THE *"MEDICATION MATTERS ... TO YOU!"* EDUCATIONAL INTERVENTION SESSION: A PILOT STUDY TO IMPROVE MEDICATION MANAGEMENT IN COMMUNITY-LIVING OLDER ADULTS

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

DEPARTMENT OF HEALTH STUDIES

COLLEGE OF HEALTH SCIENCES

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DENTON, TEXAS

MAY 2014

TEXAS WOMAN'S UNIVERSITY
DENTON, TEXAS

February 20, 2014

To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Carol L. Creech entitled, "The 'Medication Matters … To You!' Educational Intervention Session: A Pilot Study to Improve Medication Management in Community-living Older Adults." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Health Studies.

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Accepted:

Dean of the Graduate School

DEDICATION

For my father, B.G. Creech (the first Dr. Creech, my inspiration).

For my husband, Dr. Paul L. Kendall (the soul-mate, my constant support).

For my son, Robert S. Harker, II (the special friend, my backup cheerleader).

ACKNOWLEDGMENTS

I would like to gratefully acknowledge the many individuals who have made significant contributions to this dissertation. I am extremely grateful to my committee chair, Dr. Kristin Wiginton, for her repeated offerings of timely, encouraging, and constructive feedback, and for her unfailing and genuine interest in this topic. I am also grateful to my dissertation committee members, Dr. Kimberly Parker and Dr. Katie Crosslin, for their valuable guidance and input. I would like to thank Ms. Martha Fiddes and Mr. Scott Dobbs, of Christian Care Centers, Inc., for their unflagging enthusiasm and invaluable help in bringing this project to fruition. I would also like to thank Mr. Hossein Zahed, for his contribution to the statistical analysis of this project. And finally, I would like to thank all of the family members and friends who have supported me throughout this process – both those who are still with us, and those who are not.

ABSTRACT

CAROL L. CREECH

THE *"MEDICATION MATTERS ... TO YOU!"* EDUCATIONAL INTERVENTION SESSION: A PILOT STUDY TO IMPROVE MEDICATION MANAGEMENT IN COMMUNITY-LIVING OLDER ADULTS

MAY 2014

Older adults are highly susceptible to the effects of inadequate health literacy (HL). Independently-living elders comprise most of this population, and are at risk for medication misuse. Grounded in integrated HL theory, a pre-experimental, pre- and post-test study was pilot-tested with participants living in an independent-living retirement facility to determine whether a brief, low-HL tailored intervention on common medication management issues could effect immediate changes in the dependent variables of knowledge and self-efficacy (SE). Baseline HL status was evaluated using the Newest Vital Sign (NVS) tool. Nonparametric analyses were utilized to assess relationships due to the small sample size (N=14). Higher SE pre-test scores correlated with higher SE post-test scores ($\rho = .784, p = .001$). Pre-test knowledge scores strongly correlated with baseline HL scores ($\rho = .646, p = .012$). Post-test knowledge scores were significantly higher than pre-test scores for all participants ($M = 8.43$, $Mdn = 9.00$, $SD = 1.651$ versus $M = 3.93$, $Mdn = 4.00$, $SD = 1.817$; $p < .001$). Change in knowledge and SE scores were not related to age, educational attainment, or baseline HL status. Likert-

type scale assessment of participant satisfaction was not related to baseline HL status. Qualitative satisfaction assessment revealed positive themes four times as often as negative themes. Positive themes centered on the type of content, its utility and comprehensibility. Among negative themes, dislike of the NVS was strong. Results showed the intervention more than doubled knowledge scores in 100% of participants. However, SE scores were not significantly changed, pointing to need for long-term follow-up. Follow-up is also necessary to ascertain knowledge retention for long-term outcome evaluation. While the NVS is cognitively challenging for this sample population, the current study indicates its ability to identify high performers on HL knowledge assessments, lends credence to reports that it discriminates between limited/not limited HL subpopulations, and adds to the knowledge base concerning its use. These results help to elucidate effective practice strategies for improved medication management in geriatric HL interventions, and aid in evaluating HL's role in mediating public health efforts.

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CHAPTER I

INTRODUCTION

The race between health care expenditure and improved health outcomes continues to attract national attention. Health literacy (HL) lies at the heart of efforts toward both prevention and sustained health improvement (Office of Disease Prevention and Health Promotion [ODPHP], 2010). HL can be understood as the skills that are necessary to function successfully as a patient (Selden, Zorn, Ratzan, & Parker, 2000). Inadequate HL currently exists at levels of epidemic proportions, according to a report sponsored by the Institute of Medicine (IOM; Nielsen-Bohlman, Panzer, Hamlin, & Kindig, 2004). Indeed, in 2009, the Centers for Disease Control and Prevention (CDC) stated that as many as "9 out of 10 adults may lack the skills needed to manage their health and prevent disease" (CDC, 2009c, p. 2; ODPHP, n.d.a, p. 2.3).

As result, improvements in HL conceivably could impact every area of health care, saving up to $238 billion annually on costs for otherwise preventable hospitalizations, and for excessive morbidity and mortality outcomes (IOM, 2004; Potter & Martin, 2005; Vernon, Trujillo, Rosenbaum, & DeBuono, 2007). In 2007, the Office of the Surgeon General (OSG) stated that "there is a strong, independent association between health literacy and health outcomes" (p. 1). These outcomes have been documented in repeated studies for many health conditions (CDC, 2009b; Parker, 2002). This problem is not just an epidemic, but a ubiquitous epidemic; the CDC has gone on

record as stating that inadequate HL currently impacts all Americans in some manner (2009b). Older adults are especially susceptible to inadequate HL effects (Park, 2006), and the problem becomes more critical as this population expands in numbers (Parker, Ratzan, & Lurie, 2003). One crucial HL issue for the elderly is medication compliance/adherence (National Research Council, 2008). Medication nonadherence burdens the health care system (DeWalt, Berkman, Sheridan, Lohr, & Pignone, 2004; Mann, 2009), triggering severe complications, increased use of emergency services (Chia, Schlenk, & Dunbar-Jacob, 2006), and up to 10% of all hospital admissions (Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). The ambulatory, noninstitutionalized elderly, who comprise the vast majority of the senior population (Administration on Aging, 2009) are particularly at risk (Swanlund, Scherck, Metcalfe, & Jesek-Hale, 2008). The use of brief interventions to address both prescription and over-the-counter medication misuse in this population has been studied by the Florida BRITE project (Brief Intervention and Treatment for Elders; Schonfeld et al., 2010). Given that up to a third of the adverse medication events in ambulatory elders are deemed to be preventable, the preceding data suggest a potential intervention target for this problem (Gurwitz et al., 2003).

Statement of the Purpose

The intent of this single-stage, mixed methods study is to pilot-test a tailored, HL theory-based and HL guideline-informed intervention for improving medication management knowledge and self-efficacy in independently-living older adults at a non-

profit retirement facility in suburban North Texas. Independent variables include the treatment variable, in which a single group is evaluated both immediately before and immediately after an educational intervention session. Other independent variables include demographic characteristics such as age, gender, and educational attainment, as well as baseline HL level. Dependent variables include outcome evaluation satisfaction survey results, and pre- and post-test change scores in knowledge and self-efficacy related to medication management.

Hypotheses

Ho1: There will be no significant difference in participants' knowledge scores of medication management strategies after the tailored HL intervention.

Ho2: There will be no significant difference in participants' self-efficacy scores related to medication management strategies after the tailored HL intervention.

