confident about my ability to

manage my medications.” Followed by her statement “if I do need help, my daughter lives real close and would and could come at any time if I needed her.”

The other two participants relied more on their friends and family; Mr. J was very proud as he shared with the researcher, “I have so many wonderful friends that live here at the facility with me, they all help me whenever I need it and are always asking me if I need anything” and “my son would be able to help me if I needed him.” In addition, Mrs. B said, “What does anyone do without friends and family? Mine are like others, they are all real busy but if I really needed them, they would probably come.” In summary, the friends and family topic was the one area that each of the three participants warmed up to during the in-home interview. Each wanted to share many stories about their friends and family. They also showed the researcher photos of their family when discussing this particular topic.

### *Summary of Case One*

Case One represents three individuals who scored at the level of adequate health literacy (according to the TOFHLA) which means that they are able to read, process, and incorporate knowledge into their decision-making. Three themes emerged during analysis of the data: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the synthesis of the data collected, sub-themes for each of the two themes were identified. These themes explored the mechanisms, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for the participants.

Overall Case One revealed that these three individuals are able to successfully manage his or her healthcare. No one in this case had any ADEs during the 12 months leading up to this study. Some of the issues and concerns listed by participants of this case were; lack of provider-patient communication, generic substitutions, financial concerns, transportation and medication side effects. All of these issues were lessened with the multiple levels of resources and support available to them through the SenioRx program offered by SAFE. The SAFE agency coordinates with pharmacies, insurance companies, family and friends to assist seniors with quality and continuity of care. Additionally, the educational programs offered to SAFE participants of the SenioRx program via the CRC and hospital were helpful to all participants in providing them with information to improve their ability to self-advocate thus improving their self-efficacy.

#### *Case Two: Marginal Health Literacy*

Someone with marginal health literacy skills reads close to a 6<sup>th</sup> or 7<sup>th</sup> grade level and may have difficulty reading and interpreting health texts. Within a managed health care environment, providers often have little time to explain self-care instructions to these patients. Patients are expected to participate in their health care by making informed decisions. Often individuals in this category are embarrassed to admit they do not understand instructions provided to them making it very difficult for health care providers to properly care for them. These patients can be overwhelmed by medical jargon and the amount of information they receive during a health care encounter (Davis et al., 2006).

Case Two is represented by three individuals selected from Phase I of the study who scored at the marginal level of health literacy and who participated in the SenioRx



program at SAFE. Case Two health literacy scores on the Test of Functional Health Literacy in Adults (TOFHLA) were 71, 68 and 65. Scores indicating a marginal level of health literacy range from 60 to 74. Participants for Case Two are described below with their names changed to protect their identity. All information was recorded at the time of the data collection to reduce the likelihood of researcher recall error. Participants' characteristics are presented as they were at the time of the data collection for this study.

### *Participants*

#### *Mrs. Q*

Mrs. Q, a disabled 68-year old black female with a high school education, scored 71 on the TOFHLA. She does not work but has excellent private and public health care insurance. Mrs. Q is married and lives with her husband in a private home with comfortable furnishings. At the time of the visit her home was neat, clean, and she was exceptionally well groomed and dressed very well. Even though she and her husband are independent, she noted that her daughters live nearby. One of her daughters called during our home interview to check on her and when she hung up Mrs. Q said, "My girls love their mama so much and they are just angels to me." Mrs. Q was well spoken and had a good understanding of her health care needs and the medications prescribed for her.

Mrs. Q reported that she saw three physicians for her health care needs. Her primary care physician "wants to see me once a month, I think for my diabetes" care. One physician provided semi-annual follow-up care for thyroid disease and the other provided glaucoma treatment. At the time of the interview, she was prescribed eight medications,

two of which were written for pain and must have a new prescription every month. She also took supplements daily that she has discussed with her primary health care provider.

Mrs. Q, a participant in the SenioRx program offered by SAFE, had not utilized the program for assistance in purchasing her medications. She stated, “My husband makes sure I get my medications. Right now I don’t need assistance, but one day I might and I hope the assistance will still be available.” The SAFE caseworker confirmed that she had worked with Mrs. Q to inform her of all of the possibilities that were available to her. Mrs. Q acknowledged she did not need or choose to seek financial assistance for medications. Mrs. Q did confirm that she “enjoys” the programs offered at her CRC as part of the SenioRx program.

*Mr. C*

Mr. C, a 68-year old white male high school graduate, scored 68 on the TOFHLA. He receives both private and public health insurance benefits. Married, he resides with his wife in a private single family dwelling with acreage. His home environment was clean, comfortable and spacious. Mr. C stated, “My wife does everything for me. She keeps the house and makes sure I have my diet and medicines the way I should.” Mr. C was well-spoken, but often his wife spoke for him. When questioned about his diabetic care, he told her, “Tell them what they are asking.” His wife has a very good understanding of his health care needs and the medications prescribed for him.

Mr. C reported that he used three physicians for his health care. He noted, “I see someone for my heart, diabetes and prostate.” At the time of the interview, he was prescribed eight medications. He said, “I take some in the morning and some at night.

She gets them set up in pill boxes for a month. I use two pill boxes and one has the day pills and the other has the night pills.”

Mr. C, a participant in the SenioRx program offered by SAFE, had not utilized the program for assistance in purchasing his medications. His wife stated, “I take care of all his meds, we don’t use the financial assistance at this time to get his medicine but may at sometime in the future” to which he responded, “I hope I don’t have to.” The SAFE caseworker present during the interview noted, “I have gone over all the options he has for assistance, but right now he doesn’t want to ask for the financial assistance from the pharmaceutical companies,” but “because he has serious chronic conditions, we check on him often.”

As for his knowledge of SAFE and the programs they offer, he said, “The center (CRC) that we go to is mostly for socializing and games, we play cards and stuff but sometimes we go for the programs they offer,” and his wife replied, “We don’t go every day.”

*Mrs. Z*

Mrs. Z, a 61-year old white female, completed high school and scored 65 on the TOFHLA. Her home was a small single-wide older trailer, private residence that was cluttered and dirty. There was a visible insect and rodent problem. The odor of the area was almost unbearable with a combination of animal excrement and urine odor. The high temperatures (outdoors) and minimal air-conditioning (indoors) and very little lighting in the home made it difficult to conduct the interview. Pets were in and out of cages, jumping on and off her bed that she was in, which was located as you walk through the

entry to the trailer. She was totally clothed during the 4 p.m. visit including pants, top, and shoes, along with multiple rings, necklaces and earrings. Additionally, her hair looked as though she had been to a salon to have it styled and set. During the interview, she was asked if she had family close by and she said, “Yes, they live in the two trailers next to me.” Mrs. Z commented, “I don’t like people in my business and the only reason I let you come in was for the money (\$25 incentive pay).”

Mrs. Z was well-spoken and had a good understanding of her health care needs and the medications prescribed for her. She reported that she saw three physicians for her health care needs. When discussing her primary health care physician, she said, “He is the main one (physician) I use and that helps me not to get things mixed up.” At the time of the interview, she was prescribed 12 medications. Mrs. Z is a participant in the SAFE SenioRx program, but does not allow them to review her medications with her. She has attended educational programs as previously described and offered by SAFE. Mrs. Z. said, “If I happen to go and there is a program, I listen, but I mainly go because of the food.”

### *Themes*

Three themes emerged during analysis of data gleaned from participant interviews, observations, medication records, related artifacts and SAFE caseworker files. The themes were as follows: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the synthesis of the data collected, sub-themes for each

theme were identified as noted in Table 8 at the end of this chapter. These themes explored the mechanisms, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for participants in Phase II of this dissertation study.

#### *Accuracy of Self-Administration of Prescribed Medications*

The accuracy of self-administration of prescription medications for each participant of Case Two was revealed through examination of several sources. Data collected during Phase I using the PMAR were examined prior to and during each home visit. During home visits, participants' verbal explanations were recorded and compared to information gathered from the PMAR. Notes taken by the SAFE caseworker during the interview were also reviewed. These records were compared to SenioRx Wellness program files to determine the accuracy of self-administration for each participant.

After obtaining informed consent during in-home visits, each participant displayed to the researcher and SAFE caseworker all of the medications/bottles prescribed by his or her health care provider. Discussion with each participant revealed: (a) recognition of the name of each medication, route of administration (i.e. pill, liquid, patch), and dosage; (b) medication purpose; (c) time and frequency of administration; (d) beginning and ending dates of treatment; (e) name of the prescriber; and (f) occurrence of adverse drug events during the 12 previous months leading up to the study.

As participants of Case Two were reciting all of the aforementioned information, the researcher compared self-reports to written information recorded on the PMAR. The investigator noted accuracy of written and oral information as provided by participants. In addition, the assigned SAFE caseworker took detailed notes, permitting further

comparison to SAFE SenioRx files. Results revealed that each participant from Case Two accurately identified all aspects of his or her prescription medication. Comparisons of information from the PMAR to what was found in the home, as well as the participant's account of each medication, the SAFE caseworkers' notes and SenioRx files indicated no errors of understanding. Mrs. Q was excited when she brought out her medications to show the researcher and SAFE caseworker. She told them, "My diabetes is why I am taking as many (medications) as I am." She added, "The good Lord has blessed me so I can't complain." Mrs. Q, also noted, "I wish I could come off all of them (medications)."

Mrs. Q was very organized with all of her medications and was proud to tell us about her record keeping. She showed us her "pill box" where she stored her medication for 30 days so she would "remember to take them (medications)."

Participants from Case Two demonstrated 100% accuracy when self-reporting the prescription medications used by each participant both on the PMAR and during the qualitative data collection for Phase II of the study. The three participants similarly stated that they take their medicine the way they are supposed to (do).

The investigator, who is a nurse practitioner, took time to question each participant about every medication prescribed during each home visit. The purpose of this exercise was to determine his or her understanding of medication self-administration. Those with questions about their medication (for instance how supplements may interact with prescriptions) received practical information to understand potential health threats. Two of the three participants stated they were "very appreciative" of the time spent with them to better understand how to take medications.

### *Issues Related to Prescription Medication Adherence*

Data collection for Case Two participants exposed several issues that effect accurate self-management of prescribed medications. These issues are further discussed below as emergent sub-themes.

*Lack of communication.* The three participants expressed concern with their lack of provider-patient communication. Specifically, participants stated that their health care provider (physician) does not take time to explain reasons why medications are prescribed and noted that their physicians did not devote enough time with them. For example, Mrs. Q stated that “I have to go every month to get some of my meds reordered and that doctor is in and out in about 2 to 3 minutes.” Mr. C echoed what Mrs. Q had said and his wife said, “It is pitiful how little time they spend with us; we wait on them forever in the waiting room and then they rush us in and out so fast you don’t even have time to ask them questions.” Mrs. Z also felt similarly “you have to nail them (physicians) down to get them to answer your questions” adding, “my primary care doctor is doing good if he spends two minutes with me.” It was apparent to the researcher that all three felt that their physician was not spending enough time with them.

When reviewing the PMAR and other related artifacts, the researcher questioned all participants about the patient-provider communication in terms of his or her understanding of the health care information given to each. They all commented that often they had difficulty understanding some of the medical terms. Mrs. Z stated, “I make my doctor stay and answer my questions even if he is in a hurry.” Mrs. Q and Mr. C both noted that if their physician gives them hard copies of information, they keep all of it for future use. Mr. C said, “I tell my doc to explain to me in plain terms, not the medical

mumbo-jumbo (terms).” Mr. C’s wife stated, “I go to the internet if I don’t understand what they said. I write down what they say and then look it up.” Following the interview, the SAFE caseworker confirmed that the calls she most often receives from study participants are related to questions about what they were told during a visit to the health care provider.

*Generic substitutions for prescribed medications.* The participants of Case Two all noted that they have issues in recognizing prescribed generic medications when the color and shape change from month to month. They reported that they sometimes have been confused by a change in the color or shape of medications that they had been taking for a lengthy time period. Mrs. Q said, “It mixes me up sometimes if the drugs change color, my husband helps me keep it straight and I keep all the attachments they put on the envelope when I get my prescriptions filled.” Mr. C stated, “I get confused and that is why my wife does it all for me” to which she replied, “the pharmacist is good to tell me if there is going to be a change in the color or shape.” In spite of their lack of knowledge regarding generic medication appearance, each praised their pharmacy because the pharmacist spent the appropriate time to explain when there were changes. Mrs. Q said, “My pharmacist goes over any changes of the color and shape.” Mrs. Z stated, “they are supposed to tell us when there is a change (in medicines)” followed by “I take the same number every month so I just make sure I have one of each when I take them (the medicines).” The researcher cautioned Mrs. Z about relying on the number of pills to accurately self-administer her medications. Additionally, she (the researcher) encouraged her to know the names, dosages, and reason for use of each medication to reduce the possibility of adverse drug events when taking her medications.



*Financial concerns.* Concerns of the participants in Case Two included future health care costs. Two of the three participants verbalized that at the present time they do not have a problem paying for medications, but do worry that in the future finances could prohibit them from getting all the prescribed medication they might need.” Mrs. P said, “My husband is so good to me, he will always make sure I have what I need.” Mr. C said, “I worry about the continued increase in the cost of my medicines, they just keep going up.”

Participants for Case Two expressed “worry” over the cost of prescribed medications. It is important to note that two of the three individuals expressed their ability to call on their family if they needed help paying for their medicines. Mrs. Q stated, “me and my husband could call on our daughters, but hopefully we will not need to ask them to help pay for our medicines.” Mrs. Z stated, “I guess if I needed help some of my family would help or I would look for other ways to pay for them (the medications).” With assistance offered by SAFE and family members, these older adults should be able to continue the prescribed medications important to sustain their health.

*Transportation.* All participants from Case Two had the ability to visit their health care provider and pharmacy for prescribed medications, but they did worry about the possibility of decreased independence in the future. Two of the three participants own a car and continue to drive without difficulty. Mrs. Z stated, “My car is not much, but I do have one” and Mr. C told the researcher, “that (transportation) is not a problem, I have plenty of cars to get me where I need to go.” Mrs. Q noted, “My husband is retired and he checks with me every day to see where I need to go before he plans his day.” Considering the comments from all three in this case, the researcher concluded that at the time of the

interview, each were able to go where they needed to get the medications as prescribed for each.

The participants of Case Two also noted that if the need should arise where they did not have transportation to pick up their prescribed medication, the pharmacy they use provides a service for the community; they will deliver any medications prescribed for their customers. Additionally, each community resource center has a van that picks seniors up to travel to programs offered via SAFE at each (CRC) location. Transportation vouchers are also available at some of the community support programs to pay for a taxi when needed.

*Side effects.* Side effects as reported to the researcher by the participants in Case Two were mild and non-threatening. However, the participants of this case were not always aware of the cause for some of the side effects they had experienced. Mrs. Q said, “I try to pay attention, especially with my diabetic drugs, so I can make sure to eat when I need to.” Mr. C said, “I don’t worry about them” and his wife replied, “I keep up with what he takes and the side-effects associated with them so I know what to watch for.” During the interview, when questioned about ADEs experienced over the past 12 months (leading up to this study), two of the three participants reported what they thought were ADEs. In reality, most of the ADEs they each verbalized were actually not ADEs, but were instead a side effect common to the administration of the medications they were taking. The only exception was when Mr. C told the researcher about a very serious life-threatening ADE he had experienced. He said, “I nearly died and had a big blood clot,” continuing, “it was when I was in the hospital and they had taken me off my medicine to help me keep my blood thin along with an antibiotic that I was allergic to; it was really

bad.” Because this happened in the hospital, the researcher noted the ADE but did not count it as an ADE associated with this study. It occurred while in the hospital and was not the result of daily prescribed medications taken in the community.

Prior to Phase I of the study, all participants attended an informational session on the topic of “what constitutes an adverse drug event.” After that presentation, participants filled out the self-reported PMAR that contained a question that asked, “How many adverse drug events did you experience in the previous 12 months?” All participants from Phase I of the study recorded “none” on the PMAR.

During Phase II of the qualitative data collection and during the in-home interview, participants were again asked, “How many adverse drug events did you have during the previous 12 months?” The participants named several instances of what they believed to be ADEs. The researcher questioned them about specifics of each ADE. Upon investigation, it was revealed that these episodes were actually side effects that were commonly listed by the manufacturer for that particular drug (except for the one account by Mr. C that happened while hospitalized). For example, Mrs. Q takes Atenolol (a common blood pressure medication) which is approved by the FDA to slow a fast heartbeat and subsequently, it lowers blood pressure. A common side effect from taking Atenolol is dizziness. Mrs. Q complained that she “gets real dizzy sometimes after taking it (the Atenolol)” and “I make sure I am close to the phone if I feel like I am getting dizzy.”

Upon completion of the interview, the researcher for this study took the time to go over all medications prescribed for each of the participants of this study. During this informational session, the researcher (who is a nurse practitioner) covered all potential

side effects of each medication. When finishing the informational session with Mrs. Q the researcher again asked her “Did you experience any ADEs during the 12 months prior to this meeting?” to which she replied, “No.”

*Self-efficacy.* Self-efficacy as defined by Bandura (1985) describes an individual’s beliefs about their capabilities to perform a specific action or behavior and exercise influence over events that affect his/her life. According to Bandura, those with strong self-efficacy believe they can accomplish goals related to a certain issue; for this study self-efficacy is related to participants’ belief that they can self-administer their prescribed medications accurately.

During the home interviews all of the participants shared with the researcher his or her ability to properly self-manage their medications. The three members of Case Two expressed confidence in their management skills. Mrs. Q stated, “I am able to keep up with medicines because I read everything the pharmacist gives me” and Mr. C said, “I have been taking the same things (medicines) for a long time so I know most everything I need to know about them and so does my wife.” Participants were encouraged to elaborate on questions asked of them during the interview when completing the MASES. All three scored between a 2 and 3 on the MASES indicating that they all demonstrated a high level of self-efficacy in the area of confidence to properly self-administer their prescription medications. The MASES scoring procedure is described in Chapter Three.

As cited in Chapter Two of this study, researchers concluded that the MASES is useful to identify patients’ low self-efficacy for adherence to prescription medications. The MASES results for the individuals in Case Two may be one explanation of why they do not report any ADEs even though they are all in a high risk group for ADEs.

### *Support System Resources*

Resources within the community are a very important part of the SenioRx program. The participants of Case Two noted various types of support that they all receive via SAFE which are listed as emergent sub-themes below.

*Community resource centers.* The community resource centers (CRCs) were an integral part of the SenioRx program. The CRCs are the venues where SenioRx program participants gather for daily balanced hot meals as well as educational programs presented during lunch. Educational sessions feature content about nutrition, prescription medications, and diagnoses such as heart disease with a focus on prevention. Transportation is available for any resident who does not have a car or a family member to transport them to and from the CRC. Mrs. Q said, “I live so close, but since I don’t drive I have to depend on either my husband or the van (offered by the CRC) to pick me up and go to the center.”

Two of the three participants from Case Two expressed enthusiasm for programs offered at the CRC. The lunches provided, as well as other activities offered were all noted as a plus for the CRC (bingo, arts and crafts, and socialization). Mrs. Q stated “I love to go to the center for lunch; we always have so much fun!” Mr. C stated, “even though we don’t go every day, I enjoy it when we do go.” Mrs. Z had no comments about the CRC.

Two of the three participants also mentioned how fond they were of SAFE caseworker(s) for the SenioRx program. They said that they were like one of their family and indicated that they felt comfortable going to any of them (SAFE caseworkers), if they had any problems with their medications. Access to direct assistance can promote

medication self-efficacy. Mrs. Q noted, “The caseworker helps everyone at the center (CRC).” Mr. C said, “The caseworker has done a lot to help me in the past.” On the contrary, Mrs. Z said, “I don’t talk to anyone much at the Center but the meals are nice.” The general consensus of the participants from Case Two was supportive of all of the activities offered at the CRCs. All expressed their gratitude for the opportunities provided to them by the CRCs.

*Health care providers.* Participants of this case thought that physicians generally did not spend enough time with them. Two of the three reported that the physician was in the room with them 10 minutes or less during any check-up they had during the previous 12 months. Mrs. Q noted, “I see him every month and he is in and out in just 2-3 minutes” and Mr. B stated, “He (his physician) spends maybe 10 minutes with me, but I can call his nurse if I have questions later (after the visit).” Mrs. Z stated, “I try not to go (to the doctor) any more than I have to, but when I do (go), he just sees me long enough to check me out. He doesn’t really take time to ask me if I have questions.”

Additionally all three participants from this case voiced their belief that if they really needed to speak to the physician longer then the physician would make time for them as patients. Mrs. Q shared with the researcher, “my doctor doesn’t spend much time with me when I see him every month, but if something new comes up (illness or disease) he does take more time with me” and “I worry because he no longer brings a nurse in the room with him during my visit; it is just me and him. He has cut way back on his nursing staff.” Mr. C noted, “He does take more time with me when I really need him to, other times are just kinda like a well checkup and to get my medicine.” Mrs. Z noted, “If I am real sick and he doesn’t know what is wrong, he takes more time with me.”

Participants agreed they felt comfortable speaking with the nurse and never hesitated to call his or her doctor's office (or nurse) should a concern or question arise once they returned home. Mrs. Z noted, "I would rather talk to the nurse because she is easier to talk to." Mr. C and his wife both indicated they do not hesitate to call the nurse with Mr. C stating, "You can get to the nurse easier so we don't mind calling her." Mrs. Q noted, "I haven't had to call. I have a friend who is a retired nurse from the hospital and has been a nurse for one of the programs at SAFE, so I call her." It was apparent from interviewing the participants for Case Two that they felt comfortable calling their physicians' office to speak to the nurse, should the need arise. This is indicative of their self-efficacy as previously mentioned.

*Pharmacy.* The participants also listed pharmacies as an important resource. Prior to the implementation of the SenioRx program within the community, the SAFE caseworkers for the SenioRx program met with all of the pharmacies in the area to provide valuable information about how the program should be implemented. The participants of Case Two were all pleased with the service of his or her pharmacy. Mr. C reported, "I have used the same pharmacy for all my life and they know me and help me get what I need" and "if something changes in the size or color, I call them or she does (his wife) and they explain it." Mrs. Q stated, "If the doctor prescribes a new medicine for me, my pharmacist always makes sure I understand why I am supposed to take it, the dosage, and any side effects I should pay attention to, but I have to make sure I go during the week, on weekends they have different people there." As stated earlier in this section, because of this age group utilizing generic medications whenever possible (to save money), it was important for the pharmacists to be willing to spend extra time with their

customers. Responses to the PMAR indicated participants for this case rely on three different community pharmacies. This information supports the statement of the SAFE caseworker, “many of the pharmacies in the community go out of their way to help their customers, many of who are our clients at SAFE.” During the in-home interviews, all of the information gathered (about the pharmacy and pharmacist within the community) was very positive.

*Insurance companies.* Health insurance also played an important role in the self-management of prescribed medications for each participant in Case Two of the study. The caseworkers for the SenioRx program counsels each senior in the program to explain the benefits offered for them through the insurance company of their choice, how they can maximize coverage, as well as how they can save money through various programs offered by each insurance company.

Mr. C praised the two insurance companies he uses (one is private and one is public), “They are good, I have used one for a real long time and never had a problem with any of the costs to pay for what I need.” Mrs. Q also uses both private and public health insurance companies. She stated, “I love Humana, they make everything easy for me.” Mrs. Z declined to comment on her insurance coverage but acknowledged that she does have coverage. The participants expressed their concern regarding what might happen to their health care and insurance in the future with the recent health care reform bill. Mrs. Q stated, “I just don’t know how we will all (seniors) manage, but I am sure the government will figure something out for us.” From speaking to all participants in this case, it was clear that they were not sure how the health reform bill would affect them.



*Hospital.* Within the community where SAFE operates, the hospital collaborates with the SenioRx program caseworkers to offer educational programs to individuals within the community. Several of the nurses in the community work for the hospital and volunteer for the SenioRx program which allows for continuity of care in the eyes of the participants for this study. Specifically related to the hospital educational programs, Mrs. Q stated that she “had been to one of the programs in the hospital and enjoyed learning more about her medicines.” The other two participants of this program were familiar with the programs but said they had not been to any. They expressed willingness to do so if future topics were of interest. Mr. C said, “I think it is a good thing and one day I might go to one of them.” Mrs. Z said, “I don’t get out much but I am glad they offer them and might go one day.” Additionally, the participants of Case Two expressed their gratefulness for having a community hospital. Many rural hospitals have closed in recent years and the hospital in the community of interest for this research study was in jeopardy several years ago, having gone through many owners and changes in the past decade.