Ho3: There will be no statistically significant association between change scores for knowledge and self-efficacy and participants' age, educational attainment and baseline HL.

Ho4: There will be no statistically significant association between participants' satisfaction scores with the intervention and baseline HL scores.

Research Questions

1. Does the tailored HL intervention increase participants' knowledge related to medication management strategies in a population of independently living older adults?

2. Does the tailored HL intervention increase participants' self-efficacy related to medication management strategies in a population of independently living older adults?

3. Can change in knowledge and self-efficacy scores before and after the tailored HL intervention be related to age, educational attainment, and/or baseline HL in a population of independently living older adults?

4. Can participant satisfaction with the tailored HL intervention be related to baseline HL in a population of independently living older adults?

Delimitations

The delimitations for this study will be:

1. Participants' age will be over 65 years, and they will reside at a nonprofit retirement facility located in suburban north Texas.

2. Participants will be living independently, with only minimal need for family support or paid assistance. Thus, a criterion for exclusion will consist of blindness and/or cognitive impairment.

Limitations

The following may have limited the scope of this project:

1. Multiple comorbid conditions are common in this population, and may interfere with comprehension of the intervention in a manner unobservable to the researcher.

2. The study site is small and strongly health promotion-oriented. Thus, exposure to non-intervention-related HL content could have occurred, thereby altering participant responses (i.e., the threat of "diffusion of treatment"; Cook & Campbell, 1979). The

intervention was limited to a single-exposure format in order to aid in controlling this threat.

3. The participants were selected via a convenience sample of volunteers. Thus, the inability to randomize will limit the generalizability of the results.

Assumptions

This investigator assumed that:

1. Participants were able to read and write in English.

2. Participants gave truthful answers to all of the questions they were asked.

Definitions of Terms

Cognitive impairment – in the current study, this term refers to any form of impairment of executive function (such as lack of orientation to time, place, or person; Luggen, 2004) that would interfere with a participant's ability to understand the educational intervention and to answer the pre- and post-test questions.

Health literacy – "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Ratzan & Parker, 2000, as cited by the IOM, 2004, p. 4).

Inadequate health literacy – for the purposes of this study, this term refers to the inability to function successfully as a patient (Selden et al., 2000).

Limited health literacy – when specifically referring to performance on the *Newest Vital Sign* validated HL assessment tool, this term indicates scoring 3 or fewer points out of 6 possible points (Weiss et al., 2005).

Medication compliance or adherence – "the extent to which a person's behaviour … (in) taking medication … corresponds with agreed recommendations from a health care provider" (World Health Organization, 2003, p. 3).

Not limited health literacy – when specifically referring to performance on the *Newest Vital Sign* validated HL assessment tool, this term indicates scoring 4 or more points out of 6 possible points, or a minimum of 80% (Weiss et al., 2005).

Importance of the Study

HL research is a new field, and best practice interventions have not yet been defined (Berkman et al., 2004; Shohet & Renaud, 2006). Research still is needed to evaluate modes of HL interventions (McCray, 2005; OSG, 2007), especially for older adults at greater risk for health-related disparities (Park, 2006; Vernon et al., 2007). The proposed study would add to the literature by developing and testing an HL intervention on medication management for independently-living older adults, thereby helping to evaluate HL's role in mediating population health (von Wagner, Steptoe, Wolf, & Wardle, 2009). Results of this work may help inform health education researchers, educators, and policymakers concerning the development and delivery of effective practice strategies for improved medication management in geriatric HL interventions.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

In order to fully address the scope of the problem of inadequate health literacy (HL) in older adults, one must first define the term, and then detail its prevalence, consequences, and financial costs. This review will discuss specific HL issues in older adults, especially those impinging on the skill of medication management, and briefly describe the rationale for the use of brief interventions in this population. Additionally, the chapter will describe the theoretical underpinnings of HL and medication management interventions, and the contributions qualitative studies of medication management have made in older adult populations. Each section of this review will address these aspects of the problem, respectively.

Overview of Health Literacy in American Adults

Health Literacy: Definition

HL is not the same as general literacy (Pfizer, Inc., 2003). The expression *health literacy* was first coined in 1974 (Simonds), and usually is defined in one of two ways. According to the American Medical Association (AMA), the term refers to "a constellation of skills that constitute the ability to perform basic reading and numerical tasks for functioning in the health care environment and acting on health care information" (AMA, 1999, p. 553). Alternatively, Ratzan and Parker (2000) and Potter

and Martin (2005) describe HL as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Nielsen-Bohlman et al., 2004, p. 2). HL is thus a complex skill composed of a number of subskills, including numeracy (ODPHP, n.d.a). As such, HL is strongly influenced by culture, beliefs, and knowledge base (Nielsen-Bohlman et al., 2004), as well as by age, language, educational attainment, and resource availability (ODPHP, n.d.a). As a skill, HL encompasses people's ability both to utilize health information as well as to act upon it, and this includes the complex interactions with professionals that occur in medical care situations (Nielsen-Bohlman et al., 2004; ODPHP, n.d.b.). In other words, HL is the ability to "successfully function as a patient" (Selden et al., 2000, as cited by Potter & Martin, 2005, p. 1).

Inadequate Health Literacy: Prevalence of the Problem

Interest in the literacy of the American public began in the 1960s (CDC, 2009c). It is known that general literacy levels are not high in the American population (Berkman et al., 2004). In 1993 the National Adult Literacy Survey (NALS) was sponsored by the federal government and conducted by the Educational Testing Service (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). This survey rated between 40 and 44 million Americans as having the lowest of five possible literacy levels, and another 50 million as having the next lowest level (Kirsch et al., 2002). "These levels correspond to having trouble finding pieces of information or numbers in a lengthy text, integrating multiple pieces of information in a document, or finding two or more numbers in a chart and performing a

calculation" (Berkman et al., 2004, p. 1). Parker, Ratzan, and Lurie (2003) compared these low levels of literacy to being unable to fill out an application for Social Security or to understand a bus schedule. These results translated into approximately 23% of adult Americans being classified as functionally illiterate, and another 28% being categorized as only marginally literate (Potter & Martin, 2005). Some authors contend that such low levels of literacy are not sufficient to satisfy the needs of daily life in the modern age (Comings, Reder, & Sum, 2001). Taken together, these findings predicted that slightly more than half of the American population would likely have great difficulty with complex, health-related tasks (Kirsch et al., 1993; Potter & Martin, 2005). As a result of these and other findings, in 2000 the U.S. Department of Health and Human Services designated Objective 11-2 of *Healthy People 2010* as *Improvement of Health Literacy* (ODPHP, 2003), and the IOM designated HL as one of the two major overarching factors that affect health care at the national level (Adams & Corrigan, 2003, as cited by Nielsen-Bohlman et al., 2004).

In 2003 another literacy survey, the *National Assessment of Adult Literacy* (NAAL), was utilized. This survey was unique in that it included a specific HL component for the first time (ODPHP, n.d.b.). Results showed that the number of American adults scoring in the combined categories of Basic and Below Basic literacy was now between 75 and 87 million (U.S. Department of Education [DOE], 2003; Vernon et al., 2007). By 2009, the CDC stated that the 2003 NAAL illustrated that "nearly 9 out of 10 adults may lack the skills needed to manage their health and prevent

disease" (CDC, 2009c, p. 2; ODPHP, n.d.a, p. 2.3). These results confirmed growing fears regarding American adults' difficulty in managing health-related activities, such as comprehending medication directions and nutrition labels, finding and communicating with health care providers, choosing health care insurance or drug coverage plans, or responding to medical and physical emergencies (CDC, 2009c; ODPHP, n.d.a).

According to Nielsen-Bohlman and colleagues in 2004, an estimated 90 million Americans had problems comprehending complicated text. Even persons with high literacy levels are believed to have problems on occasion understanding and manipulating certain types of unfamiliar health information (Nielsen-Bohlman et al., 2004). Feelings of shame about inadequate HL skills also have been documented (Baker et al., 1996; Parikh, Parker, Nurss, Baker, & Williams, 1996; Wolf et al., 2007b). Due to the widespread prevalence of inadequate HL, the problem currently is considered to impact *all* Americans in some manner (CDC, 2009c). Inadequate HL is truly a "hidden epidemic" (DeBuono, 2006, p. 27).

Inadequate Health Literacy: Consequences and Outcomes

When a systematic review of HL and health outcomes was undertaken in 2004 for the Agency for Healthcare Research and Quality (AHRQ), five out of six studies examined were found to have some degree of significant statistical association between higher levels of knowledge concerning health care and greater literacy levels (Berkman et al., 2004). In 2007 the *Surgeon General's Workshop on Improving Health Literacy* stated that "there is a strong, independent association between health literacy and health

outcomes … (such as) emergency department use, hospitalization, self-reported physical health, and mortality" (OSG, p. 1). These outcomes have been documented in various studies for a diverse range of health conditions. For example, adults with lower HL may have higher rates of hospitalization (Baker et al., 1998a, 1998b) than other adults. In a large prospective study (N > 3200), Baker and colleagues (2002) found that new Medicare enrollees (mean age approximately 73 years, primarily Caucasian and female) had a greater adjusted Relative Risk (ARR) for hospital admission if they had inadequate HL (ARR = 1.29; 95% CI = 1.07, 1.55), or if they had marginal HL (ARR = 1.21, 95% CI = 0.97, 1.50).

Adults with lower HL tend to be less informed about their health conditions and available treatments. This may manifest as difficulty with self-care activities, including medication management. Several studies have examined this issue. In a moderately-sized study of adult outpatients at a health science center primary care clinic (N > 250, mean age 47 years, three-quarters female, two-thirds African American and one-third Caucasian), Davis and colleagues (2006a) found in multivariate analyses that participants with a lower HL were over three times more likely to misunderstand prescription warning labels (Adjusted Odds Ratio [AOR] = 3.4, 95% CI = 2.3, 4.9). Among these participants, those older than 65 years were more likely to interpret these labels incorrectly than those less than 45 years (AOR = 1.7, 95% CI = 1.1, 2.8). (Strangely enough, the *p* value was not specified for this data, leading the reader to assume that it was < 0.05.). That same year, Davis and coworkers (2006b) also found that community-living indigent patients at

primary care clinics in three different states (N < 400, mean age approximately 45 years, two-thirds female, half African American and half Caucasian) were two times more likely to misunderstand drug labels if they had low HL status (multivariate ARR = 2.32, 95% CI 1.26, 4.28) or marginal HL status (ARR = 1.94, 95% CI = 1.14, 3.27) compared to those with adequate HL status. These and other similar findings were corroborated by a systematic review of literacy and health outcomes carried out by DeWalt and colleagues in 2004, and reiterated by the Institute of Medicine in their workshop on medication label standardization (National Research Council, 2008).

Adverse health outcomes, including mismanagement of medications, may be explained further by the difficulty that those with low HL have in understanding communications from their health care providers. In 2004, Schillinger, Bindman, Wang, Stewart, and Piette showed that low HL diabetic patients (N > 400, mean age 54 years, ethnically diverse population) had a decreased likelihood of understanding physician communications on both explication of conditions (AOR = 4.85, $P = 0.03$) and processes of care (AOR = 2.70, $P = 0.03$) when compared to those with adequate HL (no CI ranges given). These findings imply that lower HL may cause patients to be more confused, have greater misunderstanding, and by extension, be less successful in managing their health conditions. This study is notable as the first apparent examination of the relationship between HL and the perceived quality of spoken communication between patients and physicians. It was limited by the fact that the major outcome measure, while specific and validated, was nevertheless a self-report of interpersonal interaction with the

physician; no data were collected by direct observation. Also, because the study did not record whether there was a concordance/disconcordance between the race or ethnicity of the physician and the patient, there may be some concern that a mismatch between these two might impact the patients' responses (Cooper & Roter, 2002). The researchers attempted to control for this limitation by including whether Spanish-speaking patients interacted with Spanish-speaking physicians as a variable in their multivariate model (Schillinger et al., 2004).

In some patients, lower HL may correlate to some degree with decreased knowledge of one's medical condition. In 1998, a moderately large study (N approximately 470) by Williams and coworkers examined a convenience sample of primarily indigent, public hospital asthma patients presenting with acute exacerbation in the emergency room, or for non-acute care in an asthma clinic. They found that lower HL status had a moderately positive correlation with lower mean asthma knowledge on a validated instrument ($r = 0.36$). In addition, the adjusted coefficient in multivariate analysis for the lowest HL status and the lowest asthma knowledge score was -2.8 (95% CI = -3.6, -2.0, $p < 0.001$). This study also analyzed metered-dose inhaler (MDI) technique as a proxy for the construct of self-care, finding that again, the adjusted coefficient in multivariate analysis for lowest HL status and the lowest MDI skill score was -1.3 (95% CI = -1.7, -0.9, $p < 0.001$; Williams, Baker, Honig, Lee, & Nowlan, 1998).

Given these issues, it is not unreasonable to theorize that adults with lower HL may be less likely to adhere to complex medication regimens. This possibility has been

investigated repeatedly with patients diagnosed with HIV/AIDS (Kalichman et al., 2000). A cross-sectional study of community-living HIV patients showed that lower HL participants were four times more likely to be non-compliant with self-reported Highly Active Anti-Retroviral Therapy (HAART; AOR = 3.9; 95% CI: 1.1, 13.4, $p < 0.05$) than those with higher HL status (Kalichman, Ramachandran, & Catz, 1999). When stratified by education, HL and treatment compliance were not significantly associated in persons who had not finished high school ($p > 0.1$). However, these variables were significantly associated in participants with *more* than a high school education ($p < 0.05$). This finding suggests that either the measure of HL used (in this case, a TOFHLA tool modified to cover additional HIV-related information) may not be sensitive enough to capture this relationship, or that the manner in which this tool was used may have been inappropriate for this sample population. It must be noted that the 86% cutoff level used here to discriminate adequate HL may be considered relatively high; for example, the cutoff used by the Newest Vital Sign (NVS) tool for HL assessment (Weiss et al., 2005) is 80%. It is also possible that factors other than HL are at play in persons with less than a high school diploma (Kalichman et al., 1999). These findings were supported in 2000 by Kalichman and Rompa, who found in a cross-sectional survey of community-living HIV patients (N < 340, mean age 40 years, primarily minority population) that lower HL status participants were less likely to be taking anti-retroviral medications than higher HL patients (AOR = 1.9; 95% CI = 1.1, 3.2; $p < 0.02$). Such findings are also in accord with those in the general patient population. An earlier *qualitative* study by Baker and

coworkers (1996) found that a small population (N = 60) of public hospital patients with marginal and inadequate HL were unable to read and comprehend medication labels. This difficulty made them less able to adhere to prescribed self-care management programs.