For many who live in urban areas, beliefs such as expressed by the participants of this study (regarding being thankful for having a hospital within the community) seem unimaginable, for those who live in the community, the threat of no hospital is very real. It is unimaginable to many that anyone would have to travel over an hour to reach a hospital. If the community hospital (from this study) were to close, it would put a tremendous hardship on the community and especially the older citizens who live in that area.

*Friends and family.* Case Two participants listed “family and friends” as an important resource for them to self-manage his or her prescribed medications. All three

noted that without family and friends to assist them with transportation, finances, and understanding of his or her prescribed medications they might not be as successful with self-management of the medications prescribed for them. Mrs. Q was very enthusiastic in telling the researcher, “I have the most wonderful family in the world and they all worry about me so much,” continuing “My three daughters are so loving and call me every day to check on me. I don’t know how people without family manage.”

Mr. C and his wife felt similarly, and he stated, “In this world, I don’t know what people do who don’t have family; we all (his family) rely on each other.” In addition, Mrs. Z said, “I try not to rely on anyone, but because my family is close, I can call them if I really need help.” The friends and family topic was the one area that each of the three participants warmed up to during the in-home interview. One of the three participants from Case Two wanted to share many stories about their friends and family. They also showed the researcher photos of their family when discussing this particular topic.

### *Summary of Case Two*

Case Two represents three individuals who scored at the level of marginal health literacy (according to the TOFHLA) approximately equal to a 6<sup>th</sup> or 7<sup>th</sup> grade reading level. Individuals that score at the marginal level of the TOFHLA may have great difficulty reading and interpreting health texts thus being unable to read, process, and incorporate knowledge into their decision-making. Three themes emerged during analysis of data: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the

synthesis of the data collected, sub-themes for each theme were identified. These themes explored the mechanisms, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for participants in Phase II of this dissertation study.

Overall Case Two revealed that these three individuals are doing very well with the management of his or her healthcare. No one in this case had any ADEs during the 12 months leading up to this study. A major portion of their success may be attributed to the multiple layers of community support, primarily due to SAFE who coordinates the SenioRx Wellness program.

Some of the issues and concerns listed by participants of this case were lack of provider-patient communication, generic substitutions, financial concerns, transportation and medication side effects. All of these issues were lessened with the multiple levels of resources and support available to them through the SenioRx program offered by SAFE. The SAFE agency coordinates with pharmacies, insurance companies, family and friends to assist seniors with quality and continuity of care. Additionally, the educational programs offered to SAFE participants of the SenioRx program via the CRC and hospital were helpful to all participants in providing them with information to improve their ability to self-advocate thus improving their self-efficacy.

### *Case Three: Inadequate Health Literacy*

Persons with inadequate health literacy are unable to read, process, or incorporate knowledge into their decision-making. Within a managed health care environment, providers do not always have time to explain self-care instructions to patients. Patients

are expected to participate in their health care by making informed decisions. Patients who are capable of reading and assimilating large amounts of information may also feel overwhelmed by medical jargon and the amount of information they receive during a health care encounter (Davis et al., 2006). Patients who are classified as having inadequate health literacy according to scores on the TOFHLA are at the highest risk for ADE related to polypharmacy (Conroy, 2000). Health care providers should be mindful to thoroughly explain instructions to patients and allow time to answer patient questions at the end of each clinical visit. As noted in Chapter Two of this dissertation Rothman suggests, “Treat every patient with universal precautions; you never know what patients are at high risk for low health literacy because most of them learn to disguise their low health literacy” (Russell Rothman, personal communication, March 25, 2008).

Case Three is represented by three individuals selected from Phase I of the study who scored at the inadequate level of health literacy and who participated in the SenioRx program at SAFE. Case Three health literacy scores on the TOFHLA were 59, 56 and 37. Scores indicating an inadequate level of health literacy range from 0 to 59. Two of the participants for Case Three scored at the upper end of the range and the third participant scored in the midrange of the lowest level of scores. Participants for Case Three are described below with their names changed to protect their identity. All information was recorded at the time of the data collection to reduce the likelihood of researcher recall error. Participants’ characteristics are presented as they were at the time of the data collection for this study.

### *Participants*

#### *Mrs. F*

Mrs. F, a 73-year old white female with a high school education, scored 59 on the TOFHLA. She is retired and lives in a private room at a senior living center. She is married, but her husband lives in a separate private room on the same hall of the senior living facility. Her home environment was very small with sparse comfortable furnishings. Her unit was clean but cluttered on the day of the visit. She is independent and her family lives nearby. Mrs. F was well-spoken and had a good understanding of her health care needs and the medications prescribed for her.

Mrs. F reported that she is treated by six physicians for her health care needs. One physician provides follow-up care for a cardiac pacemaker installed in 2003; in addition, home health nurses monitor pacemaker operation bimonthly. Other physicians she has used include a primary health care provider, two orthopedic specialists, a gastroenterologist and an ophthalmologist. At the time of the interview, she was prescribed 12 daily medications. She also had a prescription for an antifungal for use as needed.

Mrs. F, a participant in the SenioRx program offered by SAFE, had not utilized the program for assistance in purchasing her medications. Just as the others, she is concerned that at some point in the future, she may need financial assistance not only for her medications but possibly for other health care needs. Mrs. F is seen by home health care registered nurses bi-monthly for maintenance related to her pacemaker which insurance covers. She stated, "They (home health registered nurses) come every two weeks to check on my pacemaker and the thickness of my blood." The SAFE caseworker

confirmed that she had worked with Mrs. F to inform her of all of the resources that were available to her both for her medications and for home health. Mrs. F acknowledged she did not choose at this time to seek financial assistance for medications. Mrs. F did confirm that she “is appreciative” of the resource management and educational programs offered by the SenioRx program.

*Mrs. K*

Mrs. K, a 71-year old white female who completed the 10<sup>th</sup> grade, scored 50 on the TOFHLA. Mrs. K reported that she utilized two forms of health insurance benefits (Blue Cross Blue Shield of Alabama and Medicare). Her home environment was a private single-family dwelling with comfortable furnishings. Mrs. K was well-spoken and had a good understanding of her health care needs and the medications prescribed for her.

Mrs. K reported that she used two physicians for her health care. She noted, “I see a primary care physician that takes care of most of my needs and the other one is for my eyes.” At the time of the interview, she was prescribed 5 medications.

Mrs. K, a participant in the SenioRx program offered by SAFE, reported “I use the SenioRx program for assistance to purchase my medications; otherwise, they (medicines) would cost me a lot more money.” Mrs. K praised the caseworkers from SAFE and said, “They are great. I really appreciate all they do to help me manage my medications.” The SAFE caseworker reported, “Mrs. K uses all of the instructions we give her and this helps her to know more about her medications.”

### *Mrs. H*

Mrs. H is a 72-year old widowed white female completed the 8<sup>th</sup> grade and scored 37 on the TOFHLA. Her home was a private residence that was neat and clean. Mrs. H was soft-spoken and had a good understanding of her health care needs and the medications prescribed for her. She reported that she is treated by four physicians and one nurse practitioner. The physicians she used included a primary care provider, a rheumatologist, a cardiovascular specialist and a neurologist. At the time of the interview, she was prescribed 10 medications.

Mrs. H is a participant in the SAFE SenioRx program and utilizes the program for financial assistance. She has attended educational programs as previously described and offered by SAFE. Mrs. H. said, “I always learn from the programs offered by SAFE” and continued, “they do so much to help me understand how to take my meds.”

The SAFE caseworker disclosed that Mrs. H is one of the seniors in the SenioRx program who requires a great deal of assistance. SAFE caseworkers are very familiar with her needs and “we all make sure we check in with her as often as we can.” When reviewing participant responses to the PMAR, the researcher was very impressed with Mrs. H’s writing and spelling ability. Despite having little formal education and the lowest TOFHLA scores of anyone in this study, Mrs. H very successfully self-administers her daily prescribed medications.

### *Themes*

Three themes emerged during analysis of data gleaned from participant interviews, observations, medication records, related artifacts and SAFE caseworker

files. The themes were as follows: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the synthesis of the data collected, sub-themes for each theme were identified as noted in Table 8 at the end of this chapter. These themes explored the mechanisms, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for participants in Phase II of this dissertation study.

#### *Accuracy of Self-Administration of Prescribed Medications*

The accuracy of self-administration of prescription medications for each participant of Case Three was revealed through examination of several sources. Data collected during Phase I using the PMAR was examined prior to and during each home visit. During home visits, participants' verbal explanations were recorded and compared to information gathered from the PMAR. Notes taken by the SAFE caseworker during the interview were also reviewed. These records were compared to SenioRx Wellness program files to determine the accuracy of medication self-administration for each participant.

After obtaining informed consent during in-home visits, each participant displayed to the researcher and SAFE caseworker all of the medications/bottles prescribed by her health care provider(s). Discussion with each participant revealed: (a) recognition of the name of each medication, route of administration (i.e. pill, liquid, patch), and dosage; (b) medication purpose; (c) time and frequency of administration; (d)



beginning and ending dates of treatment; (e) name of the prescriber; and (f) occurrence of adverse drug events during the 12 months leading up to the study.

As participants of Case Three were reciting all of the aforementioned information, the researcher compared the information to the written information recorded on the PMAR. The investigator noted accuracy of written and oral information as provided by participants. In addition, the assigned SAFE caseworker took detailed notes, permitting further comparison to SAFE SenioRx files. Results revealed that each participant from Case Three accurately identified all aspects of their prescription medication.

When comparing information from the PMAR to what was found in the home, participant's account of each medication, the SAFE caseworkers' notes and SenioRx files the researcher found no errors of understanding. The researcher was complementary of each participant (to them), noting that each had done a very good job in keeping up with all the medications prescribed for them. Mrs. F was very proud to share with the researcher her knowledge about her health care, "sometimes I have to tell the doctor that I don't need all of the medications he wants me to take" as she continued she shared that "he (her primary care provider) thought I needed extra Vitamin D but I told him I got plenty of sunlight; when he checked my blood he said I was right." Mrs. F, who uses the most amount of medication in this case, also reported, "It takes me a while to get everything in the pill boxes, but once I do, I don't get them mixed up." Mrs. J was proud to tell us that she takes only five medications, "If you take good care of yourself, you don't need as much medicine, I try not to take any unless I really need it." Summarizing, participants from Case Three demonstrated 100% accuracy when self-reporting the prescription medications on the PMAR and during the qualitative data collection for

Phase II of the study. The three participants similarly stated that they take their medicine the way they are supposed to do.

The investigator, who is a nurse practitioner, spent time with each participant to go over every medication prescribed during each home visit. The purpose of this exercise was to determine his or her understanding of medication self-administration. Those with questions about their medication (for instance how supplements may interact with prescriptions) received practical information to understand potential health threats. All participants verbalized their appreciation of the assistance to enable them to understand how to self-administer medications.

#### *Issues Related to Prescription Medication Adherence*

Data collection for Case Three participants exposed several issues that effect accurate self-management of prescribed medications. These issues are further discussed below as emergent sub-themes.

*Lack of communication.* The three participants of this case expressed concern with lack of patient-provider communication. Specifically, participants stated that their health care provider (physician) does not allocate sufficient time during the patient visit to explain reasons why medications are prescribed. For example, Mrs. F stated, that “my doctor does not spend enough time with me to tell me about my medications.” Additionally, Mrs. F observed that she “worries about the lack of communication I have with my doctor; if he spent more time with me. I think it would make it easier for me to understand about my medicines.”

Mrs. G noted, “My doctor has a nurse practitioner who spends a lot of time with me to make sure I understand everything I need to know about my health care and medicines.” And on the other hand, Mrs. K was proud to report, “I do worry about communication, but my doctor is so wonderful, he spends as much time with me as it takes to make sure I understand everything I need to know.”

When reviewing the PMAR and other related artifacts, the researcher questioned all participants about the patient-provider communication in terms of his or her understanding of the health care information given to each. They all commented that often they did not understand the medical terms. Mrs. H stated, “When they say something that they tell I don’t understand, they stop and try to tell me in simple terms.” Following the interviews, the SAFE caseworker confirmed that the calls she often receives from study participants are related to questions about what they were told during a visit to the health care provider.

*Generic substitutions for prescribed medications.* The participants of Case Three stated that they have find it difficult to recognize prescribed generic medications due to changes in color and shape over time. Mrs. F noted, “I think they change sometimes because they can get them cheaper if they (the pharmacy) get prices from a bunch of (pharmaceutical) companies” adding, “I understand why they do it but wish they would not change.”

Mrs. K reported, “Since I don’t take many medications it doesn’t mix me up if I get something that looks different, but I always check the name (of the medication).” Mrs. H noted, “My (SAFE) caseworker helps me keep them straight.” In spite of their lack of knowledge regarding generic medication appearance, each praised their pharmacy

because the pharmacist spent the appropriate time to explain when there were changes. Mrs. H affirmed, “If there are changes, my pharmacist tells me so I know what to expect.” Mrs. K echoed Mrs. H by stating, “my pharmacist takes as much time as I need for him to explain about my medications; if they change, he tells me about it when I pick them (her medications) up.” Additionally all participants in Case Three stated that they retain leaflets and handouts stapled to their prescription envelopes to review as needed.

*Financial concerns.* Concerns of the participants in Case Three included future health care costs. Two of the three participants verbalized that at present, they do not have a problem paying for medications. These members of the Case also expressed concern that a change in future finances could prohibit them from getting all the prescribed medication they might need. Mrs. K expressed her concern by saying, “I don’t know if I can manage if anything happens to the help I get from SAFE.” Mrs. H stated, “I worry that things are going to get worse (more expensive).” She continued, “I am lucky to have good coverage (insurance), but not everybody does.”

Participants for Case Three expressed concern over the cost of prescribed medications. Additionally, Mrs. K and Mrs. H both praised the caseworkers at SAFE for making sure they have what they need and help them find a way to pay for everything. Mrs. K stated, “I am able to ask my family to help” with the costs of health care. All participants of this case noted family assists them through help to get the insurance companies to cover the cost of medications and pay for everything. With assistance offered by SAFE and family members, these older adults should be able to continue to get the items they need and their prescribed medications important to sustain their health.

*Transportation.* All participants from Case Three had the ability to visit their health care provider and pharmacy for prescribed medications, but they did worry about the possibility of decreased independence in the future. Mrs. F stated, “I don’t have any trouble getting out and about. The van or family or friends take me. I do worry about how I will get around when I get older.” Mrs. K noted, “My sister helps me get where I need to go and the van (from her CRC) helps a lot” continuing, “I try to plan things (doctor and pharmacy visits) ahead of time to get someone lined up to take me.” Further, Mrs. K stated that she “worries about health care reform” taking the money they use for the van and vouchers. Mrs. H shared with the researcher “my daughter can help me out if I don’t have a way to get there.”

Regarding transportation to and from the pharmacy or physicians’ offices, all noted that the pharmacy they use provides a service for the community; they will deliver any medications prescribed for their customers. Self-reported responses on the PMAR indicated participants for this case rely on three different community pharmacies. This information supports the statement of the SAFE caseworker, “many of the pharmacies in the community go out of their way to help their customers, many of who are our clients at SAFE.” Additionally, each community resource center has a van that picks seniors up to travel to programs offered via SAFE at each (CRC) location. Transportation vouchers are also available at some of the community support programs to pay for a taxi when needed.

*Side effects.* Listed as a concern by the participants in Case Three, side effects as reported to the researcher were mild and non-threatening. Mrs. F said, “Some of the ones (medications) I take do make me feel funny sometimes.” Additionally, each participant in Case Three had recorded on his or her PMAR “none” to the questions that asked, “How

many adverse drug events did you have during the 12 months preceding today?” The PMAR was given to all participants immediately following the educational session about what constitutes an ADE presented at each CRC, prior to Phase I of the study.

During Phase II of the qualitative data collection and during the in-home interview, participants were again asked “how many adverse drug events did you have during the previous 12 months?” Two of the three participants reported what they thought were ADEs during interviews with the researcher. However, all instances were likely side effects commonly reported for the medications they were taking. Once they completed their list of recalling ADEs, the researcher questioned them about when such ADEs occurred. All participants gave accounts for these episodes and when comparing the episodes to the period from which they took a certain drug, it was noted that these episodes were actually side effects that were commonly listed by the manufacturer for that particular drug. For example, Mrs. F takes ULTRAM which is approved by the FDA for pain. One of the common side effects is dizziness. Mrs. F said she “worries about getting dizzy” and reported to the researcher that she had several ADEs after taking ULTRAM.

Upon completion of the interview, the researcher for this study took the time to go over all medications prescribed for each of the participants of this study. During this informational session, the researcher (who is a nurse practitioner) covered all potential side effects of each medication. When finishing the informational session with Mrs. F the researcher again asked her “Did you experience any ADEs during the 12 months prior to this meeting?” to which she replied “no.” While the participants did report signs and symptoms of side effects, they were not of concern nor were any of them life-threatening.

*Self-efficacy.* Self-efficacy as defined by Bandura (1985) describes an individual's beliefs about their capabilities to perform a specific action or behavior and exercise influence over events that affect his/her life. According to Bandura, those with strong self-efficacy believe they can accomplish goals related to a certain issue; for this study self-efficacy is related to participant's belief that he or she can accurately self-administer prescribed medications.

During the home interviews, all Case Three participants shared with the researcher his or her ability to properly self-manage their medications. Each expressed confidence in skills for medication management. Mrs. F stated, "I feel pretty good about knowing what to do, I also manage all of my husband's medications." Mrs. H and Mrs. K both echoed what Mrs. F had said, but with slightly less confidence. Mrs. H said, "With the help of my caseworker, I think I do a pretty good job managing my medicines." Mrs. K noted, "Because I only take five drugs, it makes it easy for me to take them the way I should" and "the caseworker helps me a lot too."

Case Three participants of this study were encouraged to elaborate on questions asked of them during the interview when completing the MASES assessment tool to determine self-efficacy. Remarkably, all three scored between a 2 and 3 on the MASES indicating that they all demonstrated a high level of self-efficacy in the area of confidence to properly self-administer their prescription medications. The MASES scoring procedure is described in Chapter Three.

As cited in Chapter Two of this study, researchers concluded that the MASES is useful to identify patients' low self-efficacy for adherence to prescription medications.

The MASES results for the individuals in Case Three may be one explanation of why they do not report any ADEs even though they are in a high risk group for ADEs.

### *Support System Resources*

Resources within the community are a very important part of the SenioRx program. The participants of Case Three listed several types of support from the community that they all receive via SAFE which are listed as emergent sub-themes below.

*Community resource centers.* The CRCs were an integral part of the SenioRx program. The CRCs are the venues where residents of the community who are SenioRx participants gather for daily balanced hot meals as well as educational programs presented during lunch. Educational sessions feature content about nutrition, prescription medications, and diagnoses such as heart disease with a focus on prevention. Transportation is available for any resident who does not have a car or a family member to transport them to and from the CRC. Mrs. F, who lived in the senior living facility, had a slightly different situation noting that it is “very convenient” because the program is offered within the senior facility where she lives.

The participants from Case Three were very enthusiastic about their experiences when at the CRC. Mrs. F stated “I really enjoy going to the community room and socializing, my husband and I go together.” Mrs. K affirmed, “The programs presented by SAFE help me to understand more about what I am supposed to do (for health care).” Mrs. H stated, “I look forward to going to the community center; I look forward to the van picking me up every day.” Participants also mentioned the SAFE caseworker, for the



SenioRx Program. They all had praise for the work that she has done to make sure they have what they need and understand what they are supposed to do. Additionally, they all indicated that they felt comfortable going to her or any of the other SAFE caseworkers if they had any problems with their medications which could also promote their self-efficacy.

*Health care providers.* Participants of this case thought that physicians generally did not spend enough time with them. Two of the three reported that the physician was in the room with them just a few minutes during any check-up they had during the previous 12 months however, the nurses were available either after the office visit or via phone call. Even though they felt they were not always getting the time they needed with the physician, each reported good relationships with the nurses for each physician. Mrs. H stated, “The nurse practitioner who works for the doctor I see makes sure to spend plenty of time with me, every time I have an appointment.” Mrs. F stated that the nurse for her physician “always checks with me to make sure I have what I need.” All three participants of this case expressed their belief that whenever they need to stay longer or ask questions, they seem interested and are willing to take more time with them. Participants agreed they felt comfortable speaking with the nurse and never hesitated to call their doctor’s office (or nurse) should a concern or question arise once they returned home. This made the participants in Case Three feel good about whom they had chosen as their health care provider.

*Pharmacy.* The participants also listed pharmacies as an important resource. The SAFE “caseworkers for the SenioRx program met with all of the pharmacies in the area to provide valuable information about how the SenioRx program and how it should be

implemented” stated the SAFE caseworker for the SenioRx program. Mrs. K reported, “My pharmacist doesn’t have to do much with me, but if there are any changes he always makes sure to tell me.” As stated earlier in this section, because of this age group utilizing generic medications whenever possible (to save money), it was important for the pharmacists to be willing to spend extra time with their customers. Mrs. F praised her pharmacist stating, “he gives me information with each prescription and tells me to call him if I have any questions.” The consensus of this Case was that without the pharmacist following through with specific information (as related to each prescription) it would be difficult for them to know what they needed to know for each medication. All were very appreciative of the follow through from their pharmacy and pharmacist(s).

*Insurance Companies.* Health insurance also plays an important role in the self-management of prescribed medications for each participant in Case Three of the study. The caseworkers for the SenioRx program counsels each senior in the program to explain the benefits offered for them through the insurance company of their choice; how they can maximize coverage, as well as how they can save money through various programs offered by each insurance company. Mrs. F praised her insurance coverage from Blue Cross and Blue Shield of Alabama (BCBS) stating, “They cover more than anyone else (in Alabama) and I am fortunate to be able to afford them for my insurance.” Mrs. K who also uses BCBS in addition to Medicare stated, “I like my insurance and they are one of the reasons I feel good about my health care; they cover everything.” Mrs. H, who also subscribes to BCBS and Medicare, stated “I like my insurance coverage; I don’t have to worry about most of my health care expenses.” The participants expressed their concern

regarding what might happen to their health care and insurance in the future with the recent health care reform bill.

*Hospital.* Within the community where SAFE operates, the hospital collaborates with the SenioRx program caseworkers to offer educational programs to individuals within the community. Mrs. F stated, “I have been to two programs just in the last year, I really like them.” “It is good that our local hospital offers this for the community.” The other two participants for Case Three of this study noted that the hospital was an important resource for the community. Mrs. G said, “In such a small town, we are lucky to have our hospital” and Mrs. K echoed Mrs. G stating, “I don’t like to go there (the hospital) but I am glad we have it in Sylacauga in case we need it.” Several of the nurses in the community work for the hospital and volunteer for the SenioRx program which allows for continuity of care in the eyes of the participants for this study. All participants noted an appreciation for having a hospital within the community so that they did not have to travel over an hour to the nearest hospital outside of the community of interest.

*Friends and family.* Case Three participants listed “family and friends” as an important resource for them to self-manage their prescribed medications. All three noted that without family and friends to assist them with transportation, finances, and understanding of their prescribed medications they might not be as successful with self-management of the medications. Mrs. K told the researcher and caseworker during the interview, “I have some friends that check on me and my sister does too to make sure I am keeping everything (medications) straight.” Mrs. H reported, “I try not to ask anyone for help but between my family and friends, I feel very blessed” continuing “my daughter lives close and can also help me if I need her to.”

Mrs. F was very proud as she shared with the researcher, “I have my husband and so many wonderful friends that live here at the facility with me, we all try to help each other when needed.” In summary, the friends and family topic was the one area that each of the three participants warmed up to during the in-home interview. Each wanted to share stories about their friends and family. They also showed the researcher photos of their family when discussing this particular topic.

### *Summary of Case Three*

Case Three represents three individuals who scored at the level of inadequate health literacy (according to the TOFHLA) which means that can read at or below the 5<sup>th</sup> grade level. Individuals that score at the inadequate level of the TOFHLA are rarely able to read or interpret health texts, making them unable to process and incorporate health knowledge into their decision-making. Three themes emerged during analysis of data: (a) accuracy of self-administration for prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available to the persons in this study to assist with accurate self-administration of prescription medication. From the synthesis of the data collected, sub-themes for each theme were identified. These themes explored the mechanisms, personal attributes, and social factors that facilitate accurate self-management of prescribed medications for participants in Phase II of this dissertation study.