Not unexpectedly, the converse is true; *greater* HL has been shown to be associated with *improved* medication adherence in HIV patient populations. In 2007, Graham, Bennett, Holmes, and Gross examined the association between the HL level of HIV-infected men (middle-aged, mean age not given, and African American) in a moderately small study, finding that *higher* HL participants exhibited greater medication adherence (based on pharmacy refill findings); 64% of those with $\geq 9^{th}$ grade reading level showed $\geq$ 95% adherence, while only 40% of participants with lesser literacy had this same level of adherence ($X^2 = 5.06$, $df = 1$, $N = 87$, $P < 0.05$).

Ineffective utilization of preventive services may be another consequence of lower HL status. In a widely cited study, Scott, Gazmararian, Williams, and Baker (2002) found that, in a large (N > 2700) cross-sectional assessment of new Medicare enrollees (mean age 71 years, predominantly Caucasian, slightly more females than males), those with lower HL status tended to use various preventive services less frequently than those with adequate HL. For example, adjusted odds ratios for never having an influenza immunization was 1.4, 95% CI = 1.1,1.9; never having a pneumococcal immunization was 1.3, 95% CI = 1.1, 1.7; no mammogram in the preceding 2 years was 1.5, CI 95% = 1.0, 2.2; and never having a Pap smear was 1.7,

95% CI = 1.0, 3.1. According to the AHRQ, this study is particularly notable, among the preponderance of weak effect studies in HL literature, for its possession of a moderately strong evidence base (Berkman et al., 2011).

Given the multiple negative outcomes found to be associated with lower HL, it is not surprising that decreased overall health status/morbidity also may be a problem. In 1997, Baker, Parker, Williams, Clark, and Nurss found that lower HL status patients in non-urgent, urban, public hospital settings had poorer self-reported health status than those with higher HL status (AOR = 2.19, 95% CI = 1.34, 3.59; AOR = 1.72, 95% CI = 1.20, 2.48; and AOR = 2.12, 95% CI =1.38, 3.24 for English speakers in Los Angeles, Spanish speakers in Los Angeles, and English speakers in Atlanta, respectively). In 2002, Schillinger and coworkers found that lower HL status was associated with decreased glycemic control in a large (N > 400) cross-sectional study of diabetic patients (AOR = 2.03; 95% CI = 1.11, 3.73; $P = 0.02$), as well as being associated with the negative health outcome of retinopathy (AOR = 2.33; 95% CI = 1.19, 4.57; $P = 0.01$). These data were corroborated later by the findings of Kalichman and Rompa in 2000, when HIV patients (in a study mentioned previously) with lower HL displayed lower self-reported health status than those with higher HL (AOR = 1.9; 95% CI = 1.1, 3.3; $p < 0.03$). In 2003 the comprehensive, cross-sectional NAAL survey confirmed these experimental findings, determining that adults had increasingly higher HL status with each higher level of self-reported health (National Center for Education Statistics, 2006).

Most recently, two papers further corroborated the link between low HL and mortality. First, in a very large (N > 2500), prospective study of five years duration, Sudore and coworkers (2006) found community-living older adults (mean age approximately 76 years, majority female and Caucasian) with limited HL had an adjusted Hazard Ratio (AHR) for mortality of 1.75 (95% CI = 1.27, 2.41) when compared to those participants with adequate HL. While of excellent quality, it must be noted that even well-designed prospective studies such as this may underestimate the degree of association between lower HL and mortality, because lower health literate individuals may have been more likely to predecease study commencement, or to have such significant morbidity that study participation was prevented (Sudore et al., 2006). Second, in a notable prospective study, Baker and colleagues (2007) found that a very large, new Medicare enrollee cohort (N >3,000, mean age approximately 72 years, predominantly White females) with lower HL experienced greater overall mortality rates than those with optimal HL. All cause adjusted hazard ratios (AHR) for inadequate and marginal HL compared to those with adequate HL status were 1.52 (95% CI = 01.26, 1.83), and 1.13 (95% CI = 0.90, 1.41), respectively (Baker et al., 2007).

As early as 1993, the NALS found that approximately three-quarters of Americans with an illness lasting six months or longer had limited literacy skills, begging the question as to whether or not these individuals understood their condition or how to manage it (Kirsch et al., 2002). Ten years later in 2003, Weiss contended that "literacy skills are a stronger predictor of an individual's health status than age, income,

employment status, education level, or racial/ethnic group" (Weiss, 2003, p. 7). Due to data from studies such as those cited above, adverse outcomes of inadequate HL currently are considered to exacerbate pre-existing health care disparities, especially among more vulnerable populations such as the disabled and older adults (National Patient Safety Foundation [NPSF], 2008).

Inadequate Health Literacy: Financial Costs

In the year 2000, approximately 13% of the U.S. Gross Domestic Product (GDP) was spent on health. This amounts to approximately $1.3 trillion, and represents a greater percentage of GDP than that spent on health in any of the world's highly industrialized countries (IOM, 2002). Most of this expenditure is applied to medical care and to biological/medical research (IOM, 2002). The likelihood is great that low HL skill contributes to these costs to some degree. A number of small and large studies have contributed to this hypothesis, but they have been based primarily on literacy, rather than health literacy, status. In addition, they have been highly variable in terms of sample size and methodology. A typical example is the work of Weiss and Palmer (2004), who reported that adjusted mean group differences between randomized indigent Medicaid patients with the lowest literacy status, and those with higher literacy status, were significant ($p = 0.025$), and had resulted in the difference between $10,688 and $2,891 in costs per year in a small sample population ($N > 70$, half Hispanic and one-third Caucasian, predominantly female, mean age approximately 50 years).

Central to the expenditure projections of HL advocates are the tabulations derived from the NALS and the Medical Expenditure Panel Survey (MEPS) of 1998. According to the Center on an Aging Society (CAS) at Georgetown University, these show that, "in 2001, low functional literacy resulted in an estimated $32 to $58 billion in additional health care costs" (as cited by Potter & Martin, 2005, p. 3). They further stated that "the direct medical costs of low functional literacy are financed through additional hospital and office visits, longer hospital stays, extra tests, procedures, and prescriptions. While all payers fund these additional resources, taxpayers finance a disproportionate share" (Potter & Martin, 2005, p. 3) through Medicaid (47%) and Medicare (19%).

In a 2003 white paper entitled *Eradicating Low Health Literacy: The First Public Health Movement of the 21st Century*, Pfizer, Inc. stated that poor HL affects all U.S. citizens by costing billions of dollars in otherwise preventable annual health care expenditures. These projections were based on the findings of Hohn (1997), Weiss (1999), and Gazmararian et al. (1999), and estimated that costs for patients with inadequate HL could be up to four times higher than costs for patients with adequate HL skills. As early as 2003, the National Academy on an Aging Society indicated that inadequate HL "costs the health care system $30-$73 billion annually (1998 dollars)" (Friedland, 1998, as cited by Parker et al., 2003, p. 150).

In 2007 Vernon and colleagues released a policy brief through AHRQ entitled *Low Health Literacy: Implications for National Health Policy*, which updated prior cost estimates of this problem by combining the 2003 NAAL survey results with Friedland's

previous model of aggregated cost. This revised calculation revealed staggering results. The actual present cost of low HL was projected to be between $106 and $238 billion dollars annually. This report concluded, "when one accounts for the future costs of low health literacy that result from current actions (or lack of action), the real present day cost ... is closer in range to $1.6 trillion - $3.6 trillion" (Vernon et al., 2007, p. 6).

Upon closer inspection, the evidence for such estimates is seen to be confusing. In its recent evidence report, *Health Literacy Interventions and Outcomes: An Updated Systematic Review*, the AHRQ stated that adults with lower HL tend to utilize costly services, such as emergency and inpatient hospitalization care, more frequently than other adults (Berkman et al., 2011). Upon further inspection, however, it is shown that the data underlying this conclusion is mixed in terms of its strength, because only two studies rose to the level of the inclusion criteria for this aspect of the systematic review. Of those two, both covered different sample populations and utilized different payment modalities. Consequently, their findings were deemed inconsistent. The authors admitted that, as far as HL interventions were concerned, "the evidence concerning differences by health literacy level in costs of health care was low" (Berkman et al., 2011, p. 217). This conclusion may be closer to the truth of the matter. A look back at the prior AHRQ systematic review of HL studies, called *Literacy and Health Outcomes* (Berkman et al., 2004), showed that at that time, only one study had examined the relationship between HL and health care costs; this study found no relationship between the two factors (Weiss

et al., 1998). Thus, it appears that the relationship between lower HL and increased health care costs may not be as clear as previously reported.

Health Literacy and Medication Management Issues in Older Adults

General Issues in Older Adults

Non-optimal literacy levels are a common finding among older adults (Parker et al., 2003; ODPHP, 2008). In addition, this population appears to be particularly susceptible to the effects of inadequate HL (Nielsen-Bohlman et al., 2004; Park, 2006). As a quarter of all American adults are expected to be over the age of 65 by the year 2080, this population is considered to be sizable and growing rapidly (Federal Interagency Forum on Aging Related Statistics, 2008; Kirsch et al., 2002). In 2002, the second National Adult Literacy Survey (NALS) estimated that at least two thirds of American adults over the age of 60 possessed below proficient levels of HL skill (Kirsch et al., 2002). A more detailed HL evaluation, performed in 2003 as part of the NAAL survey, expanded this estimate, showing that fully 97% of adult Americans over the age of 65 were not proficient in HL. This age group exhibited the lowest level of HL among all groups studied, and HL skill impairment was observed to increase as the age of the subject population increased (U.S. DOE, 2003). The timeline of this impairment coincides with the increasing prevalence of chronic illness in this group (CDC, 2009a), necessitating more frequent physician visits and greater numbers of prescription medications. Medication-taking is considered an essential activity of daily living (Administration on Aging, 2009), and appropriate medication management is thus seen to

be a common problem for this population (Parker et al., 2003). As a result of these factors, the problem of medication compliance exists in a nexus between inadequate HL and the highly vulnerable older adult population.

Medication-taking errors are complex and have numerous causes (Osterberg & Blaschke, 2005). This review will not examine sources of error from the health care providers' side. From the point of view of the patient, however, possible sources of medication-taking error include such factors as adherence rate variations, which may be dependent upon a patient's type of medical condition and demographic background (DeMatteo, 2004). In 1997, it was estimated that approximately half of all patients did not follow medication directions as intended (Center for Health Care Strategies). According to the Pharmaceutical Research and Manufacturers of America (2011), results from a 2006 National Community Pharmacists Association survey raised this number to an alarming 75% nonadherence rate when multiple forms of nonadherence were measured. Even medications with well-known positive benefits may not be taken as directed in older adult populations (Murray, Darnell, Weinberger, & Martz, 1986).

To ensure reliable and valid results, HL researchers have been encouraged to involve their study participants in the development of research methodology and instrumentation (Nielsen-Bohlman et al., 2004). This recommendation echoes the classic health education strategy of commencing any program by involving the community to be served (McKenzie, Neiger, & Thackeray, 2009). Such involvement has elicited the continuing mismatch between the target reading level of health-related materials (both

spoken and written) and their intended audience as a major source of concern. This area has been of particular interest to the HL community since at least 1996 (Doak, Doak, & Root). The government report, *The National Action Plan to Improve Health Literacy* (ODPHP, 2010) cites several studies to bolster this claim. Among them, a 2008 content analysis study by Hill-Briggs and Smith showed that printed patient education materials from the American Heart Association (AHA) and the American Diabetes Association (ADA) were consistently unsuitable for low health literate populations, based on missing either two-thirds (ADA) or three-quarters (AHA) of objectively defined criteria for suitability in this population.

Other areas of difficulty impacting older adults' medication-taking skills are common knowledge: difficulty adapting to the demands of new or ongoing disease development (Park, 2006), the specter of cognitive impairments (such as various dementias; Osterberg & Blaschke, 2005), and the development of normal changes in working memory due to age (Levitt, Fugelsang, & Crossley, 2006). Variations within this latter category include "decreased efficiency in information processing, declines in working memory function, and difficulty remembering context or learning" (Brown & Park, 2003 as cited by Park, 2006, p. 27). Work in this area has elicited evidence of a cognitive phenomenon specifically impacting HL in the older adult population - that of the so-called "illusion of truth" effect (Skurnik, Yoon, Park, & Schwarz, 2005, p. 714). In a small (N = 64) marketing psychology study of community-living adults, assessment was made as to whether false health-related statements would be identified later as true

due primarily to their familiarity. Older adults (mean age 78 years) were compared to younger adult university students (mean age 21 years). The older adults were more likely to identify health claims incorrectly when presented with the information three times (F= 14.30, $p < .01$). Because these findings were more pronounced than when participants were presented with the claims only one time (F= 4.90, $p < .05$), this data suggests that the phenomenon may be more marked when the context in which the information was originally learned has been forgotten (Skurnik et al., 2005). Therefore, health educators seeking to use "medical myth-busting" (Ansburg & Heiss, 2012, p. 31) as a teaching strategy for older adults must be cautious. Alternate teaching strategies, such as linking new health information to pre-existing, personally relevant memories, may be preferable to myth-busting scenarios in community-living older adults.

In 2009, Glisky and Marquine determined from a small study (N < 50) that older adults (mean age 76 years) had better memory of self-referential processing tasks than of impersonal word processing tasks as a main effect ($F(1, 44) = 44.35$, $p < .001$, $\eta_p^2 = 0.50$), perhaps because they triggered higher levels of cognitive effort. The hypothesis that greater cognitive effort may encourage improved memory retention has been prevalent in learning studies for a number of years (Diemand-Yauman, Oppenheimer, & Vaughan, 2011), and may be involved in this self-referential learning phenomenon.

Rationale for the Use of Brief Interventions in Adults

Use of brief interventions to effect behavioral change has been investigated as a means of dealing with a number of health issues in diverse populations. In 2005,

mounting evidence on brief interventions for injury prevention was sufficient for the American College of Surgeons to require Level I trauma centers to screen patients and to provide brief interventions for problem drinkers. Currently, the longitudinal Disseminating Organizational Screening and Brief Intervention Services (DO-SBIS) randomized clinical trial (in progress) seeks to ascertain the effectiveness of this approach for alcohol abuse in trauma centers (Zatzick et al., 2013). Such an interventional modality is known as an SBIRT (Screening, Brief Intervention and Referral to Treatment) (Mello et al., 2013). SBIRT is a novel public health technique that has been adapted over the last 25 years from its original IOM usage (1990) as a gap filler for care of alcohol abuse patients, and has been used in a wide variety of settings, particularly with various forms of substance abuse (Agerwala & McCance-Katz, 2012).