Overall Case Three revealed that these three individuals are doing very well with the management of their healthcare. No one in this case had any ADEs during the 12 months leading up to this study. Some of the issues and concerns listed by participants of

this case were; lack of provider-patient communication, generic substitutions of medications, financial concerns, transportation and medication side effects. All of these issues were lessened with the multiple levels of resources and support available to them through the SenioRx program offered by SAFE. The SAFE agency coordinates with pharmacies, insurance companies, family and friends to assist seniors with quality and continuity of care. Additionally, the educational programs offered to SAFE participants of the SenioRx program via the CRC and hospital were helpful to all participants in providing them with information to improve their ability to self-advocate thus improving their self-efficacy.

### Cross Case Analysis

#### *Themes and Sub-themes across Cases*

Comparison of themes across the three cases discovered the emergence of the same three themes revealed in the within case analyses: accuracy of self-administration of prescribed medications, issues related to prescription medication adherence, and resources for assistance with medication administration. Additionally, the same sub-themes emerged across all three cases: lack of communication, generic substitutions for prescription medications, financial concerns, transportation, side effects, self-efficacy, SAFE, community resource centers, health care providers (doctors and nurses), pharmacy, insurance companies, hospitals, and family and friends as shown previously in Table 8 found at the end of this chapter.

#### *Accuracy of Self-Administration of Prescribed Medications*

The accuracy with which participants from each case were able to self-administer all of their prescribed medications was of great interest to the researcher. Eligibility for

this study translated to every participant being 60 to 74 years of age and taking at least five daily prescribed medications. In simple terms, all participants from each case were practicing polypharmacy and were at high risk of ADEs (Conroy, 2000). Failure to properly administer multiple prescription medications can lead to adverse drug events requiring hospitalization, and recurrent illness, thereby perpetuating an increase in health care cost, morbidity, and mortality (IOM, 2004).

Several sources were utilized to examine the accuracy of self-administration of prescribed medications across cases. Cases were analyzed and compared for similarities and differences across the three cases. Analyzed across all three cases were the PMARs, notes taken by the SAFE caseworker during interviews, and a review of the files kept at SAFE for each participant from the SenioRx Program. Additionally, each participant displayed all of their medications and demonstrated to the researcher what they knew about their prescription medications.

Review of all notes revealed there was no difference between any of the three cases when considering the knowledge of: (a) the name of each medication, route of administration (i.e. pill, liquid, patch), and dosage; (b) the purpose for using the medication; (c) time and frequency of administration; (d) beginning and ending dates of treatment; (e) name of the prescriber, of each case. All reported no occurrence of adverse drug events during the 12 previous months leading up to the study. All participants of the three cases demonstrated 100% accuracy of self-administration of prescribed medication regardless of age, gender, level of formal education, number of prescribed medications or scores on the TOFHLA.

*Issues Related to Prescription Medication Adherence*

The analysis of identified issues across cases provides the reader with an insight to the beliefs and feelings of the majority of participants in the study. Common to all cases were sub-themes that they believed affected their accurate self-management of prescribed medications. These issues are further discussed below as emergent sub-themes that were identified across all three cases. Additionally, similarities and differences in the sub-themes will be noted.

*Lack of communication.* Participants of all three cases expressed a high level of concern with the lack of provider-patient communication. Specifically, all participants stated that their health care provider (physician) does not allocate sufficient time during the patient visit(s) to explain reasons why medications are prescribed.

As noted in Chapter Two, the national average per physician office visit is 12 to 15 minutes. The participants within these cases reported his or her physician spends less time than the national average with them for the greater part of their visits. The range reported by the participants was between two minutes up to one who reported 10 - 12 minutes with his physician. However, the majority of office visits participants of this study reported were between three to five minutes. Along with reports of “not enough time with the doctor” were feelings of animosity from some of the participants who felt that their time was just as important as the physicians. Most of the participants expressed feelings of resentment because they “did not get the chance to ask questions” of the physician, due to the physician being hurried during office visits. Other concerns noted by several of the participants was the amount of time each of them spent waiting on the

physician before being ushered back to the patient room only to be rushed in and out of the room.

Regarding the time that physicians did spend with each participant two thoughts emerged: (a) the patient educational materials provided to patients by physicians about condition/diseases, and (b) medical terms used by physicians that were hard for patients (participants) to understand. Patient education materials are often an easy way for physicians to provide detailed information to patients that can answer many questions that the physician may not have time for, during an average clinic visit. All participants who acknowledged his or her physician had provided such materials to them were very “appreciative” and “kept all the pamphlets” given to them. The majority of the participants from the study noted that they were often embarrassed to tell the physician when they did not understand some of the medical “jargon” they would hear from the physician regarding their condition(s). A few of the participants reported that they told their doctor to translate what had been told to them so they could understand instructions/conditions etc.

Even though the participants were concerned about the lack of time his or her primary care provider spent with them, the majority of them noted that “the nurse” was who they received most of their answers from. Eight of the nine participants noted that the nurses within the office of their physician(s) were willing to spend the time to help them understand about prescribed medications. Some (participants) noted that they (the nurse) came in at the end of the appointment to ask if they had any questions. Others (participants) reported that they felt very comfortable calling the nurse to ask any questions.



Two of the participants reported relying on the nurse practitioners in the office of their primary care provider. These participants also noted that they rarely see the physician unless it is really “something bad” and verbalized great satisfaction with the care they were receiving from the nurse practitioners.

Other issues that arose from participants were: (a) the Internet, and (b) required monthly visits to the physician to get medications refilled. Only one participant reported that they would look on the Internet for answers to questions, and one participant reported that she was “required” to go to her “doctor’s office” every month to have prescriptions written (even though her conditions did not warrant such frequency).

Even though all participants expressed concern over the lack of communication from their physician; they all reported that they were “pleased” with their health care provider(s). Additionally, across all three cases it appeared that the participants of the SenioRx program not only call on the nurses within physician(s) offices but also rely heavily on the SAFE caseworkers of the SenioRx Wellness program.

*Generic Substitutions for Prescribed Medications.* In the past twenty years, the practice of substituting brand name medications with "generic" medications within the pharmaceutical industry has become commonplace. In order to substitute a brand name medication, the physician must give permission for a prescription to be filled with a generic substitution. Additionally, the patient may direct the pharmacist to use generics when filling prescriptions. Most often generic substitutions are requested as a cost saving measure for patients. Theoretically, generic substitutions for prescribed medications provide the same medicine and the same therapeutic result as their brand-name counterparts but at a significantly lower cost (Generic Pharmaceutical Association).

Most pharmacies contract with companies who manufacturer generic substitutions and will purchase a large supply at one time. Often a “bidding process” is used and the pharmacy will purchase a new supply based on cost alone as the quality is regulated by governmental agencies for the pharmaceutical industry. Often from contract to contract, the generic substitutions will look differently by color and sometimes shape. This can make utilization for generic medications confusing for most individuals, but especially for those who have low health literacy. The American Pharmacist Association Code of Ethics for Pharmacists acknowledges it is the responsibility of the pharmacist to ensure consumers understand when generic medications look differently from one month to the next. However, not all pharmacies take the time to make sure consumers understand when there is a change (American Pharmacists Association, n.d.).

The participants of this study all noted that generic substitutions help them to afford all of the medications prescribed for them. However, they acknowledge that sometimes they can get “confused” by the changes and shapes of their generic substitutions especially if they change appearance often.

Prior to the implementation of the SenioRx Program in the community of interest, caseworkers assigned by SAFE met with the pharmacies and pharmacist within the area. The purpose of the meetings was to reinforce to all parties involved in medication acquisition, “the importance of educational sessions” when consumers purchase medications. According to the participants of this study, they all receive important information from his or her pharmacist each time they purchase prescription medications. Specifically, they all reported that “my pharmacist” makes sure to inform me when there is a change in any way to (my) prescribed medications. The additional information or

counseling sessions provided by local pharmacist served to relieve the participants of this study from any issues that could arise from confusion over medications that look or are shaped differently from month to month. Additionally, participants of the study noted that family assists them at home should they become confused over a change in their generic medications.

Other measures used by some of the participants of this study (to assist them with proper utilization of generic medications) included: (a) counting the number of pills they take daily (i.e. they take the same number every day); (b) several relied only on the name of the medication; and (c) SAFE caseworkers for the SenioRx Program. It was apparent to the researcher that generic medication changes from month to month did concern each of the participants of this study. Each had formulated personal criteria for how they accurately self-managed all of their medications, including the generic substitutions. All acknowledged the importance of spending time with their pharmacist when “filling” prescription medications.

All praised their pharmacist for spending extra time with them when needed and were very appreciative of the educational materials the pharmacist would staple to the envelopes when prescription medications were filled. Most of the participants mentioned that they kept all of the information given to them so that family and SAFE SenioRx caseworkers could use the supplemental materials for reference should the need arise.

*Financial Concerns.*..All participants of this study noted their “worry and concern” of the future cost of health care. While most of them felt that “at the present time” they were able to afford the medications they need to sustain their health; they were concerned not

only for the overall costs of health care escalating, but also worried about the costs of their medications getting so expensive that they “might not be able to afford them.”

All participants of this study reported insurance coverage, and some had more than one type of insurance coverage, lessened the financial burden for them and their family (as related to medication adherence). Most noted that because of their finances, they do request that all of their prescription medications be filled with generic substitutions whenever possible.

Other financial concerns mentioned by the majority of the participants in this study related to the “reform” passed in 2010 by Congress. Most of them knew little about how they would be affected by the legislation. The group of participants as a whole was split between those in favor and those opposed to the legislation, but all agreed that the cost of health care had “gotten out of hand” and they all expressed fear of not being able to afford medications in the future.

The participants who had additional insurance coverage over and above government health insurance (Medicare or Medicaid) such as Blue Cross and Blue Shield or Humana outwardly expressed their gratitude for having the additional coverage. Most were able to access this additional coverage through retirement benefits from their time of employment or their spouse’s.

All noted that should the need arise when they may not have sufficient health insurance coverage to pay for his or her prescribed medications that they could rely on several sources to assist them. Specifically, they mentioned family as a source for supplemental income. Additionally, all mentioned that SAFE was available to them and hoped that the community would always be able to rely on the resources provided by

SAFE; both in terms of programs offered but also as a comfort with the caseworkers' assistance in helping them achieve optimal health goals. With assistance offered by SAFE and family members, these older adults should be able to continue to get the items they need and their prescribed medications important to sustain their health.

*Transportation.* The participants from the three cases included at least one person within each case who found transportation to be a challenge to them on a daily basis (as related to their health care needs and getting to the programs offered by the CRCs). The majority of those who took part in the study affirmed their ability (at the time of the study) to be able to “get where they needed to go”) however, each of them expressed they do “worry” about the future and how long they will be independent and able to drive.

Multiple reasons for concerns about transportation arose during the interview process in Phase II of the study. Most notably were concerns about: (a) getting to and from visits with health care providers, (b) getting to and from pharmacies to purchase prescribed medications and health care supplies, and (c) having the transportation to go to the “center” for daily lunches and educational programs offered by the SAFE SenioRx Wellness Program.

Of comfort to those who are unable to drive or who do not have a car, several sources available to the community and participants of the SenioRx program were mentioned. The CRCs where seniors gather for daily meals during week days offer transportation services for those who do not have a car or who do not have family or friends to transport them where they need to go. Several of the participants mentioned detailed daily schedules they create so that others in their family (who drive) are able to plan their days based on the needs of the seniors of this study. Some mentioned that they

rely solely on family to take them where they need to go and expressed concern over “what will happen in the future” should that person become unable to drive.

When discussing issues related to procuring prescribed medications, all participants reported their knowledge of transportation services within the community such as: (a) the pharmacies can deliver medications to customers if they do not have any a way to pick up them up, (b) vouchers for taxis are available to SenioRx participants and can be obtained through various agencies within the community, and (c) the “centers” currently have vans that can pick up SenioRx Program participants and get them to and from the centers on a daily basis (during the week).

After interviews were completed and the researcher discussed transportation as an issue that the participants had mentioned, the caseworker also expressed concern for transportation because of several issues: (a) as the number of participants in the program increases (due to boomers coming of age) her concern was that the need could outpace the supply of transportation possibilities offered via SAFE, (b) some of the vans currently in use were in need of maintenance and could in the near future become too costly to maintain thus requiring SAFE to purchase new vans (and funding might not be available), and (c) with the cost of fuel continuing to increase, she expressed concern about the operational costs with using the vans and worried that “there may come a time when we do not have the funding to continue the service” and noted “it would be devastating to our seniors if we lost the ability to help transport those who can’t or don’t drive.”

*Side Effects.* Prior to Phase I data collection for this study, the researcher who is a nurse practitioner spent time at each CRC conducting an educational session. The purpose of the session at each center was to educate all potential participants about “what constitutes

an ADE.” Through analysis of the Phase I data, the researcher found no ADEs were reported by any of the participants during the previous 12 months, prior to the study. Later during Phase II data collection (in-home interviews), several of the participants reported ADEs they had experienced during the previous 12 months to the researcher during the home visit. Upon further discussion, the researcher determined that the ADEs reported by the participants were actually side effects and not serious ADEs with the exception of one account that took place in the hospital and therefore was not counted as an ADE for this study.

As covered in Chapter Two, side effects by definition are signs and symptoms reported by consumers of the medication which are common to that particular medication. By nature, side effects are generally mild and non-threatening and cause minor discomfort to the consumer. Adverse drug events, however, are much more serious and can cause life-threatening conditions for patients. Many ADEs are related to allergies and some may be caused by combining certain drugs that should not be taken at the same time. The majority of ADEs reported occur during first time use or when another medication is added for the first time. Additionally, occasionally, based on the condition of the patient at the time of administration, ADEs may occur due to a patient’s compromised immune system.

The greatest causes of concern for participants of this study were related to the potential side effects they (participants) were not previously aware of; when the side effect occurred, it alarmed the participant. At least two participants within each case reported occasional side effects to prescription medication they were taking. Most of the side effects reported were traceable back to specific medications. The researcher spent

time at the end of each interview to go over potential side effects and ADEs those participants should be aware of for each of their medications. Many of the participants mentioned that they were not aware of the side effects that could occur and very few participants in the study were aware of the ADEs they could experience should they change the time of day they took their prescribed medications. Additionally, the researcher reviewed the educational leaflets that participants had in their homes and had kept on hand from their visits to the pharmacy. Utilizing these “leaflets” the researcher used the “teach back” method to assure understanding among participants regarding the side effects that were most common to each medication.

Because of the nature of the practice of polypharmacy which all participants in this study experience, it is of utmost importance that each of them be knowledgeable about potential side effects associated with specific medications taken on a daily basis. The researcher for this study found the lack of awareness of potential side effects with their medications to be a very troubling concern as each participant also expressed.

*Self-Efficacy.* During the home interviews, all participants shared with the researcher his or her confidence in their ability to properly self-manage daily prescription medications. When displaying the containers of every prescribed medication (for review by the researcher and the SAFE caseworker) participants were able to accurately identify: (a) their medications, (b) the reason it was prescribed, (c) how they take it and when, (d) and the route for which it is prescribed (pill, liquid syrup, capsule, patch etc).

When analyzing the data from the home interviews and self-reports from the DQ and PMAR measures, the only common thread for all participants was involvement in programs offered by SAFE. Additionally, the only major ADE reported by one



participant of this study was directly attributed to the hospital staff within an intensive care unit and had nothing to do with the ability or self-efficacy of the participant

After the interview during in-home data collection for Phase II of this study, the Medication Assessment Self-Efficacy Scale (MASES) was administered (to participants) to determine individual self-efficacy scores. The scoring procedure for the MASES is described in Chapter Three. Remarkably, all participants of the three cases scored between a 2 and 3 on the MASES with the majority scoring just under 3. These results indicated that the participants of this study have a high level of self-efficacy and confidence in their ability (to properly self-administer their prescription medications).

As cited in Chapter Two of this dissertation, researchers who developed the MASES concluded that the tool is useful to identify patients' low self-efficacy for adherence to prescription medications.

### *Support System Resources*

Resources within the community are a very important part of the SenioRx program. The participants of this study noted types of support from the community that they all receive via SAFE which are listed as emergent sub-themes below.

*Community Resource Centers.* The community resource centers (CRCs) were listed by all participants of this study as an integral part of the SenioRx Program. The CRCs are the venues where SenioRx Program participants gather for daily balanced hot meals as well as educational programs presented during lunch. Educational sessions feature content about nutrition, prescription medications, and diagnoses such as heart disease with a focus on prevention. The majority of the participants noted that their daily visit to the CRC was the highlight of their day. The greater part of the group (two of three in each

case) expressed enthusiasm for programs offered at the CRC and emphasized the socialization they receive as one of the main parts of the program that they enjoy.

Many of the seniors who participated in programs offered by the centers live alone, therefore the time spent at the CRC was the only time of the day when they had the opportunity to socialize with others in an atmosphere where they felt no pressures (such as financial) or concerns. All of the programs offered at the CRC related to the SenioRx Program were free but donations were encouraged by some of the centers.

One of the centers does offer many more opportunities for visitors at the center which required a fee to participate. Among the activities are arts and crafts, computer classes, art, bingo, and exercise classes; just to name a few.

The majority of the participants also mentioned easy access to the SAFE SenioRx caseworkers while at the CRCs. Eight of the nine participants had praise for the work that is done on their behalf by the caseworkers from the SenioRx Program. The caseworkers are often the presenters of the programs offered at the CRCs and therefore were available to answer other questions by the participants upon conclusion of the center presentations. When discussing interactions each of them had with caseworkers while visiting the CRCs, the majority of them noted that they “felt comfortable” approaching the caseworker when they had questions or concerns. Additionally, they were very complementary of the caseworkers noting how “sweet” and “kind” each caseworker was during encounters at the CRC. All expressed their gratitude for the opportunities provided to them by the CRCs and appreciation for the care and concern offered to each participant by the caseworkers.

*Health Care Providers.* Seven of the nine participants expressed disappointment when

reporting that their physicians generally did not spend enough time with them. The majority of the participants reported that the physician was in the room with them between three and five minutes during any office or clinic visit during the previous 12 months. Two of the participants reported that their physician gave them “as much time” as needed to discuss health concerns and review medications prescribed. The remainder of the group said they felt like the doctor did not spend enough time with them during any given office visit. Even though they reported this, participants all expressed that they believed their physician would spend more time with them “if I really needed” them to.

Instead of time with their physician, six of the nine participants suggested they felt very comfortable speaking with the nurse (for each physician) and “never hesitated” to call their doctor’s office (or nurse) should a concern or question arise once they returned home. Many of the participants stated that they would rather speak with the nurse when they had a concern because the nurse would spend more time with them and was “easier” to talk with than the physician.

*Pharmacy.* The participants also listed pharmacies as an important resource. Prior to the implementation of the SenioRx Wellness Program for this community, SAFE caseworkers met with all of the pharmacies in the area to provide valuable information about how the program works and how it should be implemented. All of the participants of the study reported they were “pleased” with the service from his or her pharmacy.

Since many of the participants of this study had lived in the same community for most of their adult life, many of them had used the same pharmacy for many years. Many of them reported a feeling of “comfort” and “continuity” regarding their pharmacy. Most knew their pharmacist by name and the pharmacist knew the participants just as well.

Many of the participants reported that this made them feel important and they were “not a number” as they would be if they used a big chain where the pharmacists come from out of town to work.

One of the participants noted that the only time she would go to the pharmacy was during the week because “on weekends” they had replacement pharmacists who substituted for the “real” pharmacist. As stated earlier in this section, because of this age group utilizing generic medications whenever possible (to save money), it was important to each of the participants that their pharmacists were willing to spend extra time with them when needed.

During the in-home interviews, all of the information gathered (about the pharmacy and pharmacist within the community) was very positive. All noted their appreciation of the follow through from their pharmacy and pharmacist(s). Echoed by the comments made by the SAFE caseworkers noting that most of the pharmacies used by the participants of this study “go out of their way” to help their customers.

*Insurance Companies.* Health insurance companies were mentioned by all participants as a valuable resource in the self-management of their prescribed medications. Without the various companies/government programs that insure the participants, few would be able to afford any of their prescription medications. Caseworkers for the SenioRx counsel each participant of the program to make certain they understand all of the benefits available to them via the insurance company of their choice. The caseworkers focus on how they (participants) can maximize coverage as well as how they can save money through various programs offered by each insurance company.

The majority of the participants within this study rely on Medicare and a few Medicaid; three of the participants reported private insurance in addition to their other health insurance benefits. Those with more than one type of insurance expressed feeling “fortunate” for having most of their health care expenses covered by “someone.” Seven out of the nine suggested without the help from caseworkers from the SenioRx program, they would not understand how to maximize the benefits provided to them.

Eight of the nine participants expressed their concern regarding what might happen to their health care and insurance in the future with the recent health care reform bill. It was clear that the participants of the SenioRx program were not sure how the health reform bill would affect them.

*Hospital.* Within the community where SAFE operates, the hospital collaborates with the SenioRx caseworkers to offer educational programs to individuals within the community. Many participants expressed their gratitude to the hospital for the support it offers to the community. Seven of the nine participants noted that the hospital was an “important resource” for the community.

When speaking with the Executive Director of SAFE during the planning stages of this study, the researcher learned that several of the nurses in the community work for the hospital and volunteer for the SenioRx Program; she noted their volunteerism allows for continuity of care for participants who live in the community. During discussion related to the hospital educational programs, all of the participants were aware of the educational programs offered by the hospital but only a few attended the programs designed to help attendees learn more about how to manage his or her prescribed medications. However, eight of the nine participants expressed willingness to attend

future programs if future topics were of interest to them. Additionally, all of the participants of this study expressed their gratefulness for having a community hospital. Many rural hospitals have closed in recent years and the hospital in the community of interest for this research study was in jeopardy several years ago, having gone through many owners and changes in the past decade. If the community hospital (from this study) were to close, it would put a tremendous hardship on the community and especially the older citizens who live in that area.

*Friends and Family.* Participants of this study listed “family and friends” as an important resource for self-management of their prescribed medications. All noted that without family and friends to assist them with transportation, finances, and understanding of their prescribed medications they might not be as successful with self-management of the medications. Eight of the nine suggested they would not hesitate to call on family to assist with their needs related to their medication management but all expressed reluctance asking friends for financial assistance. Seven of the nine did however, note that they would feel comfortable asking friends to help with administration or procurement of medications in terms of transportation etc. During the in-home interview this particular resource (friends and family) was a topic that each of the participants warmed up to more than any of the other areas discussed. Six of the nine participants shared countless stories of their family. Additionally, those same six participants were eager to show the researcher and caseworker photos and memorabilia of their family and some of their friends. It was clear that family and friends were important to each of these individuals and that their relationships were important to their well being.

### Chapter Summary

In this chapter, quantitative data were used to identify characteristics of each participant. Participants were stratified into three cases according to health literacy scores as determined by the TOFHLA followed by purposive selection using the maximal variation strategy to establish unique cases for the follow-up in depth qualitative Phase II of the study. Qualitative data collected during in-home personal interviews were used to explore issues and resources related to accurate self-administration of five or more daily prescribed medications for older adults ages 60 to 74. The following chapter consists of a discussion of the implications of these findings.

Table 8

*Themes and Sub-themes Derived From Three Levels of Health Literacy and From Qualitative Data Analysis and Synthesis*

Themes		
Accuracy of self-administration of prescribed medications	Issues related to prescription medication adherence	Resources for medication administration
Sub-themes		
	Lack of communication	SAFE
	Generic substitutions for medications	Community resource centers
	Financial concerns	Health care providers
	Transportation	Pharmacy
	Side effects	Insurance companies
	Self-efficacy	Hospitals
		Family /friends



## CHAPTER FIVE

### DISCUSSION, IMPLICATIONS AND RECOMMENDATIONS

The overall purpose of this mixed methods study was to explore how community-dwelling older adults, across three levels of health literacy self-manage five or more daily prescription medications. Other questions the researcher sought to answer when beginning this study included: (a) how many ADEs were experienced during the 12 months prior to the data collection, (b) what side effects were reported and how they differed from the ADEs, and (c) what barriers and/or facilitators were related to self-administration of daily prescribed medication. Questionnaires, personal medication administration records, and health literacy scores were collected during the quantitative (Phase I) of the study. Analysis of the quantitative data provided the information needed to select participants for the in-depth follow up qualitative phase of the study. Discussion and interpretation of the findings, limitations of the study, and recommendations for future research are presented in this chapter.

#### Overview of Integration

For this study, the use of a mixed methods design enhanced understanding of the research problem beyond a single quantitative or qualitative approach. Through the mixed methods design, the sum of two approaches yielded new insights about health literacy, case management and ADEs among older adults residing in a rural community. The different types of data were linked through planned integration during three points of

the study; (a) at the end of Phase I during selection of participants for Phase II, (b) at the interpretive stage when conducting within and across case analyses, and (c) in the reporting phase.

According to Erzberger and Kelle (2003), integration of results from mixed methods research may lead to three outcomes: convergence (results yield the same conclusions), complementary (results from one method supplement the other), or divergent (contradictory results). The integration of the quantitative and qualitative phases yielded complementary information useful to select the three cases defined by participants' health literacy scores on the TOFHLA. Further, the researcher interpreted integrated results and discussed the implications and suggestions for future research.

Data obtained from Phase I of the study were used to select participants for Phase II, qualitative interviews. During the interpretive phase, information self-reported by participants during Phase I (PMAR) was compared to participant demonstrations of medication self-administration during the in-home interviews. Participants had to identify: (a) each prescription medication, (b) why prescribed, (c) dosage, (d) route of administration (form-pill, liquid, capsule, etc.), (e) what time of day it should be taken, and (f) potential side effects. The combination of the two types of data (quantitative and qualitative) was invaluable to determine participants' knowledge and understanding of accurate medication administration.

## Discussion

The quantitative phase of the study (Phase I) was designed to identify: (a) demographic characteristics, (b) levels of health literacy, and (c) the number of daily

prescribed medications for each participant. Invitations to participate in the study were distributed to approximately 200 seniors from five different senior centers (within a rural community) during regularly scheduled daily meetings. Eligibility criteria for the study included: (a) 60 to 74 years of age, (b) active in the SenioRx Wellness Program offered by SAFE, and (c) daily self-management of five or more prescribed medications.

Participants had to be willing to complete all portions of both phases (quantitative and qualitative) of the study to receive incentives; only the data from those who completed both phases of the study were included in final data analysis.

Data for the quantitative Phase I of the study were collected using Demographic Questionnaire (DQ) and the Personal Medication Administration Record (PMAR). Upon completion of the DQ and PMAR, each participant was administered the Test of Functional Health Literacy for Adults (TOFHLA) to determine their level of health literacy. Enrollment criteria included age, number of medications, and willingness to complete forms and assessments. Fifteen older adults completed the DQ, PMAR and all sections of the TOFHLA.

Scores from the TOFHLA were stratified by three levels of health literacy (adequate, marginal, and inadequate). The maximal variation strategy and purposive selection were used to establish three cases of three participants, nine participants for Phase II of the study. This process of participant selection was important to sample older adults by literacy level.

Adults at the lowest literacy levels may find it difficult to understand written or verbal instructions from a health care professional (Quirk, 2000). Consent forms or labels on prescription bottles that are difficult to read can put patients at risk for ADE (Baker et

al., 1999; Zagaria, 2006). Patients with low literacy skills have more visits to emergency rooms than those with adequate or proficient levels of literacy (Wolf, Gazmararian, & Baker, 2005). Nearly half of all American adults are low literate and have difficulty understanding and acting upon health information (Zagaria, 2006). Many studies have determined what problems older adults experience when self-managing daily medications. Few if any studies have explored barriers and facilitators related to older adults' accurate self-administration of five or more daily medications.

This study found that older adults who have community support to assist them with daily prescription medication management might not fit a stereotyped perception of someone with low literacy. Kutner, Greenberg, Jin & Paulsen (2006) reported a positive association between levels of health literacy and self-reported health. Alternately, Wolf, Davis, Osborn, Skripkauskas, Bennett & Makoul (2007) found poor adherence to HIV medications among patients with low health literacy levels. Other researchers reported poor or neutral health outcomes for those with low health literacy (Gazmararian, Kripalani, Miller, et al. 2006; Fang, Machtinger, Wang & Schillinger, 2006).

A systematic review of the literature conducted by the U.S. Agency for Healthcare Research and Quality (2011) included 81 studies addressing health outcomes and 42 studies addressing interventions for persons with low literacy. Consistent differences were noted for rates of hospitalization, use of emergency services, mammography screening, receipt of influenza vaccine, self-administration of medication, interpretation of labels and health messages according to health literacy level. Among older adults, poorer health status and higher mortality were associated with low literacy level.

Results of this dissertation study revealed that community support might enhance overall health for older adults including those with low health literacy. This finding is consistent with the AHRQ (2011) recommendation for further research to test new approaches to motivate patients, deliver oral and numerical information, enhance the clinical encounter including use of patient advocates, determine effective components of evidence-based interventions and verify program cost-effectiveness.

### Quantitative Findings

Data obtained during Phase I of the study were used to select participants for Phase II. Detailed description of results is included in Chapter Four.

### Qualitative Findings and Research Questions

The qualitative phase (Phase II) of the mixed methods sequential explanatory design was guided by a central research question “How do community-dwelling older adults ages 60 to 74 self-manage five or more daily prescribed medications?” The sample population was a group of English-speaking community-dwelling older adults who had participated in the SenioRx Wellness Program offered by SAFE. Each was responsible for daily self-administration of five or more prescribed medications. Three themes emerged during analysis of Phase II of the study; (a) accuracy of self-administration of prescribed medications, (b) issues related to prescription medication adherence, and (c) resources available for medication administration.

All participants regardless of age, number of daily prescribed medications, levels of formal education, or levels of health literacy were able to demonstrate excellent

management of daily prescribed medications. Comparison of data from multiple sources (existing case management records, self-report, participant demonstration) indicated successful medication management without ADE. Sub-questions guiding the dissertation study are described below.

### Guiding Research Questions

#### *Question 1*

What role does health literacy play in daily self-management of five or more prescribed medications?

Based on the findings of this study, there was no difference in self-management among those who scored at the very lowest level of health literacy as compared with those who scored at the highest level of health literacy, regardless of the number of daily prescribed medications. This finding is an important one, but is inconsistent with findings of several studies reported in the literature.

According to *Healthy People 2000 Final Review*, the principle drug safety issue of the future for older people will be ADEs from polypharmacy (use of multiple prescription and non-prescription medications). Older adults more often use multiple prescription medication(s) than younger adults and have increased risk of experiencing ADEs (Larsen & Hoot-Martin, 1999). Individuals with low health literacy are less likely to understand the intended purpose of a prescription medication and instructions for self-administration (Parker et al., 1995).

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) tracks sentinel events, including prescription medication errors, ADEs, and patient

outcomes; sentinel event outcomes include patient death and loss of physical or cognitive function. The JCAHO (2009) identified medication errors from the practice of polypharmacy as the seventh most common sentinel event in 2008.

Gray and Gardner (2009) reported polypharmacy practices in the elderly requiring clinical monitoring to avoid drug-related problems such as ADEs. Even with specialized attention, balancing the multiple medications and their potential related side effects can be challenging.

Participants in this study received instrumental assistance to self-manage their daily prescribed medications across different levels: (a) individual, (b) interpersonal (family, friends, and peers), and (c) community. Health literacy influences an individual's ability to properly self-manage daily medications, particularly if that person lives alone and receives limited assistance. On the other hand, even those who have low literacy skills are able to self-manage medications for multiple chronic conditions if they receive adequate support. Results of the dissertation study revealed that all participants managed medications and related needs regardless of level of health literacy. A deciding factor appeared to be consistent case management received from a community support and wellness program. Older adults acquire skills for self-care and management of chronic illness over time. Perhaps health literacy level as measured by the TOFHLA is but one measure of independence.

### *Question 2*

What are the barriers to accurate daily self-administration of five or more prescribed medications?

During data analysis, issues or barriers were identified related to participants' ability to daily self-manage five or more prescription medications. All participants (regardless of health literacy level) identified concern over the lack of provider-patient communication during clinic or office visits. All remarked that their primary care provider fails to allocate sufficient time to answer questions; however, other professionals and case managers often answered their medication and self-care questions. A second concern common among study participants was clinicians' use of medical jargon. Four participants indicated asking their physicians to use "plain" language when discussing health issues.

In addition, the participants of this study all noted that physicians seldom allocate time to explain medication management, potential side effects and options to choose generic substitutions. This was true across levels of health literacy. Patient concerns led to delayed self-administration of their medications. Participants reported they would wait until the nurse or SenioRx caseworker explained medication instructions prior to purchasing or taking the medication. There are possible health consequences of delaying treatment due to patient confusion or misunderstanding.

A future barrier mentioned by study participants was transportation to and from their physicians' offices, pharmacies, CRCs, and other places they may need to go. Although lack of transportation was not an immediate problem, older adults across the three cases expressed worry about future transportation needs. At present, friends, family, CRC vans, and taxis are used to address needs.

In comparison to current research, the findings from this study are congruent with findings from the Alabama Lifespan Respite Resource Network Survey of Family



Caregivers, (Geiger & O’Neal, 2010). Six-hundred and ninety-three Alabama caregivers ranked transportation as “very difficult” for aging adults with chronic conditions and persons with disabilities under their care.

### *Question 3*

What are the facilitators for accurate daily self-administration of five or more prescribed medications?

The primary facilitator identified by this study was the SAFE SenioRx Wellness Program and dedicated caseworkers who assist older adults to understand their health care needs (including procurement of prescribed medications). The SenioRx program has many levels of support and the caseworkers work diligently to find resources to assist community-dwelling older adults. Sometimes this means that the caseworkers try new and innovative pathways to find funding, promote education, and assist with day-to-day problems such as transportation and medication financial assistance.

An important component of the SenioRx Program is the five community resource centers (CRCs) located within the community where this study was conducted. The CRCs were the venues where SenioRx participants gather for daily balanced hot meals as well as educational programs. Educational sessions planned by the caseworkers feature content about nutrition, prescription medications, and diagnosis and prevention of chronic illness including heart disease. When questioned about the CRCs, the participants from every case were very enthusiastic about their experiences, sharing various stories with the researcher about personal feelings, experiences and about their time spent at the CRC.

The second resource most often mentioned by study participants was the pharmacies and pharmacists. Through the coordination of SAFE caseworkers, the pharmacies in the community provide individualized counseling to the SenioRx participants to make sure they understand how to take medications. Additionally, participants are informed of risks and potential threats of poor medication management. All participants of the study praised their pharmacy. The pharmacists also provided each of the SenioRx participants with additional educational material enabling them to fully understand their medications.

A third resource reported by the majority of the participants of this study was the registered nurse and nurse practitioner who help them to understand their health care needs and prescribed medications. Participants agreed they felt comfortable speaking with the nurses and never hesitated to call his or her doctor's office (or nurse) should a concern or question arise once they returned home. Additionally, most reported the nurse was easier to get in touch with than was the physician. Several nurses within the community work for the hospital and volunteer for the SenioRx Program, increasing continuity of care for the participants of this study. The local hospital was also mentioned by most participants as a helpful resource for medication management.

The fourth, but seemingly most important resource, to assist with facilitation of accurate daily self-administration of prescribed medications was "family and friends." All participants noted that without family and friends to assist them with transportation, finances, and understanding of his or her prescribed medications they might not be as successful with self-management of the medications prescribed for them. Each

participant enthusiastically described relationships with friends and family during the in-home interview. Several proudly shared family photos with the researcher.

Results of the dissertation study may be compared to data from a nationwide survey of individuals over the age of 18 who receive at least one medical, education, or social service. Data indicates consumer outcomes for individuals with disabilities including mental illness, neurological problems, vision and hearing disorders. Among 451 Alabamians, 83% of those residing in communities have met with a service coordinator to assist with daily management of health and wellness needs. Further 87% reported service coordinators ask about their “wants” and help them to “get what they want.” Ninety-three percent reported service coordinators “helped them to make their own service plan (Human Services Research Institute, 2011).”

One hundred and thirty eight Alabama service providers indicated level of assistance with life skills provided during caregiver respite to an individual with a disability or chronic illness. *Complete assistance* was the most frequent response (39%-56%) across nine categories of life skills (e.g., bathing and hand washing, toileting, dressing, taking medication, cooking, feeding, oral hygiene, transportation, and communication). Further, 85 survey respondents prioritized important training needs in order to provide caregiver respite in Alabama. First priorities for training were: behavior management/modification; first aid and CPR; bathing and lifting; effective communication with families and individual with disability or chronic illness; handling forms, documents and legal issues; managing emotions/upset feelings; dementia/Alzheimer’s Disease; specific procedures to serve individuals with disabilities,

such as handling equipment and implementing agency rules, such as tube feeding; and medication management (Geiger & O’Neal, 2010).

#### *Question 4*

How do data collected by the PMAR differ from the participant demonstration of medication self-administration during a planned home observation (i.e. name of drug, dosages, administration form, drug classification, and reasons for use)?

Remarkably, very few mistakes were discovered during participant medication self-administration demonstration conducted within residences. Examples of mistakes included taking medications with or without food improperly and errors of timing. Participants verified how, what, when, where, and why they use their daily prescribed medications. The recorded information on the PMAR matched the demonstration with 100% accuracy during each in-home session. Each medication was properly identified by the participants. Occasionally, participants of the study became confused with the name of the prescription medication when generic medications were substituted for brand name medications. Often they used plain language to describe why that medication was prescribed for them. For instance, medication prescribed to help pump blood through the cardiovascular system was described as needed “for my heart.” Another example was medication to regulate insulin, which was referred to as for “high blood” or “sugar,” rather than being named a hypoglycemic medication.

*Question 5*

How do records on file at SAFE for the SenioRx Medication Wellness Program participants differ from participants' self-reported PMAR data?

Files kept at SAFE for the SenioRx Program were accurate up to the date of last visit by caseworkers for in-home assessments of program participants. The researcher identified records in need of updating. The caseworkers noted this as a concern for them and discussed with one another how they could keep the SenioRx Wellness files current at all times.

*Question 6*

How does the level of self-efficacy explain the number of reported adverse drug events?

Medication self-efficacy was determined using the Medication Adherence Self-Efficacy Scale (MASES). Self-efficacy describes the confidence level of each participant to successfully manage a medication regimen (Gregson et al., 2001). Bandura (1985) defined self-efficacy as “an individual’s personal belief regarding their capabilities to carry out a specific task in order to achieve a desired outcome” (p. 1176).

Developed by Ogedegbe, Mancuso, Allegrante, and Charlson (2003), the MASES study set the threshold for the item-to-total correlation coefficient as 0.5. Researchers concluded that the scale is useful to identify patients' low self-efficacy for adherence to prescription medications. Since its development, the MASES has been widely used by other researchers (Veazie & Cai, 2005; Makoul, & Clayman, 2006; Schroeder et al., 2006; Zeller, Schroeder, & Peters, 2008; Krousel-Wood et al., 2009;

Gozum, & Hacıhasanoglu, 2009; Ogedegbe et al., 2007; Berna et al., 2008; & Johnson, Mackinnon).

For this dissertation study, the MASES was administered toward the end of the in-home interview. Participants were allowed to elaborate on questions asked of them to determine their self-efficacy as it related to daily self-administration of prescribed medications. All participants of this study scored very close to “3,” which meant that they were at the upper end of the self-efficacy scale. This finding could have been why the majority of the participants from this group felt empowered and able to self-advocate during interactions with their physician, nurse or pharmacist. Additionally, individuals with a strong-self-efficacy belief for medication management may show higher confidence to manage without assistance from others.

#### *Question 7*

What role do economic constraints play in accurate self-management of five or more daily prescribed medications?

All participants of this study reported financial concerns related to health care provider expenses, medications, transportation, and, if needed, hospitalization. Most notably, all of the participants reported they used generic medications whenever possible to save money. They felt confident in the pharmacist’s ability to explain to them what to expect when choosing generics including changes in medication appearance (size, shape, color).

Another resource reported by participants was the SenioRx assistance they received to manage their health care insurance. The caseworkers for the SenioRx

Program counsel each participant to explain the benefits offered to them through the insurance company of their choice, how they can maximize coverage, as well as how they can save money through various programs offered by each insurance company.

### *Question 8*

How many constructs of the SEM were useful to explain the number of ADEs experienced by participants during the 12 months preceding this study?

All levels of the SEM were useful to explain the successful daily self-administration of prescribed medication, resulting in no ADEs reported by participants of this study. Details of each level are described below.

### Conceptual Framework

As covered in Chapter Two of this study, the SEM emerged in the mid 1970s through the scholarship of Urie Bronfenbrenner (1977, 1979). Bronfenbrenner's ecological systems theory distinguished four levels of influence for change: intercultural, community, organization, and intrapersonal or individual. Used for this study was the model as designed by McLeroy and colleagues (1988) specifying five levels as influential to health promotion: (a) intrapersonal or individual, (b) interpersonal, (c) institutional or organizational, (d) community, and (e) public policy.

Some older adults may not be able to initiate changes in self-care without support and assistance. Change across multiple levels (person, behavior, and environment) may improve patient outcomes (JCAHO, 2007) including enhanced health literacy and accurate self-management of medications (Hohn, 1997; Schwartzberg et al., 2005).

Throughout this study, the researcher compared facilitators deemed important to accurate daily self-management of prescribed medications. Findings suggest that the influence of these support systems within the community where SAFE operates played an important role in keeping the participants of this study healthy (through proper self-management of prescribed medication).

Within the framework of the study, the researcher examined characteristics of the community-dwelling older adult, participants' interactions with health care providers, family, friends and other supports and SAFE case managers. Visiting participants' homes for demonstration of medication self-administration was an important strategy for data collection. The SAFE executive director and caseworkers receive reports of inaccurate medication management, a dangerous situation. Case managers were able to intervene in each instance preventing adverse health outcomes. Study findings interpreted within the levels of the SEM are summarized below.

### *Individual Level*

The individual characteristics that influence behavior such as knowledge, attitudes, beliefs, and psychological, cognitive, and personality traits are represented at the intrapersonal level and may affect receptivity to health information (Gregson et al., 2001; McLeroy et al., 1988). Older adults may benefit from one-on-one assistance from a health care provider allowing for repetition of the prescribed drug regime for improved medication management (Kilker, 2000; Simon & Gurwitz, 2003). This includes case management or "wrap around" health services.



The high level of self-efficacy for daily self-administration of medication among each participant was an important study finding. Additionally, regular assistance received from the SenioRx caseworkers, pharmacists, and nurses was perceived as invaluable by study participants, enabling each to self-administer daily medications. Expansion of health literacy training among health professionals, caregivers of older adults, and senior citizens may enhance understanding of self-care including medication management (Archambault, 2003).

### *Interpersonal Level*

Influences from primary social referents, family, peers, and co-workers comprise the second or interpersonal level of the SEM (Moore, 2008). Interpersonal influences may exert positive, neutral, or negative influences on health outcomes (Glanz, 2002). Behavior is the result of individual knowledge and beliefs, and influences from associates across different environments (workplace, school, faith community, residence) (McLeroy et al., 2003). A review of professional literature supports the active involvement of others to enhance level of health literacy (Kim et al., 2004).

Specified within the planning document *Healthy People 2020* is the aim of increasing population health literacy through health care provider action to (a) present easy-to-understand instructions for self-management of illness and chronic conditions (an aim consistent with the actions of health care providers and SAFE case managers in this study); (b) ask patients to describe aloud how to follow self-care instructions (also accomplished through the SenioRx Program); (c) assist patients to complete insurance and other forms; and (d) practice active communication skills (study participants praised

nurses for spending time with them to ensure understanding). In addition, U.S. Department of Health and Human Services asked health care providers to (e) clearly explain health information using plain language (nurses, pharmacists and SAFE caseworkers demonstrated this behavior); (f) respect patients' concerns and listen to their needs; (g) allocate sufficient time during the patient encounter (this was not the case for all study participants; however, others within the support system filled this gap); and (h) actively involve patients in decisions about their health care as much as they wanted.

### *Institutional or Organizational Level*

The organizational level includes factors that influence group behavior across private, public, and nonprofit sectors. In recent years, patients' contact time with their health care provider has been restricted by rules of health insurers to contain costs and maximize reimbursement (Foreman, 2005; Moran, 2001; Weijer & Emanuel, 2000). Within the study community, self-management of prescribed medication(s) was not always accomplished through organizational support services at the time of the health care visit, but rather after the health care provider meets with patients, allowing for an in-depth educational session with the nurse and possible follow-up with the SenioRx caseworker and pharmacist.

Anticipated funding restrictions within the state and nations may negatively affect future organizational resources to improve low health literacy and self-care among the aging population. SAFE received multiple federal, state, and local grants to implement senior assistance programs such as the SenioRx Program. Additionally, SAFE works with pharmaceutical companies to pay for medications when participants of programs are

unable to afford the medications. The SenioRx Program aggressively seeks to make certain participants are able to take advantage of every benefit and opportunity offered to them by participating health insurance companies.

### *Community Level*

Comprised of social networks, norms, and standards that exist formally or informally, the community level fosters partnerships among individuals, groups, and organizations (Green & Kreuter, 2004; Gregson et al., 2001). Residents of a community can actively participate and contribute to solving health and social problems (Green & Kreuter, 2004). Community-wide partnerships may result in policy changes necessary to implement an intervention to improve self-management of prescribed medications.

Implementation of this level is evident in the study community as shown by many contributions of financial and human resources to SAFE and the SenioRx Program. The Chamber of Commerce and other prominent community organizations have made SAFE a priority for community funding and volunteer efforts. In addition, an active board of directors supports SAFE's success.

A notable resource problem in the community of interest is recruitment of physicians and related providers to treat older adults. As noted, many of the participants reported dissatisfaction with time spent with physicians during office visits. Unfortunately, for many rural communities this is a growing problem due to the lack of primary care providers across America (Lakhan & Laird, 2009). Thankfully, SAFE caseworkers assist individuals to learn more about their health care conditions and empower patients to ask questions of the nurses.

Through collaboration between the community agencies, nurses, and the local hospital, this level of support does exist for this community; however, improvements are needed to maximize patients' understanding of self-management techniques. Possibilities include the utilization of trained health educators such as certified health education specialists, nurse educators and nurse practitioners within the primary care model. The addition of a specific educator within physician offices for the purpose of better provider-patient communication could greatly enhance the knowledge of aging patients as it relates to prescribing regimen or proper self-administration of prescribed medications.

#### *Social Structure, Policy, and Systems*

The broadest level of influence in the SEM is that of social structure, policy, and systems (Stokols, 1996). Guided by local, state, and federal policies, this level provides support to organizational or institutional behavior (Gregson et al., 2001; McLeroy et al., 1988). Federal support is needed to address difficulties faced by community-dwelling older adults with low health literacy who must self-manage multiple medications (Parker et al., 2003). To improve health literacy among the aging population, "policymakers and leaders outside of the health sector must be aware of the critical elements that contribute to health illiteracy," thereby "influencing social, economic and environmental determinants" (Ratzan, 2001, p. 208).

In 2010, the Department of Health and Human Services, Office of Disease Prevention and Health Promotion, released a *National Action Plan to Improve Health Literacy, 2010* specifying seven recommendations for change. The community of interest for this study has implemented many of these recommendations. The plan emphasizes

that (1) everyone has the right to health information that helps them make educated decisions, and (2) health services should be delivered in a logical manner to enhance quality and length of life. Six of the seven recommendations to improve health literacy are pertinent to results of this study:

1. Develop and disseminate health and safety information that is accurate, accessible, and actionable;
2. Promote changes in the health care system that improve health information, communication, informed decision making, and access to health services;
3. Support and expand local efforts to provide adult education, English language instruction, and culturally and linguistically appropriate health information services in the community;
4. Build partnerships, develop guidance, and change policies;
5. Increase basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy;
6. Increase the dissemination and use of evidence-based health literacy practices and interventions.

### Implications

The accuracy with which participants were able to self-administer their prescribed medications was the most important outcome of this study. Due to consistent case management and social support, participants were able to eliminate ADEs during the previous 12 months prior to this study. Participants who were eligible for this study were by nature at high risk for ADEs because of age and the number of prescribed medications

for self-administration each day. Other factors that may have increased risk of ADEs included length of time that had elapsed since each had completed formal education and TOFHLA scores. Six of the nine participants ranked at the marginal to low health literacy level (Conroy, 2000).