The use of brief interventions in older adult populations residing in independent-living communities is now of interest due to their potential applicability in overcoming barriers of poor attendance and lack of motivation (Mihalko, Wickley, & Sharpe, 2006; Rejeski & Brawley, 2006). Such interventions have been shown to be effective among this population for encouraging interest in physical activity. In a modestly sized ($N < 60$), quasi-experimental, Australian pilot study of community-living older adults (mean age approximately 74 years), Gardiner, Eakin, Healy, and Owen (2011) found a modest effect (using paired t-tests and repeated measures ANOVA) with the use of just one theory-based, goal-setting intervention session and one follow-up tailored mailing for the intervention and control groups, respectively. Findings included a significant decrease in

the amount of time participants spent in sedentary pursuits (-3.2%, 95% CI = -4.18%,-2.14%, $p < 0.001$) and an increase in both participants' light physical exercise (2.2%, 95% CI = 1.40%, 2.99%), $p < 0.001$) and moderately vigorous exercise levels (1.0%, 95% CI = 0.55%, 1.38%, $p < 0.001$) (Gardiner et al., 2011).

Of particular interest to the current study was the use of a brief intervention to improve the attendance of older adults (mean age approximately 82 years) at a physical activity program held in three retirement communities (Mihalko et al., 2006). Results from this moderately small (N < 80), randomized controlled trial of older adults (mean age 81.6 years) found that a brief, tailored, interactive and individual session significantly improved follow-up group activity session attendance when compared to a control group (which received only a mailed promotional flyer; X^2 [1, N= 79] = 24.31, $P < 0.001$). In general, this suggests that brief interventions for older adults may be more successful if they are tailored to be sufficiently individualized and personally engaging.

In particular, the use of the SBIRT modality to effect changes in elders' medication management skills has been studied through the prospective 2004-2007 Florida BRITE project (Brief Intervention and Treatment for Elders), as recently described by Schonfeld and colleagues (2010). In this setting, SBIRT (varying from 1 to 5 sessions on goal-setting and medication management, and given as motivational interviews within a 30-90 day window) was administered to older adults (mean age 75 years; predominantly female and Caucasian) in four Florida counties. Analysis via repeated ANOVAs and two-tailed Tukey tests indicated that the intervention improved

medication misuse for prescription drugs in 32% of screened participants ($p < 0.05$; N < 190), and for misuse of over-the-counter drugs in nearly 96% of screened participants ($p < 0.05$; N = 24) by the time of discharge.

Theoretical Foundations of Health Literacy and Medication Management

Historical Background

Historically, HL literature has focused upon four successive, overlapping areas of inquiry. The first major category addressed the prevalence of the problem in various populations (Kirsch et al., 2002; ODPHP, n.d.b.; OSG, 2007; Parker et al., 2003), while the second area focused on analysis of mismatch readability issues between HL skill levels and textual materials (Estrada, Hryniewicz, Higgs, Collins, & Byrd, 2000; Forbis & Aligne, 2002; Paasche-Orlow, Taylor, & Brancati, 2003). The third literature category targeted patient navigation issues within the healthcare system, and touches upon the issues examined in the current study. To date, this has been the broadest area of study, covering complex problems associated with the quality of patient-provider communication, and identifying many adverse outcomes associated with inadequate HL, especially in specific disease states such as HIV, diabetes, and cardiovascular disease. Patient-provider communication has been investigated from the standpoint of communication style, treatment compliance (including medications), and shared decision-making models (Chapman, Abraham, Jenkins, & Fallowfield, 2003; Dickinson & Raynor, 2003; Piette, Schillinger, Potter, & Heisler, 2003; Schillinger et al., 2003). The fourth, most recent area of literature has addressed the development and impact

assessment of novel interactive health communication technologies for HL interventions (Hahn et al., 2004; McCray, 2005; Oenema, Brug, & Lechner, 2001). Because HL research is a relatively new field, a recognized set of best practice strategies for interventions has not yet been defined (Berkman et al., 2004).

Research into adult medication adherence and HL has been particularly fruitful in HIV patient populations, where a number of studies have shown a significant association between low HL and lack of adherence to medication instructions. The work of Kalichman, Ramachandran, and Catz (1999) in this field has been previously mentioned, as has that of Kalichman and Rompa (2000). In 2007 these findings were buttressed by a widely cited study from Wolf and colleagues documenting the association between decreased HL and medication adherence in HIV patients. In a moderately large population of these patients presenting at infectious disease clinics in two states ($N > 200$, approximately half African-American, predominantly male), it was found that lower HL participants had a 3.3 times greater likelihood of being non-compliant with their medication protocol than higher HL patients ($p < 0.001$), and that SE strongly mediated this association (AOR 7.4; 95% CI 2.7, 12.5) (Wolf et al., 2007a).

Information regarding the HL of older adults and its effects on medication management/compliance represent a small subset of articles within these larger topic areas. In particular, quantitative HL research on effective educational interventions in vulnerable populations, such as older adults, is not a common finding (Vernon et al., 2007). Such research is especially needed to assess the nature of the pathway between

low HL and negative health outcomes, and to evaluate the efficacy of various modes of health literacy intervention (McCray, 2005; OSG, 2007). As a result, the present literature review seeks to focus on the overall information available on this topic at the current stage of development in the HL field.

Classic Theoretical Frameworks

A number of so-called "classic" theoretical frameworks have been used to inform health communication / health literacy studies over the years, among them Bandura's Social Cognitive Theory (SCT; Bandura, 1986; Bernhardt, 2001), the Health Belief Model (HBM; Janz & Becker, 1984; Rosenstock, 1974), the Theory of Planned Behavior (TPB; Ajzen, 1991), and the Transtheoretical Model (TTM; Prochaska, 1984), as well as Decision-Making Theory (Charles, Gafni, & Whelan, 1999), Diffusion of Innovations (Rogers, 1995), and varieties of learning theory. In 2000, Guttman asserted that, "as a result, health communication interventions have tended to focus on expert-driven, risk-based information and rational decision-making by individuals about discrete behavior change" (Neuhauser & Kreps, 2003, p. 10), rather than on the dynamic interface between the individual and the larger society.

SCT constructs such as self-efficacy (SE) have heavily informed HL (Bernhardt, 2001) and the concept of self-management skill (Tobin, Reynolds, Holroyd, & Creer, 1986, as cited by Gallant, 2003), also known as self-care. In turn, self-management has long been considered to include medication compliance (Clark et al., 1991, as cited by Gallant in 2003). Gallant states that, overall, self-efficacy holds a major place among

constructs which mediate self-management skills. The absolute centrality of the HBM (Rosenstock, 1974) to patient self-care behaviors was examined in a 1996 study by Pham, Fabienne, and Thibaudeau. According to these authors, a major factor mediating lack of compliance with self-care regimens in a chronic disease population ($N < 80$, diabetic, predominantly ≥ 60 years) is the degree to which patients feel a mode of therapy is congruent with their own personal "health beliefs model" (Langer, 2008, p. 386). This personal model is based on individual feelings about perceived susceptibility (based on age), costs (including regimen complexity, according to Ley in 1988, and body image, according to Langer in 2008), disease severity, and treatment efficacy.

The concept of patient activation, as a measure of a patient's readiness to become actively involved in their own self-care was developed by Hibbard, Stockard, Mahoney, and Tusler in 2004 as a health behavior-specific extension of the constructs of locus of control, self-efficacy, and readiness to change. As a stage, patient activation corresponds roughly with the two TTM stages of precontemplation and action. The "Patient Activation Measure" (PAM) was developed as a unidimensional way to assess this construct, and various studies have shown that higher PAM scores correlate (modestly) with better health management behaviors.