As noted in Chapter Two, failure to properly administer multiple prescription medications can lead to ADEs requiring hospitalization, recurrent illness, and may lead to death. Any of these events can perpetuate the cycle of admissions, discharge, and hospital admission, thereby increasing health care costs, morbidity and mortality. Multiple sources of data enabled the researcher to examine the accuracy of self-administration of prescribed medications within and across cases, confirming participants' self-reports and researchers' observations. During data integration, the researcher identified similarities and differences across the three cases. Regardless of age, health literacy level, or number of daily prescribed medications, there were no differences among participants or cases in their knowledge of: (a) medication names, route of administration, and dosage; (b) the purpose for using the medication; (c) the time and frequency of administration; (d) beginning and ending dates of treatment; (e) prescriber's name. All reported no occurrence of ADE during the 12 months prior to the study. Two participants were unsure of side effects versus ADEs associated with each medication. At least one participant from each case during Phase II data collection reported they had experienced an ADE during the previous 12 months. When the researcher reviewed what was reported on the PMAR from Phase I of the study, the findings were inconsistent. All self-reported "no" ADEs on the PMAR.

Upon further discussion with participants who reported ADEs during in-home

interviews, it was revealed that participants' accounts were consistent with side effects and not ADEs. Review of pharmaceutical manufacturer's information for each medication confirmed the symptoms the participant(s) described were side effects and not ADEs.

Retrospectively, the researcher has reviewed the data to explore what made the difference in accuracy of daily self-administration of prescription medication for this group of older adults. The researcher discovered multiple levels of support were provided to participants from individuals, agencies, health providers, family and friends. Over a decade ago, SAFE began as a small community agency with little more than a building and a few programs offered to improve family cohesion. Since that time, the commitment of the executive director and her staff has served as a catalyst for countless programs for that area, many of which have turned lives around. In terms of economic cost to the community, it would be difficult to imagine life without SAFE for those who utilize its helpful services.

Within the U.S., an estimated \$238 billion of unnecessary costs per year related to low health literacy have been added to an already overburdened health care system. Perhaps policy makers and funders should support programs aimed at reducing unnecessary health costs through interventions specifically to improve health literacy. Monies are needed to reimburse costs for patient educators (either nurse or health education specialist) within physician offices. Imagine benefits from teaching self-care and wellness behaviors, rather than trying to "fix" a patient after years of neglecting his or her health care.

### Recommendations for Future Research

Based on the findings of this study, the recommendations for future research are as follows:

1. Conduct further research enrolling a larger number of participants across multiple states to explore how health literacy is related to medication management among older adults.
2. Examine potential revision of the Test of Functional Health Literacy of Adults (TOFHLA) for use with older adults. Few participants of this study finished the test due to time constraints; however, completers had slightly higher levels of accuracy than indicated by test scores due to missing items. Test developers indicated that there was a statistically significant difference found in scores according to age, with older adults scoring less than younger adults (Williams et al., 1995). This supports the recommendation for additional testing of this tool specifically for the older population.
3. Explore effectiveness of programs such as SenioRx, which provide case management assistance in different communities.
4. Conduct research to create a standardized medication record, possibly a portable electronic record, which may be altered easily when medications are changed.
5. Validate senior support programs currently used and widely diffuse methods; a systematic review found few effective programs for persons with low literacy including those managing multiple medications (AHRQ, 2011).



6. Examine how theory is best used to guide program design and implementation to assist low health-literate individuals and reduce occurrence of health care disparities.
7. Explain differences in level of self-efficacy for medication management and related self-care among different groups of older adults.

### Summary

This study revealed that community-dwelling older adults ages 60 to 74 who daily self-manage five or more medications demonstrated a high level of accuracy and reported no ADE during the 12 months prior to data collection for this study. In addition, results indicated that multiple levels of support enhanced self-efficacy among all older adults regardless of health literacy level, enabling accurate daily self-management of five or more prescribed medications.

## REFERENCES

- Adair, J. G. (1984). The Hawthorne effect: A reconsideration of the methodological artifact. *Journal of Applied Psychology*, 69(2), 334-345.
- Aday, L. A. (1994). Health status of vulnerable populations. *Annual Review of Public Health*, 15, 487-509.
- Agency for Healthcare Research and Quality. (2010, December). Advancing excellence in health care (AHRQ Pub. No. 11-P006). Rockville, MD: Author.  
<http://www.ahrq.gov/about/profile.pdf>
- American Association of Retired Persons. (n.d.). *My personal medication record*. Retrieved October 2, 2008, from <http://www.ahrq.gov/about/profile.htm>.
- American Medical Association Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs. (1999). Health literacy: Report of the Council on Scientific Affairs. *Journal of American Medical Association*, 281(6), 552-557.
- American Pharmacists Association (n. d.). Code of ethics for pharmacists. Available at: [http://www.pharmacist.com/AM/Template.cfm?Section=Code\\_of\\_Ethics\\_for\\_Pharmacists&Template=/CM/HTMLDisplay.cfm&ContentID=5420](http://www.pharmacist.com/AM/Template.cfm?Section=Code_of_Ethics_for_Pharmacists&Template=/CM/HTMLDisplay.cfm&ContentID=5420). Accessed September 7, 2007.
- Andrus, M. R., & Roth, M. T. (2002). Health literacy: A review. *Pharmacotherapy*, 22(3), 282-302.

- Agency for Healthcare Research and Quality (2011, March). Health literacy interventions and outcomes: An updated systematic review. *Evidence Report/Technology Assessment, Number 199*. Rockville, MD: Author.
- Archambault, D. (2003). Health literacy: Understanding health information. *Community Health Forum, 5*(4), 35-37.
- Baker, D. W., Parker, R. M., Williams, M. V., & Clark, W. S. (1998). Health literacy and risk of hospital admission. *Journal of General Internal Medicine, 13*(12), 791-798.
- Baker, D. W., Parker, R. M., Williams, M. V., Pitkin, K., Parikh, N. S., & Coates, W. (1996). The health care experience of patients with low literacy. *Archives of Family Medicine, 5*(6), 329-334.
- Baker, D. W., Williams, M. V., Parker, R. M., Gazmarian, J. A., & Nurss, J. (1999). Development of a brief test to measure functional health literacy. *Patient Education and Counseling, 38*(1), 33-42.
- Bandura, A. (1985). Human agency in social cognitive theory. *American Psychologist, 44*(9), 1175-1184.
- Barrett, S. E., Puryear, J. S., & Westpheling, K. (2008). Health literacy practices in primary care settings: Examples from the field. *The Commonwealth Fund* pub. no. 1093.
- Bartlett, E. E., Grayson, M., Barker, R., Levine, D. M., Golden, A., & Libber, S. (1984). The effects of physician communication skills on patient satisfaction, recall, and adherence. *Journal of Chronic Diseases, 37*, 755-764.

- Bass, P. F., III, Wilson, J. F., Griffith, C. H., & Barnett, D. R. (2002). Residents' ability to identify patients with poor literacy skills. *Academic Medicine*, 77(10), 1039-1041.
- Bergman-Evans, B., Adams, S., & Titler, M. G. (2006). Evidence-based protocol: Improving medication management for older adult clients. *Journal of Gerontological Nursing*, 32(7), 6-14.
- Berkman, N. D., DeWalt, D. A., Pignone, M. P., Sheridan, S. L., Lohr, K. N., & Lux, L., et. al. (2004). Literacy and health outcomes. *Evidence Report/Technology Assessment No. 87* (Prepared by RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016). AHRQ Publication No. 04-E007-2. Rockville, MD: Agency for Healthcare Research and Quality.
- Berna, G. M., Sol, Y. V., Jaap, J. V., Bertine, M. B., Goessens, M. B., & Visseren, F. L., (2008). The role of self-efficacy in vascular risk factor management: A randomized controlled trial. *Patient Education and Counseling*, 71(2), 191-197.
- Bernhardt, J. M., & Cameron, K. A. (2003). Accessing, understanding, and applying health communication messages: The challenge of health literacy. In T. L. Thompson, A. M. Dorsey, K. I. Miller, & R. Parrott (Eds.), *Handbook of health communication* (pp. 583-608). Mahwah, NJ: Erlbaum.
- Braddock, C. H., III, Edwards, K. A., Hasenberg, N. M., Laidley, T. L., & Levinson, W. (1999). Informed decision making in outpatient practice: Time to get back to basics. *Journal of American Medical Association*, 282(24), 2313-2320.

Bronfenbrenner, U. (1977). Toward an experimental ecology of human development. *American Psychologist*, 32(7), 513-531.

Bronfenbrenner, U. (1979). *The ecology of human development*. Cambridge, MA: Harvard University Press.

Brown, E. R. (1991). Community action for health promotion: A strategy to empower individuals and communities. *International Journal of Health Services*, 2 (3)1, 441-456.

Brown, S. C., & Park, D. C. (2003). Theoretical models of cognitive aging and implications for translational research in medicine. *The Gerontologist*, 43(Suppl.), 57-67.

Byrne, M. (2001). Data analysis strategies for qualitative research - Research Corner *AORN Journal*, 74(6), 904-5.

Center for Health Care Strategies, Inc. (2005). *Who has health literacy problems? Fact Sheet #2*. Accessed on March 13, 2011. Available at [http://www.chcs.org/usr\\_doc/Health\\_Literacy\\_Fact\\_Sheets.pdf](http://www.chcs.org/usr_doc/Health_Literacy_Fact_Sheets.pdf).

Chewning, B., & Sleath, B. (1996). Medication decision-making and management: A client-centered model. *Social Science Medicine*, 42(3), 389-398.

Collins, K. S., Hughes, D. L., Doty, M. M., Ives, B. L., Edwards, J. N., & Tenny, K. (2002). Diverse communities, common concerns: Assessing health care quality for minority Americans: Findings from the Commonwealth Fund 2001 health care quality survey. New York: The Commonwealth Fund Pub No. 523.

- Committee on Health Literacy, Nielsen-Bohlman, L., Panzer, A. M., & Kindig, D. A. (Eds.). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
- Commonwealth Fund (2001). *2001 health care quality survey*. New York: Author.
- Conry, M. (2000). Polypharmacy: Pandora's medicine chest? *Geriatric Times*, 1(3).
- Cooper-Patrick, L., Gallo, J. J., Gonzales, J. J., Vu, H. T., Powe, N. R., & Nelson, C., (1999). Race, gender, and partnership in the patient-physician relationship. *Journal of American Medical Association*, 282(6), 583-589.
- Creswell, J. W. (1998). *Qualitative inquiry and research design: Choosing among five traditions*. Thousand Oaks, CA: Sage Publications.
- Creswell, J. W. (2002). *Educational research: Planning, conducting, and evaluating quantitative and qualitative research*. Upper Saddle Creek, NJ: Pearson Education.
- Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches* (3<sup>rd</sup> ed.). Thousand Oaks, CA: Sage.
- Creswell, J. W., & Miller, D. (2000). Determining validity in qualitative inquiry. *Theory into practice*, 39(3), 124-130.
- Creswell, J. W., & Plano Clark, V. I. (2007). *Designing and conducting mixed methods research*. Thousand Oaks, CA: Sage.
- Creswell, J. W., Plano Clark, V. I., Gutmann, M. L., & Hanson, W. E. (2003). *Advanced mixed methods research designs*. Thousand Oaks, CA: Sage.
- Creswell, J. W. & Tashakkori, A. (2007). Editorial: Developing Publishable Mixed Methods Manuscripts. *Journal of Mixed Methods Research*, 1(2), 107-111.

- Daniel, J. L., Hess, J., & Merson, M. (2005). Health and literacy. *The Change Agent*, 11, 3.
- Davis, T., Crouch, M., & Long, S. (1993). Rapid Estimate of Adult Literacy in Medicine. *Family Medicine*; 25:391-5.
- Davis, T. C., Wolf, M. S., Bass, P. F., Middlebrooks, M., Kennen, E., Baker, D. W., Bennett, C. L., Durazo-Arvizu, R., Bocchini, A., Savory, S., & Parker, R. M. (2006). Low literacy impairs comprehension of prescription drug warning labels. *Journal of General Internal Medicine*, 21(8), 847-851.
- Davis, T. C., Wolf, M. S., Bass, P. F., III, Thompson, J. A., Tilson, H. H., Neuberger, M., & Parker, R. M. (2006). Literacy and misunderstanding of prescription drug labels. *Annals of Internal Medicine*, 145, 887-894.
- Dennehy, C. E., Kishi, D. T., & Louie, C. (1996). Drug-related illness in emergency department patients. *American Journal of Health-System Pharmacy*, 53, 1422-1426.
- Department of Health and Human Services (2010). *Health People 2020* retrieved June, 5 2010 from <http://www.healthypeople.gov/hp2020/>.
- DeWalt, D. A., Berkman, N. D., Sheridan, S., Lohr, K. N., & Pignone, M. P. (2004). Literacy and health outcomes: A systematic review of the literature. *Journal of General Internal Medicine*, 19, 1228-1239.
- Doak, L. G., Doak, C. C., & Root, J. H. (Eds.). (2002). Pfizer principles for clear health communication: A handbook for creating patient education materials that enhance understanding and promote health outcomes. Potomac, MD: Pfizer Corp.

- E-Learning Council. (2008, October 22). *Workforce demographics drive workforce training*. Retrieved January 29, 2010, from <http://www.elearningcouncil.com/content/workforce-demographics-drive-workforce-training>.
- Eisen, M., Zellman, G. L., & McAlister, A. L. (1992). A health belief model-social learning theory approach to adolescents' fertility control: Findings from a controlled field trial. *Health Education & Behavior, 19*, 249-262.
- Elder, N. C., Jacobson, C. J., Zink, T., & Hasse, L. (2005). How experiencing preventable medical problems has changed patients' interactions with primary health care. *Annals of Family Medicine, 3*, 537-544.
- Emanuel, E. J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? *Journal of the American Medical Association, 283*, 2701-2711.
- Epstein, R. M., Alper, B. S., & Quill, T. E. (2004). Communicating evidence for participatory decision making. *Journal of American Medical Association, 291*, 2359-2366.
- Erzberger, C., & Kelle, U. (2003). Making inferences in mixed methods: The rules of integration. In: A. Tashakkori & C. Teddlie (Eds.), *Handbook on mixed methods in the behavioral sciences* (pp. 457-488). Thousand Oaks, CA: Sage Publications.
- Fang, M., Machtinger, E. L., Wang, F., & Schillinger, D. (2006). Health literacy and anticoagulation-related outcomes among patients taking warfarin. *Journal of General Internal Medicine, 21*(8), 841-846.



Foreman, J. (2005, September 19). Make the most of a doctor's visit. *The Boston Globe*.

Retrieved on April 18, 2009 from

<http://www.boston.com/yourlife/health/diseases/articles>

[/2005/09/19/make\\_the\\_most\\_of\\_a\\_doctors\\_visit](http://www.boston.com/yourlife/health/diseases/articles/2005/09/19/make_the_most_of_a_doctors_visit).

Gazmararian, K., Baker, D., Parker, R., & Blazer, D. G. (2000). A multivariate analysis of factors associated with depression: Evaluating the role of health literacy as a potential contributor. *Archives of Internal Medicine*, 160, 3307-3314.

Gazmararian, J. A., Kripilani, S., Miller, M. J., Echt, K.V., Ren, J., & Rask, K. (2006). Factors associated with medication refill adherence in cardiovascular-related diseases: A focus on health literacy. *Journal of General Internal Medicine*, 21, 1215-1221.

Geiger, B. F., & O'Neal, M. R. (2010). Alabama Lifespan Respite Resource Network: Survey of family caregivers results. Unpublished manuscript, Center for Educational Accountability, University of Alabama at Birmingham, Birmingham, Alabama.

Geiger, B. F. & O'Neal, M. R. (2010). *Alabama Respite Coalition. Results of a survey of agencies and respite service providers*. Unpublished manuscript, Center for Educational Accountability, University of Alabama at Birmingham, Birmingham, Alabama.

Generic Pharmaceutical Association (n. d.). Generic medicines: improving lives for less. Available at: [http://www.gphaonline.org/sites/default/files/GPhA\\_CE-broch.pdf](http://www.gphaonline.org/sites/default/files/GPhA_CE-broch.pdf). Accessed August 15, 2007.

- Gilcrest, V. J., McCord, G., Schrop, S. L., King, B. D., McCormick, K. F., & Oprandi, A. M., (2005). Physician activities during the time out of the examination room. *Annals of Family Medicine*, 3, 494-499.
- Glanz, K. (2002). Perspectives on using theory: Past, present, and future. In K. Glanz, B. K. Rimer, & F. M. Lewis (Eds.), *Health behavior and health education: Theory, research, and practice* (3rd ed., pp. 545-558). San Francisco: Jossey-Bass.
- Gozum, S., & Hacıhasanoglu, R. (2009). Reliability and validity of the Turkish adaptation of medication adherence self-efficacy scale in hypertensive patients. *European Journal of Cardiovascular Nursing*. 8 (2), 129-136.
- Gray, C. J., & Gardner, C. (September, 2009). Adverse drug events in the elderly: An ongoing problem *Journal of Managed Care Pharmacy*, 15(7), 568-571.  
<http://www.amcp.org>.
- Green, J. C., Caracelli, V. J., & Graham, W. F. (1989). Toward a conceptual framework for mixed-method evaluation designs. *Educational Evaluation and Policy Analysis*, 11, 255-274.
- Green, L. W., & Kreuter, M. W. (2004). *Health program planning: An educational and ecological approach* (4th ed.). New York: McGraw-Hill.
- Green, L. W., Richard, L., & Potvin, L. (1996). Ecological foundations of health promotion. *American Journal of Health Promotion*, 10, 270-281.

Gregson, J., Foerster, S. B., Orr, R., Jones, L., Benedict., J., & Clarke, B., (2001).

System, environmental, and policy changes: Using the social-ecological model as a framework for evaluating nutrition education and social marketing programs with low-income audiences. *Journal of Nutrition Education*, 33(Suppl. 1), S4-S15.

Gurwitz, J. H., Field, T. S., Harrold, L. R., Rothschild, J., Debellis, K., Seger, A. C., Cadoret, C., Fish, L. S., Garger, L., Kelleher, M., & Bates, D. W. (2003).

Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *Journal of the American Medical Association*, 289, 1107-1116.

Hatch, J. A. (2002). *Doing qualitative research in education settings*. Albany, NY: State University of New York Press.

Hauser, R. M., Edley, C. F., Koenig, J. A., & Elliott, S.W. (Eds.) (2005). Developing performance levels for the national adult literacy survey. In *Measuring literacy: Performance levels for adults* (pp. 50-86). Washington, DC: National Academies Press.

Healthy People 2020 (n. d.). *Health communication and health information technology objectives*. Accessed on April 7, 2011 from <http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/HealthCommunication.pdf>

Hochbaum, G. M., (1958). *Public participation in medical screening programs: A sociopsychological study* (Public Health Publication No. 572). Washington, D C: U.S. Government Printing Office.

- Hohn, M. D. (1997). Empowerment health education in adult literacy: A guide for public health and adult literacy practitioners, policy makers and funders. Lawrence, MA: National Institute for Literacy.
- Holladay, J. T., & Prager, T. C. (1991). Mean visual acuity. *American Journal of Ophthalmology*. 111, 372-373.
- Human Services Research Institute & National Association of State Directors of Developmental Disabilities Services. (2011, March). *Consumer outcomes: Phase XII final report, 2009-2010 data*. Cambridge, MA: Authors.
- Institute of Medicine. (2004). *Health literacy: A prescription to end confusion*. In: Nielsen-Bohlman, L., Panzer, A., & Kindig, D. A., eds. Washington, DC: National Academy Press.
- Johnson, B. & Christensen, L. (2008). Educational research quantitative, qualitative, and mixed approaches (3rd ed) Thousand Oaks, CA: Sage
- Johnson, G., Mackinnon, A., Kong, D. C., & Stewart, K. (2006). Development and validation of the Beliefs and Behaviour Questionnaire. *Patient Education and Counseling*, 64(1), 50-60.
- Joint Commission on Accreditation of Health Care Organizations. (2007). “What did the doctor say?” *Improving health literacy to protect patient safety. Health care at the crossroads reports* [series]. Oakbrook Terrace, IL: Author.
- Joint Commission on Accreditation of Health Care Organizations . (2009). *Sentinel event statistics-Updated through June 30, 2009*. Retrieved October 7, 2009, from <http://www.jointcommission.org/SentinelEvents/Statistics/>.

Joint Committee on National Health Education Standards (1995). *The national health education standards: Achieving health literacy*. Washington, DC: U.S.

Department of Education, Office of Educational Resources Information Center.

(ERIC Document Reproduction Service No. ED386418).

Joint Committee on National Health Education Standards (2007). *National health education standards: Achieving excellence* (2nd ed.) Atlanta, GA: American Cancer Society.

Jones, S. R., Torres, V., & Arminio, T. (2006) *Negotiating the complexities of qualitative research in higher education: Fundamental elements & issues*. N.Y.: Routledge, pp. 37-61.

Kaiser Family Foundation. (n.d.) (2009, January 6). National Health Care Expenditures per Capita. Retrieved March 12, 2009 from <http://facts.kff.org/chart.aspx?ch=203>.

Kaufman, D. W., Kelly, J. P., Rosenberg, L., Anderson, T. E., & Mitchell, A. A. (2002). Recent patterns of medication use in the ambulatory adult population of the United States. The Slone survey. *Journal of the American Medical Association*, 287, 337-344.

Kilker, K. (2000). *Considering Health Literacy*. Center for Medicare Education, 1(6), 1-8.

Kim, S., Love, F., Quistberg, D. A., & Shea, J. A. (2004). Association of health literacy with self-management behavior in patients with diabetes. *Diabetes Care*, 27 (12) 2980-2982.

- King, D. B., & Wertheimer, M. (2005). *Max Wertheimer & Gestalt theory*. New Brunswick, NJ: Transaction Publishers.
- Kretzer, E. K., & Larson, E. L. (1998). Behavioral interventions to improve infection control practices. *American Journal of Infection Control*, 26(3), 245-253.
- Kripalani, S., Henderson, L. E., Chiu, E. Y., Robertson, R., Kolm, P., & Jacobson, T. A. (2006). Predictors of medication self-management skill in a low-literacy population. *Journal of General Internal Medicine*, 21, 852-856.
- Kripalani, S., Robertson, R., Love-Ghaffari, M. H., Henderson, L. E., Praska, J., & Strawder, A., (2007). Development of an illustrated medication schedule as a low-literacy education tool. *Patient Education and Counseling*, 66, 368-377.
- Krisberg, K. (2008, February). APHA lends support to health literacy. *The Nation's Health*, p. 2.
- Krousel-Wood, M. A., Muntner, P., Islam, T., Morisky, D. E., & Webber, L. S. (2009). Barriers to and determinants of medication adherence in hypertension management: Perspective of the cohort study of medication adherence among older adults. *Medical Clinics of North America*, 93(3), 753-769.
- Kutner, M., Greenburg, E., & Baer, J. (2005). *A first look at the literacy of America's adults in the 21st century* (NCES 2006-470). U.S. Department of Education, National Center for Education Statistics. Washington, DC: U.S. Government Printing Office.
- Lakhan S. E., & Laird, C. (2009). Addressing the primary care physician shortage in an evolving medical workforce. *International Archives of Medicine*, 2(14).  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2686687/pdf/1755-7682-2-14.pdf>.

- Larsen, P. D., & Hoot-Martin, J. L. (1999). Polypharmacy and elderly patients. *AORN Journal*, 3, 619-628.
- Lilley, L. L., & Guanci, R. (1996). Polypharmacy in elders. *American Journal of Nursing*, 96(11), 12-14.
- Lincoln, Y., & Guba, E. (1985). *Naturalistic inquiry*. New York: Sage.
- Makoul, G., & Clayman, M. L. (2006). An integrative model of shared decision making in medical encounters. *Patient Education and Counseling*, 60(3), 301-312.
- Mancuso, C. A., & Rincon, M. (2006). Impact of health literacy on longitudinal asthma outcomes. *Journal of General Internal Medicine*, 21(8), 813-817.
- Matthews, T. L. & Sewell, J. C. (2002). *State official's guide to health literacy*. Lexington, KY: The Council of State Governments.
- McLeroy, K. R., Bibeau, D., Steckler, A., & Glanz, K. (1988). An ecological perspective on health promotion programs. *Health Education Quarterly*, 15, 351-377.
- McLeroy, K. R., Norton, B. L., Kegler, M. C., Burdine, N., & Sumaya, C. V. (2003). Community-based interventions. *The American Journal of Public Health*, 93(4), 529-533.
- McMillan & Schumacher, S. (1993). *Research in education: A conceptual introduction* (3<sup>rd</sup> ed). New York: HarperCollins College Publishers
- Merriam, S. B. (1998). *Qualitative Research and Case Study Applications in Education*. Revised and Expanded from "Case Study Research in Education." San Francisco, CA: Jossey-Bass Publishers .

Metlay, J. P., Cohen, A., Polsky, D., Kimmel, S. E., Koppel, R., & Hennessy, S. (2005).

Medication safety among older adults: Home-based practice patterns. *Journal of the American Geriatrics Society*, 53, 976-982.

Milken Institute. (2007). Executive summary and research findings an unhealthy

America: The economic burden of chronic disease charting a new course to save lives and increase productivity and economic growth retrieved from

[http://www.milkeninstitute.org/pdf/ES\\_ResearchFindings.pdf](http://www.milkeninstitute.org/pdf/ES_ResearchFindings.pdf) .

Moore, J. (2008). *Social-ecological model: Looking beyond the individual*. Retrieved

June, 13, 2008, from <http://www.balancedweightmanagement.com/TheSocio-Ecological Model.htm>.

Moran, M. (2001, January 17). *Are shorter doctors' visits just a myth?* WebMD.

Retrieved March 2, 2008 from

<http://www.medicinenet.com/script/main/art.asp?articlekey=51395>.

Morse, J. M. (2002b). Enhancing the usefulness of qualitative inquiry: Gaps, directions, and responsibilities. *Qualitative Health Research*, 12(10), 1419-1426.

Nash, A. (1997). Moving out of the classroom: Health education and social change. *The Change Agent*, 4, 10-18.

National Asthma Education Program, National Heart Lung and Blood Institute

(1991). Check your asthma IQ. *Journal of Allergy and Clinical Immunology*, 88, 468-469.

National Center for Education Statistics (1992). National adult literacy survey: A

*nationally representative and continuing assessment of English language literary skills of American adults*. Washington, DC: Author.



- National Center for Education Statistics (2003). *National assessment of adult literacy: A nationally representative and continuing assessment of English language literary skills of American Adults*. Washington, DC: Author.
- National Center for Health Statistics. (2000). *Healthy people 2010: Understanding and improving health*. Hyattsville, MD: U.S. Centers for Disease Control, Public Health Service.
- National Center for Health Statistics (2001). *Healthy people 2000 final review: National Health Promotion and Disease Prevention Objectives*. Hyattsville, MD: U.S. Centers for Disease Control, Public Health Service.
- National Coalition on Health Care (September, 2009). *Health Care Facts: Costs*. Retrieved on October 29, 2009 from <http://nchc.org/sites/default/files/resources/Fact%20Sheet%20-%20Cost.pdf>.
- National Institute for Literacy (1991). *Public Law 102-73, the National Literacy Act of 1991*. Retrieved on November 18, 2008 from <http://www.nifl.gov/public-law.html>
- National Survey on Health Literacy Initiatives (2003). *Health literacy tool kit*. Washington, DC: Author.
- Nielsen-Bohlman, L., Panzer, A. M., Institute of Medicine Committee on Health Literacy, & Kindig, D. A. (Eds). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
- Nurss, J., Parker, R., Williams, M., & Baker, D. (2001). *TOFHLA: Test of functional health literacy in adults* (Technical Report). Snow Camp, NC: Peppercorn Books & Press.

- Nutbeam, D. (1998). Health promotion glossary. *Health Promotion International*, 13, 349-364.
- Oetzel, J. G., Ting-Toomey, S., & Rinderle, S. (2006). Conflict communication in contexts: A social ecological perspective. In J. G. Oetzel & S. Ting-Toomey (Eds.), *The SAGE handbook of conflict communication: Integrating theory, research, and practice* (pp. 727-756). Thousand Oaks, CA: Sage.
- Ogedegbe, G., Mancuso, C. A., Allegrante, J. P., & Charlson, M. E. (2003). *Medication adherence self-efficacy scale*. Retrieved April 4, 2008, from <http://www.musc.edu/dfm/RCMAR/MedAdherSE.html>.
- Ogedegbe, G., Schoenthaler, A., Richardson, T., Lewis, L., Bulue, R., Espinosa, E., Spencer, J., Allegrante, J. P., & Charlson, M. E. (2007). An RCT of the effect of motivational interviewing on medication adherence in hypertensive African Americans: Rationale and design. *Contemporary Clinical Trials*, 28(2), 169-181.
- Ong, L. M. L., de Haes, J. C. J. M., Hoos, A. M., & Lammer, F. B. (1995). Doctor-patient communication: A review of the literature. *Social Science & Medicine*, 40, 903-918.
- Onwuegbuzie, A. J. (2003). Effect sizes in Qualitative Research: A prolegomenon. *Quality and Quantity*, 37, 393-409.
- Onwuegbuzie, A. J., & Johnson, R. B. (2006). The validity issue in mixed research. *Research in the Schools*, 13, 48-63.
- Paasche-Orlow, M. K., Cheng, D. M., Palepu, A., Meli, S., Faber, V., & Samet, J. H. (2006). Health literacy, antiretroviral adherence, and HIV-RNA suppression: A longitudinal perspective. *Journal of General Internal Medicine*, 21, 835-840.

- Paasche-Orlow, M. K., Parker, R. M., & Gazmararian, J. A., Nielsen-Bohlman, L. T., & Rudd, R. R. (2005). The prevalence of limited health literacy. *Journal of General Internal Medicine*, 20, 175-184.
- Parikh, N. S., Parker, R. M., Nurss, J. R., Baker, D. W., & Williams, M. V. (1996). Shame and health literacy: The unspoken connection. *Patient Education and Counseling*, 27, 33-39.
- Parker, R. M., Baker, D. W., Williams, M. V., & Nurss, J. R. (1995). The test of functional health literacy in adults (TOFHLA): A new instrument for measuring patients' literacy skills. *Journal of General Internal Medicine*, 10, 537-541.
- Parker, R. M., Ratzan, S. C., & Lurie, N. (2003). Health literacy: A policy challenge for advancing high-quality health care. *Health Affairs*, 22(4), 147-153.
- Parker, R. M., Williams, M. V., Baker, D. W., & Nurss, J. R. (1996). Literacy and contraception: Exploring the link. *Obstetrics and Gynecology*, 88(Suppl. 3), 72S-77S.
- Pincus, T., Esther, R., DeWalt, D. A., & Callahan, L. F. (1998). Social conditions and self-management are more powerful determinants of health than access to care. *Annals of Internal Medicine*, 129, 406-411.
- Prochaska, J. O., & DiClemente, C. C. (1983). Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology*, 51, 390-395.
- Quirk, P. A. (2000). Screening for literacy and readability: Implications for the advanced practice nurse. *Clinical Nurse Specialist*, 14, 26-32.

- Ratzan, S. C. (2001). Health literacy: Communication for the public good. *Health Promotion International*, 16, 207-214.
- Reinhard, S. C., Scala, M. A., & Stone, R. (2000). *Considering Health Literacy*. Washington DC: Center for Medicare Education.
- Rice, W. R. (1989). Analyzing tables of statistical tests. *Evolution*, 43(1), 223-225.
- Rosenstock, I. M. (1960). What research in motivation suggests for public health. *American Journal of Public Health*, 50, 295-301.
- Rosenstock, I. M. (1974). The health belief model and preventive health behavior. *Health Education Monographs*, 2, 354-386.
- Roter, D. L. (2000). The outpatient medical encounter and elderly patients. *Clinics in Geriatric Medicine*, 16, 95-107.
- Rudd, R., Kirsch, I., & Yamamoto, K. (2004). *Literacy and health in America: Policy information report*. Princeton, NJ: Educational Testing Service. (ERIC Document Reproduction Service No. ED486416).
- Safeer, R. S., & Keenan, J. (2005). Health literacy: The gap between physicians and patients. *American Family Physician*, 72, 463-468.
- SAS Institute (1985). *SAS User's Guide*. Version 5. Cary, NC: SAS Institute.
- Schillinger, D., Piette, J., Grumbach, K., Wang, F., Wilson, C., Daher, C., Leong-Grotz, K., Castro, C., & Bindman, A. B. (2003). Closing the loop: Physician communication with diabetic patients who have low health literacy. *Archives of Internal Medicine*, 163(1), 83-90.
- Schneider, E. L., & Guralnik, J. M. (1990). The Aging of America: Impact on health care cost. *Journal of the American Medical Association*. 263(17), 2335-2340.

- Schroeder, K., Fahey, T., Hay, A. D., Montgomery, A., & Peters, T. J. (2006). Adherence to antihypertensive medication assessed by self-report was associated with electronic monitoring compliance. *Journal of Clinical Epidemiology*, 59(6), 650-651.
- Schwartzberg, J. G., VanGeest, J. B., & Wang, C. C. (Eds.). (2005). *Understanding health literacy: Implications for medicine and public health*. Chicago: AMA Press.
- Selden, C. R., Zorn, M., Ratzan, S. C., & Parker, R.M. (2000). *National Library of Medicine current bibliographies in medicine: Health literacy*. (No. CBM 2000-1). Bethesda, MD.
- Sewell, J. (2003). Kids are the key: Elementary and secondary health literacy education. In *Health literacy tool kit*. Washington, DC: Author.
- Shay, K. (2004). The evolving impact on aging America and dental practices. *The Journal of Contemporary Dental Practice*. 5(4), 101-110.
- Shojania, K. G., Duncan, B. W., McDonald, K. M., & Wachter, R. M. (Eds.). (2001). *Making health care safer: A critical analysis of patient safety practices*. Rockville, MD: Agency for Healthcare Research and Quality.
- Simon, S. R., & Gurwitz, J. H. (2003). Drug therapy in the elderly: Improving quality and access. *Clinical Pharmacology & Therapeutics*, 73, 387-393.
- Simonds, S. K. (1974). Health education and social policy. *Health Education Monographs*, 2(Suppl. 1), 1-30.

- SOS Rx Senior Outpatient Medication Safety, Full Coalition Meeting. (September, 25, 2007, (n.d.). Retrieved December 1, 2010, from <http://www.nclnet.org/sosrx/membersonly/04022008/SOS%20Rx%20Sept%2025%20Meeting%20Report%20032808.pdf>).
- Soskolne, C. L. (1997). Ethical, social, and legal issues surrounding studies of susceptible populations and individuals. *Environmental Health Perspectives*, 105(Suppl. 4), 837-839.
- St. Leger, L. (2001). Schools, health literacy and public health: Possibilities and challenges. *Health Promotion International*, 16, 197-205.
- Stake, R. E. (1980). The case method inquiry in social inquiry. In H. Simons (Ed.), *Towards a science of the singular* (pp. 62-75). CARE Occasional Publications No. 10. Norwich, UK: Center for Applied Research in Education, University of East Anglia.
- Stake, R. E. (1995). *The Art of Case Study Research*. Thousand Oaks, CA: Sage.
- Stenner, A. J., Horabin, I., Smith, D. R., & Smith, M. (1998). *The Lexile Framework*. Durham, NC: Metametrics.
- Stewart, M., Makwarimba, E., Barnfather, A., Letourneau, N., & Neufeld, A. (2008). Researching reducing health disparities: Mixed-methods approaches. *Social Science & Medicine*, 66, 1406-1417.
- Stokols, D. (1996). Translating social ecological theory into guidelines for community health promotion. *American Journal for Health Promotion*, 10, 282-298.
- Stommel, M., & Wills, C. (2004). *Clinical research: Concepts and principles for advanced practice nurses*. Philadelphia: Lippincott Williams & Wilkins.

- Sudore, R. L., Yaffe, J., Satterfield, S., Harris, T. B., Mehta, K. M., Simonsick, E. M., Newman, A. B., Rosano, C., Rooks, R., Rubin, S. M., Ayonayon, H. N., & Schillinger, D. (2006). Limited literacy and mortality in the elderly: The health, aging, and body composition study. *Journal of General Internal Medicine*, 21, 806-812.
- Tashakkori, A., & Teddlie, C. (1998). *Mixed methodology: Combining qualitative and quantitative approaches* (Applied Social Research Methods, No. 46). Thousand Oaks, CA: Sage.
- Teddlie, C., & Tashakkori, A. (Eds.). (2009). *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences*. Thousand Oaks, CA: Sage.
- Thrall, D. T., & Bent, K. N. (2006). Assessing health literacy in veterans with diabetes. *Federal Practitioner*, 23(10), 9-11, 13, 16.
- Tobin, D. L., Wigal, J. K., Winder, J. A., Halroyd, K. A., & Creer, T. L. (1987). The Asthma Self-efficacy Scale. *Annals of Allergy*, 59, 273-277.
- U.S. Census Bureau, It's In Our Hands (2010). *Population Distribution and Change: 2000 to 2010*. Retrieved from <http://2010.census.gov/2010census/data/>.
- U.S. Census Bureau, American Fact Finder (2000). *Profile of General Demographic Characteristics: 2000*. Retrieved from <http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml>.

- U.S. Census Bureau, Population Division. (2009, May 14). Table 1: Annual estimates of the resident population by sex and five-year age groups for the United States: April 1, 2000 to July 1, 2008 [NC-EST2008-01]. Retrieved January 29, 2010, from <http://www.census.gov/popest/national/asrh/NC-EST2008-sa.html>.
- U.S. Census Bureau. (2006, October 12). *Nation's population to reach 300 million on Oct. 17*. Retrieved January 29, 2010, from <http://www.census.gov/Press-Release/www/releases/archives/population/007616.html>.
- U.S. Census Bureau. (2004). *Maps representing levels of education and states' rankings related to percentage of Americans age 65 and older*. Retrieved from [http://southnow.org/southnow-publications/special-reports/03.04\\_southern\\_population\\_changes.pdf](http://southnow.org/southnow-publications/special-reports/03.04_southern_population_changes.pdf).
- U.S. Department of Health and Human Services. (2010). *Healthy People: The road ahead*. Retrieved April 25, 2010, from <http://www.healthypeople.gov/hp2020/>.
- U.S. Department of Health and Human Services. (2010). *National action plan to improve health literacy*. Retrieved June 25, 2010 from <http://health.gov/communication/HLActionPlan/>.
- U. S. National Library of Medicine (NLM). (n.d.). *Health literacy*. Retrieved July 5, 2009, from <http://www.nlm.nih.gov/medlineplus/healthliteracy.html>.
- Veazie, P. J., & Cai, S. (2005). A connection between medication adherence, patient sense of uniqueness, and the personalization of information. *Medical Hypotheses*, 68 (2), 335-342.



- Vernon, J. A., Trujillo, A., Rosenbaum, S., & DeBuono, B. (2007). Low health literacy: Implications for national health policy. Retrieved October 27, 2008 from [http://www.gwumc.edu/sphhs/departments/healthpolicy/chsrp/downloads/LowHealthLiteracyreport10\\_4\\_07.pdf](http://www.gwumc.edu/sphhs/departments/healthpolicy/chsrp/downloads/LowHealthLiteracyreport10_4_07.pdf)
- Ware, J. E., Kosinski, M., Bayliss, M. S., McHorney, C. A., Rogers, W.H., & Raczek, A. (1995). Comparison of methods for scoring and statistical analysis of SF-36 Health Profile and summary measures: Summary of results from the Medical Outcomes Study. *Medical Care*, 33, 264-279.
- Weijer, C., & Emanuel, E. J. (2000). Protecting communities in biomedical research. *Science*, 289, 1142-1144.
- Weinreich, N. K. (1999). *Hands-on social marketing: A step-by-step guide*. Thousand Oaks, CA: Sage.
- Weiss, B. D. (2003). *Health literacy: A manual for clinicians*. Chicago: American Medical Association (AMA) Foundation.
- Wertheimer, M. (1959). *Productive thinking*. New York: Harper.
- Williams, M. V., Baker, D. W., Parker, R. M., & Nurss, J. R. (1998). Relationship of functional health literacy to patients' knowledge of their chronic disease: A study of patients with hypertension and diabetes. *Archives of Internal Medicine*, 158, 166-172.
- Williams, M. V., Davis, T., Parker, R. M., & Weiss, B. D. (2002). The role of health literacy in patient-physician communication. *Family Medicine*, 34, 382-389.

- Williams, M. V., Parker, R. M., Baker, R. W., Parikh, N. S., Pitkin K., Coates, W. C., & Nurss, J. R. (1995). Inadequate Functional Health Literacy among Patients at Two Public Hospitals. *Journal of The American Medical Association*, 274,1677-1682.
- Witmer, A., Seifer, S. D., Finocchio, L., Leslie, J., & O'Neil, E. H. (1995). Community health workers: Integral members of the health care work force. *American Journal of Public Health*, 85, 1055-1058.
- Wolf, M. S., Davis, T. C., Osborn, C. Y., Skripkauskas, S., Bennett, C. L., & Makoul, G. (2007). Literacy, self-efficacy, and HIV medication adherence. *Patient Education and Counseling*, 65, 253-260.
- Wolf, M. S., Gazmararian, J. A., & Baker, D. W. (2005). Health literacy and functional health status among older adults. *Archives of Internal Medicine*, 165, 1946-1952.
- Yesavage, J. A., & Brink, T. A. (1983). Development and validation of a Geriatric Depression Screening Scale: A preliminary report. *Psychiatric Resident*, 17, 37-49.
- Yin, R. K. (2003). *Case Study Research Design and Methods*. Thousand Oaks, California: Sage Publications.
- Zegar, S. L., Liang, K.Y., & Albert, P. S. (1988). Models for longitudinal data: A generalized estimating equation approach. *Biometrics*, 44, 1049-1060.
- Zagaria, M. E. (2006). Low health literacy: a safety concern among the elderly. *US Pharmacist*, 31, 28-34.

Zeller, A., Schroeder, K., & Peters, T. J. (2008). An adherence self-report questionnaire facilitated the differentiation between nonadherence and nonresponse to antihypertensive treatment, *61*(3), 282-288.

APPENDIX A  
DEMOGRAPHIC QUESTIONNAIRE

## Demographic Questionnaire (DQ)

Title of Research Study:

*Health Literacy: A Community  
Based Mixed Methods Study to  
Explore Self-Management of  
Prescription Medication Among  
Community Dwelling Older Adults*

1. Date for Phase I of Data  
Collection

\_\_\_\_/\_\_\_\_/\_\_\_\_

2. Participant's Birth date

\_\_\_\_/\_\_\_\_/\_\_\_\_

3. Gender

Male

Female

4. Highest grade completed in  
school : \_\_\_\_\_

5. Number of people you live with  
that you take care  
of \_\_\_\_\_

6. Do you take the drugs your  
doctor prescribes for you without  
help from anyone else?

☐ Yes

☐ No

7. Are you married?

☐ Yes

☐ No

8. Are you employed?

☐ Yes – If yes, how many hours a  
week do you work?

☐ No

9. Please check what kind of insurance you  
have

☐ Private- (Example Blue Cross Blue Shied)

☐ Public or Federally funded (Medicaid or  
Medicare)

☐ I do not have insurance

10. My annual yearly  
income is: (Optional)

☐ Less than \$15,000

☐ \$15,000 to \$25,000

☐ \$26,000 to \$40,000

☐ Greater than \$40,000

## APPENDIX B

## PERSONAL ADMINISTRATION MEDICATION RECORD

## Personal Administration Medication Record

# Personal Medication Administration Record (PMAR)



## My Personal Information

Name \_\_\_\_\_

Date of Birth \_\_\_\_\_

Phone Number \_\_\_\_\_

### ***Emergency Contact***

Name \_\_\_\_\_

Relationship \_\_\_\_\_

Phone \_\_\_\_\_

Number \_\_\_\_\_

### ***Primary Care Physician***

Name \_\_\_\_\_

Phone \_\_\_\_\_

Number \_\_\_\_\_

### ***Pharmacy/Drugstore***

Pharmacist \_\_\_\_\_

Phone Number \_\_\_\_\_

## How to Use This Guide

Use to keep track of your medications (including prescription drugs, over-the-counter drugs, herbal supplements, and vitamins.)

Share the information with your doctors and pharmacists at all visits.

Keep a printed copy always with you.

*You should review this record when*

- Starting or stopping a new medicine.
- Changing a dose.
- Visiting your doctor

**Last Updated:** \_\_\_\_\_

**How many Adverse Drug Events did you experience in the last 12 months? This could be anything that made you afraid that you took your medicine wrong.**

\_\_\_\_\_

# Other Physicians

Name of Physician

Specialty

Phone Number

Name of Physician

Specialty

Phone Number

Name of Physician

Specialty

Phone Number

# My Allergies

# My Medical Conditions

	What I'm taking	Form (pill, injection, liquid, patch, etc.)	Dosage	How Much and When	Use (regularly or occasionally)	Start/Stop Dates (1/5/05 - 3/5/05) (1/5/05 - ongoing)	Notes, Directions, Reasons for Use
* Be sure to include ALL prescription drugs over-the-counter drugs, vitamins, and herbal supplements.							
1							
2							



3							
---	--	--	--	--	--	--	--

What I'm taking	Form (pill, injection, liquid, patch, etc.)	Dosage	How Much and When	Use (regularly or occasionally)	Start/Stop Dates (1/5/05 - 3/5/05) (1/5/05 - ongoing)	Notes, Directions, Reasons for Use
* Be sure to include ALL prescription drugs over-the-counter drugs, vitamins, and herbal supplements.						
4						
5						
6						

	<b>What I'm taking</b>	<b>Form</b> (pill, injection, liquid, patch, etc.)	<b>Dosage</b>	<b>How Much and When</b>	<b>Use</b> (regularly or occasionally)	<b>Start/Stop Dates</b> (1/5/05 - 3/5/05) (1/5/05 - ongoing)	<b>Notes, Directions, Reasons for Use</b>
	* Be sure to include ALL prescription drugs over-the-counter drugs, vitamins, and herbal supplements.						
<b>7</b>							
<b>8</b>							

If you run out of spaces to list your drugs, please contact Ms. Margaret Morton,  
Executive Director at SAFE for extra sheets.  
Her phone number is 256-245-4343

APPENDIX C  
TEST OF FUNCTIONAL HEALTH LITERACY

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# TOFHLA

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Test of Functional Health Literacy in Adults

Joanne R. Nurss, Ph.D.  
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## Introduction

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Low functional health literacy has been determined to be a barrier to receiving adequate health care. The high prevalence of inadequate functional health literacy in adults means that health care providers must be aware of which patients are unable to read and understand health care information such as prescription labels and instructions for common medical practices. Researchers must take into account the possible effect of low functional health literacy on the results of their research. The Test of Functional Health Literacy in Adults (TOFHLA) was developed and validated to provide a measure of functional health literacy to be used by health care providers and researchers.

Included in this publication are the full-length Test of Functional Health Literacy in Adults (English and Spanish, 12-point and 14-point font versions), the Short Test of Functional Health Literacy in Adults (English and Spanish, 14-point font versions), and the Directions for Administration and Scoring and the Technical Manual for each. Also included is a bibliography of published articles concerning the development and validation of the instrument and research studies using it.

The following information will help you decide whether to use the full-length TOFHLA or the Short TOFHLA. Both are valid, reliable measures of functional health literacy. The full-length TOFHLA gives more information about the person's level of functioning, while the Short TOFHLA takes less time to administer.

Use the Short TOFHLA to:

- Screen patients in a medical clinic.
- Determine literacy levels for a health education program.
- Include literacy level as a descriptive variable in research.

Use the Full-length TOFHLA to:

- Include literacy as a dependent or independent variable in research.

You are welcome to make copies of the instruments for use in your research or testing program. Please cite the instrument and authors in any papers or publications resulting from your research.

## Directions For Administration & Scoring

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### I. Introduction

#### A. Background

A review of existing literacy assessment instruments shows that most concentrate on word recognition or narrative text comprehension skills. To answer the need for a more comprehensive evaluation of literacy, and a different conceptual framework for understanding the impact of low literacy on health status and/or health care delivery, the Literacy in Health Care Project developed the Test of Functional Health Literacy in Adults (TOFHLA). TOFHLA is a functional literacy assessment tool designed to evaluate adult literacy in the health care setting. The instrument measures functional literacy on the assumption that more than classroom reading ability is necessary to understand and negotiate the health care system adequately. TOFHLA is especially directed toward capturing numeracy and reading comprehension skills in the middle to low levels of literacy ability.