Primary among the studies using the PAM was an extremely large ($N > 4000$) randomized, cross-sectional survey of chronic disease outpatients (mean age approximately 62 years; predominantly Caucasian; one-half female; Mosen et al., 2007). This study found a significant independent association between the highest PAM scores

and the use of multiple self-management strategies (AOR = 1.68, 95% CI 1.31, 2.16), as well as with the highest level of medication adherence (AOR = 2.65, 95% CI 1.74, 4.03), the highest level of satisfaction with medical care (AOR = 10.01, 95% CI 7.49, 13.39) and the highest rating on self-reported quality of life (AOR = 5.04, 95% CI 3.83, 6.63), when compared to participants with lower PAM scores in multivariate logistical regression. Furthermore, the PAM tool was proven to be extremely robust, in that each increased level of PAM scores was found to be associated in a continuous fashion with better health management behaviors/outcomes in every functional category; i.e., Stage 2 PAM scores showed better outcomes than Stage 1, Stage 3 showed better than Stage 2, and Stage 4 showed the best outcomes of all (Mosen et al., 2007).

Also in 2007, Hibbard, Peters, Dixon, and Tusler assessed HL, numeracy, and patient activation in a convenience sample (N > 300, mean age 37 years; no ethnicity or gender data given). Using the PAM as a stand-in for the construct of motivation, Hibbard and coworkers found that the correlation between literacy and numeracy (a sub-domain of HL) was strongly positive at $r = 0.51$ ($p < 0.001$), but that the correlation between HL and patient activation was not significant. Patient activation appeared to play "a stronger role in outcomes" (Hibbard et al., 2007, p. 385), when clients' HL skills were low than when they were higher, possibly serving as a type of compensatory mechanism – this was seen for both those with lower HL as well as for those with lower numeracy, where participants with higher activation levels had higher comprehension scores than those with lower activation levels [multiple data sets given, no summary data available].

Two years later, in a moderately large (N < 290) cross-sectional survey of adult patients in a metropolitan public diabetes clinic (mean age 51.5 years, 90% African-American, predominantly female), Rask and colleagues (2009) attempted to validate the PAM as a method for assessing patient activation. This study found that the PAM construct correlated with a greater likelihood of performing several self-care activities, but medication compliance was not one of them. However, higher PAM scores did correlate with significant differences in *attitude* about medication compliance (70.0 mean score for no to little difficulty taking medications versus 64.8 mean score for somewhat to very difficult taking medications, $p = 0.41$). PAM scores were not predictive of any changes in health care utilization during the 6 months follow up period of this study (Rask et al., 2009). It must be noted that, as the first formal use of the PAM in an indigent population, these results may have been skewed by self-selection of more activated clients. In addition, the indigent participants in this study may have been inclined subconsciously to present themselves in a favorable manner to the health care researchers in a form of social desirability bias; this behavior might artifactually elevate their activation scores. This study also was limited by the fact that it purported to assess the validity of the PAM tool, but neither content validity, construct validity (Malmgreen, 2005), criterion-related validity (Kimberlin & Winterstein, 2008), test-retest reliability (Malmgreen, 2005) or internal consistency (Cronbach, 1951) issues were addressed (Rask et al., 2009). Given the state of the literature, patient activation has not been found to be a strongly significant construct for mediating HL.

Lesser Known Models Addressing Health Literacy

Lesser known models used to inform HL interventions have included the Elaboration Likelihood Model of Petty and Caccioppo (1986), the Theory of Construct Preferences (Lichtenstein & Slovic, 2006), and the 2007 causal pathway model of HL provided by Paasche-Orlow and Wolf. Each of these will be discussed in the following sections.

According to Bernhardt (2001), the Elaboration Likelihood Model of Petty and Caccioppo (1986) is a health communication theory that helps to "explain and predict how and why people attend to and process communication messages" (Bernhardt, 2001, p. 292). It has been used as the basis for development of visually appealing guidelines for written materials targeted to low HL clients. These guidelines include, among others, the use of ample white space, 12- to 14- point font sizes, and the inclusion of only one visual image per message (Canadian Public Health Association, 1998; CDC, 1999) as strategies for written presentation of material.

Peters, Dieckmann, Dixon, Hibbard, and Mertz (2007) used a cross-sectional, randomized survey (convenience sample, mean age 37 years) to test the Theory of Construct Preferences (TCP). The TCP states that individuals in new and complex environments do not really know what issues are important to them. Thus, consumer health care information presented in these scenarios must be carefully organized and arranged in order to maximize comprehension, especially for less health literate clients (such as older adults). This study was unique in that it separated out numeracy as a

distinct HL subskill, instead of subsuming it into the overall construct of HL, as is usually done (Peters et al., 2007), and in that it used health care quality data as the type of text to be comprehended. When the minimum amount of random but pertinent information was presented, versus random, pertinent information plus additional extraneous information, ANOVA results showed that the former, more parsimonious format resulted in better comprehension than the latter [$F(1,298) = 12.8, p < 0.001$]. These findings were taken to indicate that "less is more" (Peters et al., 2007, p. 169) when presenting numerical health information. In addition, lower numeracy-skilled respondents both understood and performed better than higher-numeracy skilled participants [interaction effect $F(2,295) = 3.4, p < 0.05$] when the presentation was streamlined and when important information was highlighted. Lower HL participants also performed better when presentation was ordered logically versus ordered randomly [$F(1,130) = 7.1, p < 0.01$], and performed better when information presented was minimal in amount as opposed to minimal plus extraneous [$F(1,130) = 13.5, p < 0.01$].

Integrated Conceptual Models of Health Literacy

Of the 12 different conceptual models posited for HL so far (Sorensen et al., 2012), one of the most comprehensive, integrated theoretical models was put forth in 2009 by von Wagner, Steptoe, Wolf and Wardle. As such, it will be discussed in detail here. These authors proposed a modification of the HL and health outcome causal pathway model of Paasche-Orlow and Wolf (2007). The theoretical foundation of the 2007 model had, in turn, been based upon earlier Social Cognitive Theory (Bandura,

1986), the Health Belief Model (Janz & Becker, 1984; Rosenstock, 1974), and the Theory of Planned Behavior (Ajzen, 1991), thereby making it a highly integrated model.

In the modified 2009 model, von Wagner and colleagues describe an overarching, inclusive framework for understanding HL actions and outcomes, thereby anchoring HL within the overall network of intrapersonal and extrapersonal (community-level) factors that influence it (Figure 1). Within this causal pathway, the cognitive and psychosocial determinants which mediate health actions were subdivided in to a *motivational phase* and a *volitional* or *action control phase*, with system factors impinging upon each (Figure 1). Within the *Motivational phase,* knowledge and understanding, attitudes and beliefs were included. Thus, this phase was informed by the Health Belief Model (Janz & Becker, 1984) and the Theory of Planned Behavior (Ajzen, 1991), and encompassed the sub-domains of both knowledge and attitudes. Within the *Volitional phase*, *Task-specific skills* (such as *information processing* and *navigational skills*, *decision-making skills*, and *cognitive and illness management skills*) were included. Thus, this phase was informed by the SCT (Bandura, 1986).