#### B. Special Considerations for Testing Low Literate Patients

An important part of health literacy features personal ability. Those with few or reduced skills often feel vulnerable when literacy inability is brought to their attention or to the attention of those around them. The force of this vulnerability is heightened by peer and social pressure. Consequently, low literate persons employ sophisticated mechanisms to conceal their literacy skill level and to prevent subsequent discovery or embarrassment, not to mention outright anger.

You very likely will encounter some of these low literacy behaviors:

- pointing to the text with a finger, while reading
- lifting the text closer to be read
- claiming "the light's not good"
- complaining about "having trouble seeing"
- expressing fatigue
- explaining that they don't have time
- stating that they don't think the material is interesting

When you encounter low literacy, soften the impact of unmasking by stating compassionately, "I am not here to embarrass you, frustrate you, or make you feel uncomfortable. I am willing to stop if you want to, but the information you can give me is very special and valued highly by all of us here. (PAUSE) May I continue?" Honor the dignity to which every human is entitled.

## II. Preliminary Procedures

### A. Informed Consent

Your hospital or health-care setting may require you to obtain a signed Informed Consent from the patient before testing may begin. Your institution may have a standard form and/or a procedure for developing one. The informed consent must be read orally verbatim. Paraphrasing is allowed, but not as a substitute for verbatim reading. When the respondent signs the consent, in effect he/she gives you permission to ask them questions, but they do not commit themselves to answering the questions. It is normal, however, for the respondent to answer all questions asked. Typically, the informed consent provides the respondent with information about procedures, risks and discomforts, expected benefits, withdrawal of consent, confidentiality and project disclaimer of financial liability in the event of injury. Manage the consent procedure with the same diligence you use to administer a data collection tool.

### B. Visual Acuity

Routinely, low literate persons will mask reading problems by saying that they cannot see the materials they are given. This test is intended to measure the basis of the claim objectively. We assume adequate visual acuity if vision tests at least at 20/50. This not only has precedence in previous research, but also is the acceptable limit for most state's driver licensing. If the respondents wear glasses, ask them to put them on for this test. If they do not have their glasses, administer the visual acuity test and follow directions given below.

Using a ruler that measures at least 14 inches, it is best to sit or stand beside the respondent and measure 14 inches along their line of vision from the cornea. You may find it comfortable to rest the ruler on the respondent's cheekbone. Place either a Snellen or Rosenbam hand-held vision card at the 14 inch mark perpendicular to the plane of respondent's face, hold the card steady and remove the ruler. (You may want to place the ruler just below the 20/50 line of test items on the card to cover lower lines and reduce visual distraction.) Ask the respondent to read the first group of numbers at the left of the card, just above the ruler. After this, point out to the respondent that one next sees three E's pointing in directions. Ask the respondent to tell you or show you the directions in which the E's are pointing. Finally, ask the respondent to read the final 3 letters on that line. A simple majority of correct responses on this assessment constitutes adequate visual acuity. If there is not a simple majority correct at this line, continue with lines of larger print until the respondent achieves a majority correct. If the respondent cannot read a simple majority correctly at the 20/100 line, then the patient should not be given the TOFHLA. If the respondent reads correctly at 20/50 or higher, then administer the large-print version of TOFHLA.

### C. Language Preference

If the patient's dominant language is Spanish, administer the Spanish-version of Short TOFHLA (STOFHLA-Spanish). However, it is important to remember this gives information on the patient's literacy in Spanish, not English. The health care facility needs to provide written material in Spanish as well as English for these patients.

## III. TOFHLA: Numeracy

### A. Description

A significant measurement of functional health literacy is the patient's ability to understand and act on numerical directions given by the health care provider or pharmacist. These test items reproduce real-life situations in receiving, following, and paying for medication plans. They are arranged in increasing levels of difficulty.

### B. Directions for Administration

TOFHLA: Numeracy uses a series of prompts to which the patient responds. These prompts consist of: prescription vials, an appointment slip, a chart describing eligibility for financial aid, and an example of results from a medical test. Since this is a 10-minute, timed assessment, arrange the prompts in order before beginning.

Hand the patient the prompt for each question, then read each question, and record responses. Begin the administration with the following scripted introduction:

These are directions you or someone else might be given at the hospital. Please read each direction to yourself. Then I will ask you some questions about what it means.

Follow item prefaces as printed. Two options are given that may be used in response to questions from the patient. No other options are allowable. Especially important, do not repeat "This is an example of...". As is usual with any assessment, you may follow each response with "Fine," "Thank You," or "Great." Questions about performance posed by the respondent should be answered with "You are doing very well."



### C. Special Directions for Uniform Administration

- |            |   |
|------------|---|
| Prompt 1.  | Be sure you read 7:00 a.m. and not "in the morning." Part of the test intention for this prompt is to determine if the patient understands that "a.m." means "morning."   |
| Prompt 2.  | Some respondents have difficulty separating directions for their own medication from the information printed on the vial label. In this case, repeat the first sentence from the general introduction, but do not tell the respondent that this is only an example. |
| Prompt 4.  | Some patients will give their own blood sugar status. All you can do is repeat the question. The respondent must figure out independently if the data provide the basis for the answer.   |
| Prompt 5.  | Some respondents will incorrectly give the date for their next appointment.   |
| Prompt 10. | The questions about financing health care will elicit some anecdotal information from the patient.  |

### D. Directions for Scoring TOFHLA: Numeracy

Some questions have peculiarities that require special attention when determining if an answer is correct. These are explained below.

- |           |  |
|-----------|--|
| Prompt 1. | Variations in lifestyles, therapeutic results of medications, and preferences among physicians necessitate accepting a range of responses as correct. Any time interval that is $\geq 3$ hours or $\leq 6$ hours is acceptable for all three questions about this prompt. This takes into account calculating dose intervals from a 12-hour through a 24-hour day.                 |
| Prompt 2. | "No" is the only correct answer to this question.  |
| Prompt 3. | Friday is correct for the first question, and Monday for the second. Since the intent of the question is to determine ability to calculate the third day correctly, however, it is possible to miss the first question and correctly answer the second. For example, answers of "Thursday" and "Sunday" would be scored incorrect for the first and correct for the second answer. |
| Prompt 4. | "No" is the only correct answer to this question. Some will be unable to separate their own situation from this question. Others will claim inability to read medical test results or will claim no knowledge of blood sugar. It is especially important not to lead the respondent on this item.  |

- Prompt 5. First, because patients will remember the weekday of an appointment, but not necessarily the correct weekday, the only correct response is "April 2." They may, of course, say "Thursday, April 2," but the answer must be specific about date. Second, since this is a functional test, it is acceptable to allow answers of "Third Floor" or "Diabetic Clinic" or both for the second question.
- Prompt 6. There are two acceptable answers: "All of them" or "40."
- Prompt 7. The correct answers are: 2, 12/28/92, and June. This prompt is similar to prompt 3 in that later items are scored correct if they represent a correct time interval from an earlier answer, even if the earlier answer is incorrect. Specifically, if the answer to the third part of item 7 is six months from the responded date of issue, then the third part is scored correct regardless of correctness on the second question. Any time in the month or just the name of the month is scored correct. If they give a year for June, however, the year must be correct, or the answer is scored incorrect.
- Prompt 8. Only one time is correct for the first question: 11:00. The second question may be answered correctly with 2-3:00, inclusively.
- Prompt 9. January is the only correct answer. Year is optional, but if given it must be correct or the answer is scored incorrect.
- Prompt 10. "No" is the only correct answer to this question.

#### E. Directions for Raw and Weighted Score Totals

**Numeracy Raw Score:** For each item circle the number one (1) for a correct response and the number zero (0) for incorrect. The respondent accumulates a simple sum of correct responses for a raw score. Total the number of correct (1) responses for a raw score from 0-17. Record on the back cover of the test booklet.

**Numeracy Weighted Score:** Use Table 1 on the next page to find the weighted score. Look up the patient's raw score in the left-hand column and record the weighted score in the appropriate box on the back cover of the test booklet. For example, a patient who earned a raw score of 10 will have a weighted score of 30.

Table 1. Numeracy Raw Scores / Weighted Scores Equivalent

Raw Scores	Weighted Scores
0	0
1	3
2	5
3	9
4	12
6	15
6	18
7	21
8	24
9	27
10	30
11	33
12	36
13	39
14	42
15	45
16	48
17	50

## IV. TOFHLA: Reading Comprehension

### A. Description

TOFHLA: Reading Comprehension tests a patient's ability to read passages using real materials from the health care setting. The test of 50 items uses a modified Cloze procedure. Passages are selected from instructions for preparation for an upper GI series, the patient rights and responsibilities section of a Medicaid application form, and a standard hospital informed consent. Readability levels on the Gunning Fog index are grades 4.3, 10.4, and 19.5, respectively. The three passages are ordered by increasing difficulty.

### B. Directions for Administration

It is important to present the reading comprehension section verbatim from the scripted introduction. Once introduced, fold the preceding pages back so that the respondent sees only the text passages. Turn one or two pages to show the respondent what you mean, and turn them in a way that only shows the text passages. If the respondent asks about the score columns, tell them that the boxes are for use in the office. Do not tell the respondent that they are score columns. This is a timed test and should be stopped at the end of 12 minutes. Do not inform the respondent in advance that the test is timed. When 12 minutes have elapsed, tell the respondent that "That should give us what we are looking for. Thank you for your cooperation." and remove the test materials.

### C. Directions for Scoring TOFHLA: Reading Comprehension

Score the results immediately on the spot, after the respondent has left. You will need to do six things to confirm and transcribe respondent data to appropriate boxes in the column of boxes appearing on the page opposite the text:

1. For each blank, circle the letter in the box corresponding to the letter selected by the respondent.
2. Compare the answers by page and variable name to the appropriate scoring key provided below.
3. In the score box, circle "1" for correct or "0" for incorrect for each blank.
4. Sum the correct answers for each page, and record the total at bottom of the page.

5. Sum the subtotals for all pages and record total on the last scoring column page as the Reading Comprehension Raw Score. Record in the appropriate box on the back cover of the test booklet.

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6. Sum the Weighted Numeracy Score and the Reading Comprehension Raw Score to obtain the patient's Total TOFHLA Score. Record in the appropriate box on the back cover of the test booklet.

TOFHLA: Reading Comprehension

Score Keys for Regular and Large Font (English)

## TOFHLA: Reading Comprehension Score Key

English: 12 Point Font

Passage A	Passage A	Passage B	Passage B	Passage C	Passage C
A1 a	A8 b	B17 c	B26 c	C37 b	C45 c
A2 b	A9 d	B18 a	B27 d	C38 d	C46 a
A3 d	A10 b	B19 d	B28 d	C39 a	C47 b
A4 a	A11 c	B20 b	B29 a	C40 c	C48 c
A5 c	A12 c	B21 d	B30 c	C41 b	C49 d
A6 a	A13 b	B22 c	B31 b	C42 b	C50 d
A7 c	A14 c	B23 a	B32 a	C43 d	
	A15 d	B24 d	B33 d	C44 a	
	A16 a	B25 b	B34 c		
			B35 b		
			B36 b		

## TOFHLA: Reading Comprehension Score Key

English: 14 Point Font

Passage A	Passage A	Passage A	Passage B	Passage B	Passage B	Passage C	Passage C
A1 a	A6 a	A12 c	B17 c	B24 d	B33 d	C37 b	C43 d
A2 b	A7 c	A13 b	B18 a	B25 b	B34 c	C38 d	C44 a
A3 d	A8 b	A14 c	B19 d	B26 c	B35 b	C39 a	C45 c
A4 a	A9 d	A15 d	B20 b	B27 d	B36 b	C40 c	C46 a
A5 c	A10 b	A16 a	B21 d	B28 d		C41 b	C47 b
	A11 c		B22 c	B29 a		C42 b	C48 c
			B23 a	B30 c			C49 d
				B31 b			C50 d
				B32 a			

TOFHLA: Reading Comprehension

Score Keys for Regular and Large Font (Spanish)

## TOFHLA: Reading Comprehension Score Key

Spanish: 12 Point Font

Passage A	Passage A	Passage B	Passage B	Passage C	Passage C
A1 b	A10 c	B17 a	B26 b	C37 a	C45 b
A2 a	A11 a	B18 b	B27 c	C38 d	C46 c
A3 c	A12 c	B19 a	B28 b	C39 c	C47 a
A4 c	A13 a	B20 b	B29 b	C40 a	C48 a
A5 a	A14 b	B21 a	B30 a	C41 b	C49 b
A6 d	A15 a	B22 d	B31 a	C42 c	C50 b
A7 c	A16 a	B23 c	B32 d	C43 a	
A8 c		B24 a	B33 c	C44 b	
A9 b		B25 c	B34 a		
			B35 d		
			B36 b		

## TOFHLA: Reading Comprehension Score Key

Spanish: 14 Point Font

Passage A	Passage A	Passage B	Passage B	Passage B	Passage C	Passage C
A1 b	A10 c	B17 a	B24 a	B34 a	C37 a	C43 a
A2 a	A11 a	B18 b	B25 c	B35 d	C38 d	C44 b
A3 c	A12 c	B19 a	B26 b	B36 b	C39 c	C45 b
A4 c	A13 a	B20 b	B27 c		C40 a	C46 c
A5 a	A14 b	B21 a	B28 b		C41 b	C47 a
A6 d	A15 a	B22 d	B29 b		C42 c	C48 a
A7 c	A16 a	B23 c	B30 a			C49 b
A8 c			B31 a			C50 b
A9 b			B32 d			
			B33 c			

## V. Functional Health Literacy

### A. Functional Correlation of TOFHLA Score

Look up the Total TOFHLA Score on the Table below. Record the patient's Functional Health Literacy Level on the back cover of the test booklet.

Level	TOFHLA Score	Functional Health Literacy Description
Inadequate Functional Health Literacy	0-59	Unable to read and interpret health texts.
Marginal Functional Health Literacy	60-74	Has difficulty reading and interpreting health texts.
Adequate Functional Health Literacy	75-100	Can read and interpret most health texts.

### B. Functional Interpretation of TOFHLA Scores

1. Patients who have **Adequate Functional Health Literacy** should be able to read, understand, and interpret most health texts.
2. Patients who have **Marginal or Inadequate Functional Health Literacy** will have difficulty reading, understanding, and interpreting most health materials. They are not going to be able to read and understand directions for their health care. They are likely to take their medications incorrectly or to fail to follow prescribed diets or treatment regimens. Modifications must be made in the health care setting in order to accommodate these persons. Recommendations include the following:
  - Suggest the person bring someone along with them to read and interpret health texts.
  - Suggest the person use someone at home to read and interpret health texts.
  - Rewrite health materials, including prescription bottle labels at a lower literacy level (below 5th grade readability level).
  - Use pictures, graphic directions, symbols to indicate directions, information, and procedures.
  - Have staff available to assist patients whose functional health literacy level is low.
  - Provide important information on audio-tape and/or video-tape.



Remember that persons with low functional health literacy often are ashamed of their literacy status. They will be unlikely to volunteer that they can not read or to ask for assistance. Low literacy does not mean low intelligence. Treat them with dignity and respect, offering literacy help but not talking down to them.

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Test of Functional Health Literacy in Adults

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Large Print Version  
English, 14 point font

Test of Functional Literacy in Adults  
**TOFHLA**  
 NUMERACY

HAND PATIENT PROMPT FOR EACH QUESTION. THEN READ EACH QUESTION, AND RECORD RESPONSES. STOP AT THE END OF 10 MINUTES.

PREFACE FIRST QUESTION WITH:

These are directions you or someone else might be given at the hospital. Please read each direction to yourself. I will ask you some questions about what it means.

PREFACE SUCCEEDING QUESTIONS WITH:

Have a look at this one OR Here is another direction you might be given.

PROMPT 1:

If you take your first tablet at 7:00 am, when should you take the next one?

N-1

(1) (0)

And the next one after that?

N-2

(1) (0)

What about the last one for the day, when should you take that one?

N-3

(1) (0)

PROMPT 2

Could you take that medicine on July 10, 1993?

N-4

(1) (0)

PROMPT 3:

If you began taking your medicine Tuesday, when should you take it next?

N-5

(1) (0)

What day would you take it after that?

N-6

(1) (0)

PROMPT 4

If this were your score, would your blood sugar be normal today?

N-7

(1) (0)

PROMPT 5:

When is your next appointment?

N-8

(1) (0)

Where should you go?

N-9

(1) (0)

PROMPT 6:  
How many of those pills should you take?

N-10
(1) (0)

PROMPT 7:  
How many times can you get that prescription refilled?

N-11
(1) (0)

When is the date of issue?

N-12
(1) (0)

When is six months from the date of issue?

N-13
(1) (0)

PROMPT 8:  
If you eat lunch at 12:00 noon, and you want to take this medicine before lunch, what time should you take it?

N-14
(1) (0)

If you forgot to take it before lunch, what time should you take it?

N-15
(1) (0)

PROMPT 9:  
Let's just say the last time you came to the clinic was on Jul 12, 1992.  
When would you have to reapply for financial aid?

N-16
(1) (0)

PROMPT 10:  
Let's say that after deductions, your monthly income and other resources are \$1,129. And, let's say you have 3 children. Would you have to pay for your care at that clinic?

N-17
(1) (0)

Total Raw Score

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COMMENTS

## Test of Functional Literacy in Adults

## TOFHLA

## READING COMPREHENSION

HAND PATIENT THE READING COMPREHENSION PASSAGES TO BE COMPLETED. FOLD BACK THE PAGE OPPOSITE THE TEXT SO THAT THE PATIENT SEES ONLY THE TEXT.

PREFACE THE READING COMPREHENSION EXERCISE WITH:

Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, circle the letter in front of that word, and go on to the next one. When you finish the page, turn the page and keep going until you finish all the pages.

STOP AT THE END OF 12 MINUTES

PASSAGE A: X-RAY PREPARATION

PASSAGE B: MEDICAID RIGHTS AND RESPONSIBILITIES

PASSAGE C: HOSPITAL CONSENT FORM

## PASSAGE A

---

Your doctor has sent you to have a \_\_\_\_\_ X-ray.

- a. stomach
- b. diabetes
- c. stitches
- d. germs

You must have an \_\_\_\_\_ stomach when you come for \_\_\_\_\_.

- a. asthma
- b. empty
- c. incest
- d. anemia

- a. is.
- b. am.
- c. if.
- d. it.

The X-ray will \_\_\_\_\_ from 1 to 3 \_\_\_\_\_ to do.

- a. take
- b. view
- c. talk
- d. look

- a. beds
- b. brains
- c. hours
- d. diets

## PASSAGE A

A1	(1)	(0)
a.		
b.		
c.		
d.		

A2	(1)	(0)	A3	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A4	(1)	(0)	A5	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total

## THE DAY BEFORE THE X-RAY.

For supper have only a \_\_\_\_\_ snack of fruit, \_\_\_\_\_ and jelly,

- |           |           |
|-----------|-----------|
| a. little | a. toes   |
| b. broth  | b. throat |
| c. attack | c. toast  |
| d. nausea | d. thigh  |

with coffee or tea.

After \_\_\_\_\_, you must not \_\_\_\_\_ or drink

- |              |          |
|--------------|----------|
| a. minute,   | a. easy  |
| b. midnight, | b. ate   |
| c. during,   | c. drank |
| d. before,   | d. eat   |

anything at \_\_\_\_\_ until after you have \_\_\_\_\_ the X-ray.

- |         |        |
|---------|--------|
| a. ill  | a. are |
| b. all  | b. has |
| c. each | c. had |
| d. any  | d. was |



A6	(1)	(0)	A7	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A8	(1)	(0)	A9	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

A10	(1)	(0)	A11	(1)	(0)
a.			a.		
b.			b.		
c.			c.		
d.			d.		

Sub-Total
-----------

---

A12 (1) (0)
-------------

- |    |
|----|
| a. |
| b. |
| c. |
| d. |

A13 (1) (0)
-------------

- |    |
|----|
| a. |
| b. |
| c. |
| d. |

A14 (1) (0)
-------------

- |    |
|----|
| a. |
| b. |
| c. |
| d. |

A15 (1) (0)
-------------

- |    |
|----|
| a. |
| b. |
| c. |
| d. |

A16 (1) (0)
-------------

- |    |
|----|
| a. |
| b. |
| c. |
| d. |

Sub-Total
-----------

## THE DAY OF THE X-RAY.

Do not eat \_\_\_\_\_.

- a. appointment.
- b. walk-in.
- c. breakfast.
- d. clinic.

Do not \_\_\_\_\_, even \_\_\_\_\_.

- |           |            |
|-----------|------------|
| a. drive, | a. heart.  |
| b. drink, | b. breath. |
| c. dress, | c. water.  |
| d. dose,  | d. cancer. |

If you have any \_\_\_\_\_, call the X-ray \_\_\_\_\_ at 616-4500.

- |               |               |
|---------------|---------------|
| a. answers,   | a. Department |
| b. exercises, | b. Sprain     |
| c. tracts,    | c. Pharmacy   |
| d. questions, | d. Toothache  |

B17 (1) (0)

- a.  
b.  
c.  
d.

B18 (1) (0)

- a.  
b.  
c.  
d.

B19 (1) (0)

- a.  
b.  
c.  
d.

B20 (1) (0)

- a.  
b.  
c.  
d.

B21 (1) (0)

- a.  
b.  
c.  
d.

B22 (1) (0)

- a.  
b.  
c.  
d.

B23 (1) (0)

- a.  
b.  
c.  
d.

Sub-Total

## PASSAGE B

I agree to give correct information to \_\_\_\_\_ if I can receive Medicaid.

- a. hair
- b. salt
- c. see
- d. ache

I \_\_\_\_\_ to provide the county information to \_\_\_\_\_ any

- |          |              |
|----------|--------------|
| a. agree | a. hide      |
| b. probe | b. risk      |
| c. send  | c. discharge |
| d. gain  | d. prove     |

statements given in this \_\_\_\_\_ and hereby give permission to

- a. emphysema
- b. application
- c. gallbladder
- d. relationship

the \_\_\_\_\_ to get such proof. I \_\_\_\_\_ that for

- |                 |                |
|-----------------|----------------|
| a. inflammation | a. investigate |
| b. religion     | b. entertain   |
| c. iron         | c. understand  |
| d. county       | d. establish   |

Medicaid I must report any \_\_\_\_\_ in my circumstances

- a. changes
- b. hormones
- c. antacids
- d. charges

B24 (1) (0)	B25 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

B26 (1) (0)	B27 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

B28 (1) (0)	B29 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

B30 (1) (0)
a.
b.
c.
d.

B31 (1) (0)	B32 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

Sub-Total
-----------

within \_\_\_\_\_ (10) days of becoming \_\_\_\_\_ of the change.

- |          |          |
|----------|----------|
| a. three | a. award |
| b. one   | b. aware |
| c. five  | c. away  |
| d. ten   | d. await |

I understand \_\_\_\_\_ if I DO NOT like the \_\_\_\_\_ made on my

- |         |               |
|---------|---------------|
| a. thus | a. marital    |
| b. this | b. occupation |
| c. that | c. adult      |
| d. than | d. decision   |

case, I have the \_\_\_\_\_ to a fair hearing. I can \_\_\_\_\_ a

- |           |            |
|-----------|------------|
| a. bright | a. request |
| b. left   | b. refuse  |
| c. wrong  | c. fail    |
| d. right  | d. mend    |

hearing by writing or \_\_\_\_\_ the county where I applied.

- a. counting
- b. reading
- c. calling
- d. smelling

If you \_\_\_\_\_ AFDC for any family \_\_\_\_\_, you will have to

- |          |              |
|----------|--------------|
| a. wash  | a. member,   |
| b. want  | b. history,  |
| c. cover | c. weight,   |
| d. tape  | d. seatbelt, |

B33 (1) (0)	B34 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

B35 (1) (0)	B36 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

Sub-Total
-----------



\_\_\_\_\_ a different application form. \_\_\_\_\_, we will use \_\_\_\_\_

a. relax	a. Since,
b. break	b. Whether,
c. inhale	c. However,
d. sign	d. Because,

the \_\_\_\_\_ on this form to determine your \_\_\_\_\_ .

- |           |                   |
|-----------|-------------------|
| a. lung   | a. hypoglycemia.  |
| b. date   | b. eligibility.   |
| c. meal   | c. osteoporosis.  |
| d. pelvic | d. schizophrenia. |

C37 (1) (0)

- a.
- b.
- c.
- d.

C38 (1) (0)

- a.
- b.
- c.
- d.

C39 (1) (0)

- a.
- b.
- c.
- d.

C40 (1) (0)

- a.
- b.
- c.
- d.

C41 (1) (0)

- a.
- b.
- c.
- d.

C42 (1) (0)

- a.
- b.
- c.
- d.

Sub-Total

## PASSAGE C

It has been explained to \_\_\_\_\_ that during the course of the

- a. my
- b. me
- c. he
- d. she

\_\_\_\_\_ or procedure, unforeseen conditions may be \_\_\_\_\_

- |              |              |
|--------------|--------------|
| a. syphilis  | a. revealed  |
| b. hepatitis | b. depressed |
| c. colitis   | c. directed  |
| d. operation | d. notified  |

that necessitate an extension of the \_\_\_\_\_ procedure(s) or

- a. appendix
- b. another
- c. original
- d. addict

different procedure(s) than those \_\_\_\_\_ forth in paragraph 2.

- a. get
- b. set
- c. see
- d. go

I, therefore, \_\_\_\_\_ and request that the above named

- a. exercise
- b. authorize
- c. energize
- d. pressurize

C43 (1) (0)	C44 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

C45 (1) (0)
a.
b.
c.
d.

C46 (1) (0)	C47 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

C48 (1) (0)
a.
b.
c.
d.

C49 (1) (0)	C50 (1) (0)
a.	a.
b.	b.
c.	c.
d.	d.

Sub-Total
-----------

READING COMPREHENSION  
RAW SCORE

--

\_\_\_\_\_, his assistants or attending physicians \_\_\_\_\_ such

- |               |            |
|---------------|------------|
| a. infection, | a. perform |
| b. pregnant,  | b. smear   |
| c. insurance, | c. onset   |
| d. physician, | d. stress  |

procedures as are necessary and \_\_\_\_\_ in the exercise of professional judgment.

- a. undesirable
- b. emergency
- c. desirable
- d. diagnosis

The authority \_\_\_\_\_ under this Paragraph 3 shall \_\_\_\_\_

- |            |            |
|------------|------------|
| a. granted | a. pretend |
| b. treated | b. extend  |
| c. tested  | c. recede  |
| d. X-rayed | d. proceed |

to treating all conditions that \_\_\_\_\_ treatment and are not known

- a. reason
- b. refer
- c. require
- d. relate

\_\_\_\_\_ the time the operation or \_\_\_\_\_ is commenced.

- |       |                |
|-------|----------------|
| a. us | a. cholesterol |
| b. be | b. menopause   |
| c. or | c. gonorrhea   |
| d. at | d. procedure   |

*Test of Functional Health Literacy in Adults (TOFHLA)*

Joanne R. Nurss, Ph.D., Ruth M. Parker, M.D., Mark V. Williams, M.D., &amp; David W. Baker, M.D., M.P.H.

TOFHLA is a measure of the patient's ability to read and understand health care information, their functional health literacy. TOFHLA Numeracy assesses their understanding of prescription labels, appointment slips, and glucose monitoring. TOFHLA Reading Comprehension assesses their understanding of health care texts such as preparation for a diagnostic procedure and Medicare Rights & Responsibilities.

Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Name \_\_\_\_\_ M \_\_\_\_ F

Birthdate \_\_\_\_/\_\_\_\_/\_\_\_\_ Age \_\_\_\_ SSN or ID# \_\_\_\_\_

Hospital or Health-care Setting \_\_\_\_\_

City, State \_\_\_\_\_

Form Administered: \_\_\_\_English Regular-print \_\_\_\_Spanish Regular-print  
 \_\_\_\_English Large-print \_\_\_\_Spanish Large-print

TOFHLA - ScoreNumeracy Raw Score (0-17) Weighted Numeracy Score (0-50) Reading Comprehension Raw Score (0-50) TOFHLA Total Score (0-100) 

Functional Health Literacy Level:

0 - 59 -- Inadequate Functional Health Literacy	<input type="text"/>
60 - 74 -- Marginal Functional Health Literacy	<input type="text"/>
75 - 100 -- Adequate Functional Health Literacy	<input type="text"/>

July 1995  
 © Emory University

**TOFHLA: Reading Comprehension  
Scoring Key**

**14 Point Font**

Passage A	Passage A	Passage A	Passage B	Passage B	Passage B	Passage C	Passage C
A1 a	A6 a	A12 c	B17 c	B24 d	B33 d	C37 b	C43 d
A2 b	A7 c	A13 b	B18 a	B25 b	B34 c	C38 d	C44 a
A3 d	A8 b	A14 c	B19 d	B26 c	B35 b	C39 a	C45 c
A4 a	A9 d	A15 d	B20 b	B27 d	B36 b	C40 c	C46 a
A5 c	A10 b	A16 a	B21 d	B28 d		C41 b	C47 b
	A11 c		B22 c	B29 a		C42 b	C48 c
			B23 a	B30 c			C49 d
				B31 b			C50 d
				B32 a			

TOFHLA Numeracy  
14 point font - English

Prescription Bottle Labels and Prompts  
(to be laminated)

The prescription bottle labels for items 1, 2, 3, 6, 7, & 8 should be duplicated, cut to size, laminated, and taped on an actual prescription bottle that can be handed to the patient to read.

The prompts for items 4, 5, 9, & 10 should be duplicated on card stock (heavy paper), cut to size, and laminated to be handed to the patient to read.



1. GARFIELD IM 16 Apr 93  
FF941858 Dr. LUBIN, MICHAEL
- 

PENICILLIN VK  
250MG 40/0  
Take one tablet by mouth four  
times a day

02 (4 of 40)

2. GARFIELD IM 16Apr93  
FF941861 Dr. LUBIN, MICHAEL

AMOXICILLIN LIQ  
125MG/5ML 15OML 1/0

Refrigerate-Shake well; discard  
after March 15, 1993

02 12 (1 of 1)

3. GARFIELD IM 16 Apr 93  
FF941860 Dr. LUBIN, MICHAEL

---

METHOTREXATE  
2.5 MG 10/0

Take every third day.

08 11 14 31 (1 out of 10)

6. GARFIELD IM 16 Apr 93  
FF941860 Dr. LUBIN, MICHAEL

TETRACYCLINE  
250 MG 40/0

Important: Finish all this  
medication unless otherwise  
directed by prescriber

02 03 04 11 31 (4 of 40)

7. GARFIELD IM 28 Dec 92  
FF941857 Dr. LUBIN, MICHAEL

---

PHENOBARBITAL  
30 MG 90/2

After two refills or six months  
from date of issue, this  
prescription can only be refilled  
by authority of physician.  
(2 refills)

01 08 (9 of 90)

8. GARFIELD IM 16 Apr 93  
FF941862 Dr. LUBIN, MICHAEL

DOXYCYCLINE

100 MG 20/0

Take medication on empty  
stomach one hour before or  
two to three hours after a  
meal unless otherwise  
directed by your doctor.

02 11 (0 of 20)

4. Normal blood sugar is 60 - 150.

---

Your blood sugar today is 160.

---

5.

## CLINIC APPOINTMENT

CLINIC: Diabetic

LOCATION: 3rd floor  
a.m.DAY: Thurs. DATE: April 2<sup>nd</sup>HOUR: 10:20  
p.m.

Issued by

YOU MUST BRING YOUR PLASTIC CARD WITH YOU

10. You can get care at no cost if after deductions your monthly income and other resources are less than:

---

\$ 581 for a family of one	\$ 1,196 for a family of four
\$ 786 for a family of two	\$ 1,401 for a family of five
\$ 991 for a family of three	\$ 1,606 for a family of six.

## APPENDIX D

## SUPPORT LETTER FROM SAFE



## SYLACAUGA ALLIANCE FOR FAMILY ENHANCEMENT

Margaret Morton  
Executive Director

November 25, 2008

BOARD OF DIRECTORS

JESSE CLEVELAND  
PRESIDENT

CHARON DOUGLASS  
VICE-PRESIDENT

VANESSA GREEN  
SECRETARY

JERRY "CISCO" KING  
TREASURER

MARY ASHCRAFT

LEON CLEVELAND

DR. JANE CORRA

JOHN FLOYD

REP. RON JOHNSON

REV. HENRY LOONEY

EDNA MAXWELL

ALBA MCEVERN

WANDA MCELBRATH-FRAZER

NANCY MCKAY

DOUG MURPHREE

BERT SIMS

DEANDE SINCLAIR

GLENN SMITH

DAVID WILBANKS

YAN WILKINS

MICHAEL WILLIAMS

MARION BARR WRIGHT

Institutional Review Board at UAB  
c/o Shelia Moore  
Room 470, Administration Building  
701 20<sup>th</sup> Street  
Birmingham, Alabama 35294-1301

Dear Ms. Moore:

The Sylacauga Alliance for Family Enhancement, Inc. Administrative Staff has met with and discussed a planned research study for the purpose of a dissertation proposed by Ms. Joy Deupree. We welcome the opportunity to partner with Ms. Deupree for this project.

If you have any questions regarding this project, please contact me at 256-245-4343.

Sincerely,

*Margaret Morton*

Margaret Morton  
Executive Director  
Sylacauga Alliance for Family Enhancement, Inc.

*All families have the right to thrive.*

*We support families because children from resilient families have the best opportunity to succeed.*

78 Batley Ross Lane • Post Office Box 1122 • Sylacauga, Alabama 35150 • Telephone: 256-245-4343 • Fax: 256-245-3675



APPENDIX E

CHECKLIST FOR IN-HOME INTERVIEWS

## CHECKLIST FOR IN-HOME INTERVIEWS

1. Did you arrange the interview at a time convenient to participants of the study?
2. When beginning the interview did you choose a setting with the least distraction?
3. Did you begin with the terms of confidentiality and secure the informed consent prior to beginning the interview?
4. Did you explain the purpose of the interview?
5. Did you explain the format for the interview prior to asking questions?
6. Prior to beginning did you indicate approximately how long the interview usually takes?
7. Did you provide contact information of the interviewer to each participant should they have questions?
8. Did you allow the interviewee to clarify any doubts about the interview before during and after the interview?
9. Did you ask one question at a time?
10. Did you remain natural during the interview process?
11. Were you careful not to show opinions especially when note taking?
12. Did you provide transition between major topics?
13. Did you allow for questions?
14. Did you ask at the end of the interview if the participant had any questions or did they want to provide any other information?
15. Prior to leaving each home did you go back over all the information recorded to verify that you understood the answers correctly?
16. After leaving each home did you go back over all the information recorded with the casework who accompanied you to make sure she understood the answers the same way that the interviewer did?

APPENDIX F  
INTERVIEW AND OBSERVATIONAL PROTOCOL

## Interview and Observational Protocols

*Interview Protocol*

## ADHERENCE TO PRESCRIBED MEDICAL REGIMENS IN OLDER ADULTS

Name \_\_\_\_\_

Date \_\_\_\_\_

Thank you so much for meeting to talk with me today. \_\_\_\_\_ will transcribe our talk for the study. After our talk, I will ask you to read what we have recorded and make sure that we understand what you said and that it is correct. It is very important that the record is correct and reflects your own words and thoughts. Also, you can withdraw from this study at any time during this meeting.

I want to study, how you take the drugs prescribed for you by your doctor. I also want to know how well you understand about the drugs you are taking and why you are taking them. I also want to know about any adverse drug events or problems that you may have experienced in the past 12 months. I've given you a copy of the questions that I'm going to ask today. I want to know how you feel about your prescription medications, what concerns you have (if any), what you have found to be helpful or what things you might find helpful if you were able to get them. I may ask you some other questions as we progress in this meeting to explain what you have told me.

## QUESTION 1

Please tell me about the drugs that you take. How many times a day do you take your drugs?

## QUESTION 2

Please tell me about why you take the drugs?

## QUESTION 3

Talk to me about how SAFE can help you get your drugs?

**QUESTION 4**

Tell me about your visits with your doctor(s)? Do they talk with you about how to take your drugs? Do they tell you why you need to take this drug(s)?

**QUESTION 5**

How many doctors do you go to for treatment(s)?

**QUESTION 6**

Tell me about any adverse drug events that happened to you in the past 12 months.

**QUESTION 7**

Tell me about any group of people you have used to support your health care treatment? Who has been the most helpful? Who has been least helpful?

**QUESTION 8**

Tell me about any particular concerns/worries about your current medical treatment?

**QUESTION 9**

Are there any outreach groups like a church that help you with your drug management

**QUESTION 10**

Does anyone help you with the management of your drugs?

If you answered yes to Question 10, please tell me more about who helps you

**QUESTION 11**

Are there any barriers that you face when managing your prescribed drugs?

Money? Transportation? Hard to swallow? Do you get drugs mixed up and sometimes take the wrong medication?

*Observational Protocol***ADHERENCE TO PRESCRIBED MEDICAL REGIMENS IN OLDER ADULTS**

Setting: \_\_\_\_\_

Observer: \_\_\_\_\_

Role of the Observer: \_\_\_\_\_

Date: \_\_\_\_\_

Time: \_\_\_\_\_

Length of Observation \_\_\_\_\_

Transcriber \_\_\_\_\_

**Descriptive/Observational Notes:**

**Comments:**

## APPENDIX G

## MEDICATION ADHERENCE SELF-EFFICACY SCALE

## **Medication Administration Self-Efficacy Scale (MASES)**

Phase II of the study for: Health Literacy: A Community Based Mixed Methods Study to Examine Self-Management of Prescription Medication among Older

Please answer the following questions using one of the three answers

1= Not sure at all

2= Somewhat sure

3= Very sure

0=Does not apply

How confident are you that you can take the drugs prescribed for you.....

1. When you are busy at home\_\_\_\_\_
2. When you are at work \_\_\_\_\_
3. When there is no one to remind you\_\_\_\_\_
4. When you worry about taking the drugs for the rest of your life \_\_\_\_\_
5. When the drugs cause some side effects \_\_\_\_
6. When the drugs cost lots of money \_\_\_\_\_
7. When you come home late \_\_\_\_\_
8. When you do not have symptoms \_\_\_\_
9. When you are with family members \_\_\_\_\_
10. When you are in a public place \_\_\_\_\_
11. When you are afraid of becoming dependent on the drugs \_\_\_\_\_
12. When you are afraid they may affect your sexual performance \_\_\_\_\_
13. When the time to take the drugs is between you meals \_\_\_\_\_
14. When you feel you do not need them \_\_\_\_\_
15. When you are traveling\_\_\_\_\_
16. When you take the drugs more than once a day \_\_\_\_\_
17. If they sometimes make you tired \_\_\_\_\_
18. If they sometimes may you feel dizzy \_\_\_\_\_
19. When you have many drugs to take \_\_\_\_\_
20. When you feel well \_\_\_\_\_
21. If they make you want to urinate while away from home \_\_\_\_\_
22. Get refills for your drugs before you run out \_\_\_\_\_



- 23. And will fill your prescriptions whatever they cost \_\_\_\_\_
- 24. Make taking your drugs part of your daily routine \_\_\_\_\_
- 25. Always remember to take your drug(s) \_\_\_\_\_
- 26. Take your drugs for the rest of your life \_\_\_\_\_

This Self-Efficacy Scale was adapted from a field-tested instrument developed by Gbenga Ogedegbe, Carol, A. Mancuso, John P. Allevante, and Mary E. Charlson. Findings from the study that sought to validate the findings are found in the Journal of Clinical Epidemiology, Volume 56, Issue 6, June 2003, pages 520-529. The title of the journal article is *Development and Evaluation of a Medication Adherence Self-Efficacy Scale in Hypertensive African-American Patients*. The authors of this study report “Clinicians and researchers can use this scale to identify situation in which patients have low self-efficacy in adhering to prescribed medications” (p. 521).

## APPENDIX H

### CHECKLIST FOR REVIEW OF SENIORX WELLNESS FILES

## CHECKLIST FOR REVIEW OF SENIORX WELLNESS FILES

1. Did you arrange the review at a time convenient review all of the data for each participant with a caseworker from the SenioRx program?
2. When beginning the review did you choose a setting with the least distraction?
3. Did you reinforce the terms of confidentiality with the caseworker?
4. Did you explain the purpose of the review?
5. Did you explain the format for the review prior to asking questions?
6. Did you provide contact information of the interviewer to the caseworker should they have questions?
7. Did you allow the caseworker to clarify any doubts about the information before during and after the review?
8. Did you ask one question at a time?
9. Did you remain natural during the review process?
10. Were you careful not to show opinions especially when note taking?
11. Did you allow for questions?
12. Did you ask at the end of the review ask the caseworker if she had any questions or did they want to provide any other information?
13. Prior to leaving the review session did you go back over all the information recorded to verify that you understood the answers correctly?

APPENDIX I  
IRB APPROVAL



Form 4: IRB Approval Form  
Identification and Certification of Research  
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on September 29, 2013. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: DEUPREE, JOY P

Co-Investigator(s):

Protocol Number: **X081223006**

Protocol Title: *Health Literacy: A Community Based Mixed Methods Study to Examine Self-Management of Prescription Medication among Older Adults*

The IRB reviewed and approved the above named project on 2-22-11. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 2-22-11

Date IRB Approval Issued: 2-22-11

Marilyn Doss, M.A.

Vice Chair of the Institutional Review  
Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building  
701 20th Street South  
205.934.3789  
Fax 205.934.1301  
irb@uab.edu

The University of  
Alabama at Birmingham  
Mailing Address:  
AB 470  
1530 3RD AVE S  
BIRMINGHAM AL 35294-0104

## APPENDIX J

## INVITATION LETTER (PHASE I)

### Information Sheet /Invitation

**TITLE OF RESEARCH:**   **Health Literacy: A Community Based Mixed Methods Study to Examine Self-Management of Prescription Medication among Older Adults.**

**IRB PROTOCOL NUMBER:**    [X081223006](#)

**INVESTIGATOR:**           Joy P. Deupree

**SPONSOR:**               Department of Human Studies at the University of Alabama at Birmingham, School of Education

Dear Participant of Sylacauga Alliance for Family Enhancement,

My name is Joy Deupree and I am a student at the University of Alabama at Birmingham (UAB). You are invited take part in a research study. If you take part in this study, it will help us find out if you take your drugs the way you should. This letter and invitation have been sent to adults between 60 and 74 years old that speak English, and use programs at SAFE. One hundred fifty people will be invited to Part I of the study. After you turn in the papers from this packet to me on the day of a planned event including lunch, you may also be invited to join Part II of the study that will only have 15 people. You may not benefit directly from taking part in this study but this study may help me know how to help others take their drugs correctly in the future.

This packet sent to you by Ms. Margaret Morton from SAFE has an (a) Invitation, (b) Information Sheet, (c) a survey asking you about your age, gender, marital status, last grade in school, your job status, what types of health insurance you have, and your annual income, and (d) a drug record that asks you the name of the drug(s) you take, the dose, how you take the drug, what time you take the drug, and why your doctor wants you to take the drug. You can answer all of the questions if you want to or you may choose to leave a question unanswered.

The day of the lunch, you are invited to come to J. Craig Community Center at 9:00 a.m. You should bring the papers that were mailed to you. Please fill them out before you come to the event. At 10:00 a.m. the day of the event, I will review the Information Sheet. If you choose to take part in the study, you will be given a number to identify you. No one but you and I will see the documents that you bring. A folder with your identification number will be made for you and will store all the papers you give to me. If you choose to be in Part I of the study, you will give the papers to me, filled out before the lunch. If you choose not to take part in the study, you can still have lunch by turning in the blank papers to me. No one but me will know who decides to take part in the study.

On the day of the event, after you have lunch you will take a test known as the Test of Functional Health Literacy in Adults (TOFHLA). It will take you about 22 minutes to

take the test. Spaces between seats for test takers will give you privacy so no one else can see your answers. When you finish the test, you will turn in the answer sheet to me and I will place it in a folder with the other papers you gave me.

The risks for this study are considered to be no more than the risks of daily living. If after you complete the study, you have any emotional distress; please speak with your doctor. Information obtained about you for this study will be kept private to the extent allowed by law. The results of the study may be published for scientific purposes. These results could include your test results but your identity will not be given out.

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with SAFE.

There will be no cost to you from taking part in this study. You will be offered lunch to be in Part I of the study. I will contact you soon to answer questions you might have and post cards will be sent to you from Ms. Morton one week prior to the event and lunch to remind you of the date.

If you have any questions, concerns, or complaints about the research, please contact Ms. Joy Deupree. She will be glad to answer any of your questions. Ms. Deupree's number is 205-975-1964.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll-free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.



APPENDIX K  
INFORMED CONSENT



## Informed Consent Document



**TITLE OF RESEARCH:** Health Literacy: A Community Based Mixed Methods Study to Examine Self-Management of Prescription Medication among Older Adults

**IRB PROTOCOL:** X081223006

**INVESTIGATOR:** Joy P Deupree

**SPONSOR:** Department of Human Studies at the University of Alabama at Birmingham, School of Education

### **Explanation of Procedures**

---

You are invited take part in Part II of a research study to see how well you take drugs prescribed for you by your doctor. This letter has been sent to adults between 60 and 74 years old who are in good health that speak English, have good vision, and use programs at Sylacauga Alliance for Family Enhancement (SAFE) and who took part in Part I of the study.

For Part II of the study, private visits with you in your home will be scheduled. You will asked questions and will be observed in your home as you prepare all of your drugs that you take on a daily basis. Your drug record kept by SAFE will be reviewed to determine if you are taking your drugs the way you should be. The visit in your home will provide valuable information about your confidence when you prepare your drugs. The time spent with you in your home will be between 2 to 3 hours. The meeting will be arranged to fit your schedule and based on when you want to meet. This part of the study (Phase II) will enroll twelve to sixteen participants from Phase I of this study, in which you already participated.

### **Risks and Discomforts**

---

The risks for this study are considered to be no more than the risks of daily living. If after you complete this part of the study, you have any emotional distress; please speak with your doctor.

### **Benefits**

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You may not benefit directly from taking part in this study but this study may help the research team know how to help others take their drugs correctly for the future.

## **Alternatives**

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An alternative available to you, if you are being invited to participate in Phase II of this study is to choose not to participate.

## **Confidentiality**

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Information obtained about you for this study will be kept private to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of Department of Human Studies; The results of the treatment may be published for scientific purposes. These results could include your test results but not your identity.

## **Refusal or Withdrawal without Penalty**

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Taking part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with SAFE.

## **Cost of Participation**

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There will be no cost to you from taking part in this study.

## **Payment for Participation in Research**

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If you participate in Part II of this study, you will receive a \$40 cash card for use at Wal-Mart that will be given to you at the end of your in-home visit.

## **Questions**

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If you have any questions, concerns, or complaints about the research please contact Ms. Joy Deupree. She will be glad to answer any of your questions. Ms. Deupree's number is 205-975-1964.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact Ms. Sheila Moore. Ms. Moore is the Director of the Office of the Institutional Review Board for Human Use (OIRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816. If calling the toll-free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

## **Legal Rights**

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You are not waiving any of your legal rights by signing this informed consent document.

## **Signatures**

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Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

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Signature of Participant

Date

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Signature of Investigator

Date

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Signature of Witness

Date

**University of Alabama at Birmingham**  
**AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION  
FOR RESEARCH**

**What is the purpose of this form?** You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name: \_\_\_\_\_

UAB IRB Protocol Number: X08122300

Research Protocol: Health Literacy: A  
Community Based Mixed Methods Study to  
Examine Self-Management of Prescription  
Medication among Older Adults

Principal Investigator: Joy P. Deupree

Sponsor: Department of Human Studies, The  
University of Alabama at Birmingham, School of  
Education

**What health information do the researchers want to use?** All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

**Why do the researchers want my health information?** The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

**Who will disclose, use and/or receive my health information?** The staff at Sylacauga Alliance for Family Enhancement, , nurses, dissertation committee members, and staff working on the research protocol (whether at UAB or elsewhere) as necessary for their operations; the IRB and its staff; and the sponsor agency, The Department of Human Studies.

**How will my health information be protected once it is given to others?** Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

**How long will this Authorization last?** Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

**Can I cancel the Authorization?** You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study principal investigator and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

**Can I see my health information?** You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: \_\_\_\_\_ Date: \_\_\_\_\_

or participant's legally authorized representative: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name of participant's representative: \_\_\_\_\_

Relationship to the participant: \_\_\_\_\_

Participant's Initials: \_\_\_\_\_