These various cognitive and psychosocial determinants then were posited to produce one of three possible domains of health action: 1) *access and use of health care*, 2) the *patient-provider interaction* (also known as *shared decision-making*), and 3) *management of health and illness* (formerly known as *self-care*) (Figure 1). It is this last health action domain that included the outcome of *adherence to medication*, which becomes crucial when considering the current research under discussion (Figure 1 and

Figure 2). By positioning the domain of *Sociocognitive or psychological determinants* between HL and health outcomes, von Wagner and colleagues (2009) have improved the 2007 causal model, more effectively explaining the diverse range of effects that HL can exert on distal health outcomes. In contrast, HL in the 2007 model had been positioned as the direct moderator of three key areas of health outcomes (von Wagner et al., 2009).

In 2012 an even more comprehensive integrated model of HL was proposed by Sorensen and colleagues. This model attempted to synthesize all of the 17 different definitions of HL with all of the 12 different extant conceptual models for it. This model was an advance over prior models with regards to its completeness, and is shown in Figure 3. However, due to its complexity, Sorensen's model does not serve as a significant improvement over that of prior versions for the purpose of the current study on a medication management intervention. By developing a model in which knowledge, attitudes, beliefs, and task-specific skills were designated as crucial components mediating the effect of HL on health outcomes, von Wagner and coworkers (2009) described a comprehensive, inclusive theoretical framework that is convenient and suitable for testing – specifically, as to whether the improvement of knowledge of medication management, and assessment of self-efficacy about medication management activities, may be effected by utilizing a targeted intervention suitable for a community of independently living older adults.

This same phenomenon has been noted in a systematic review of literature describing direct testing of participants' HL and describing low HL status prevalence in

the U.S. (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005), the conclusion of which was that motivation, volition, and skill sets are all appropriate targets for improving medication compliance in regards to health literacy. To date, however, most studies in this area have been disease-specific, and an assessment of the role played by HL in mediating general population health has been lacking (von Wagner et al., 2009). These findings point to additional need for evaluating generalized medication management interventions.

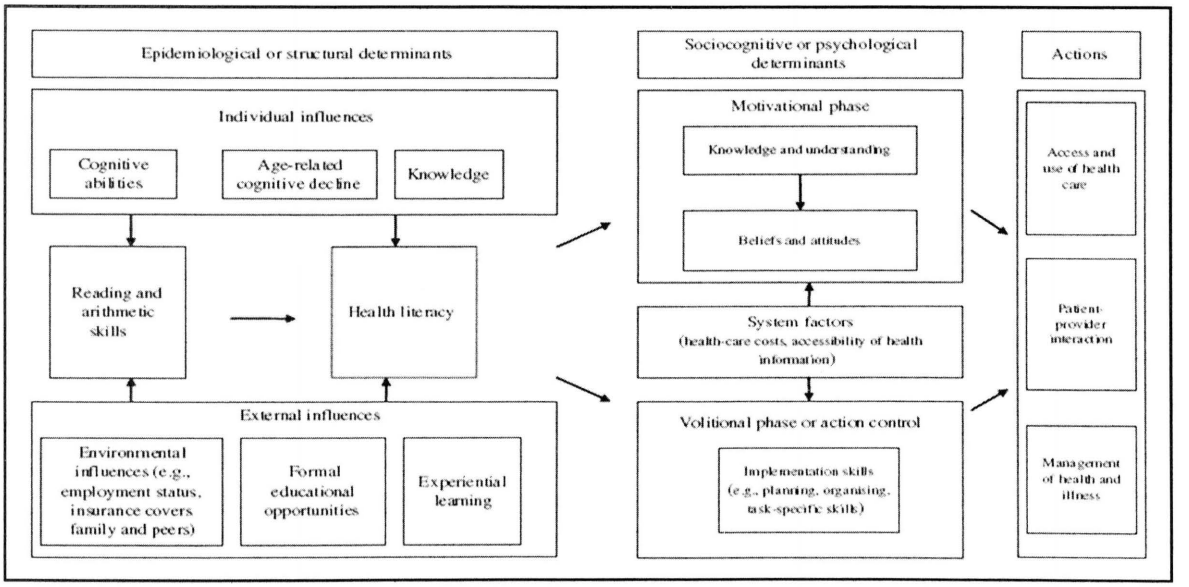

Figure 1. Overall framework of health literacy, its psychosocial determinants, and various health actions. From Von Wagner, C., Steptoe, A., Wolf, M. S., & Wardle, J. (2009, October). Health literacy and health actions: A review and a framework from health psychology. *Health Education and Behavior, 36*(5), p. 863. Reprinted courtesy of SAGE Publications.

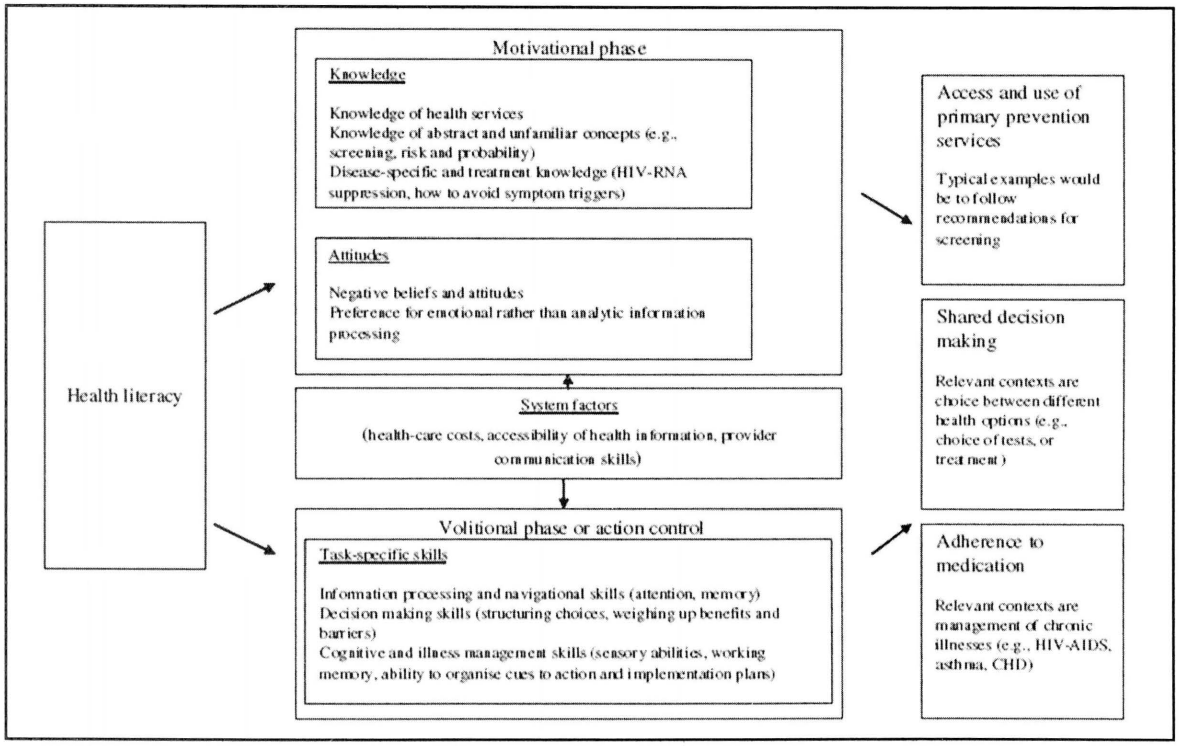

Figure 2. Expanded view of pathways between health literacy and health action outcomes, including adherence to medication. From Von Wagner, C., Steptoe, A., Wolf, M. S., & Wardle, J. (2009, October). Health literacy and health actions: A review and a framework from health psychology. *Health Education and Behavior, 36*(5), p. 866. Reprinted courtesy of SAGE Publications.

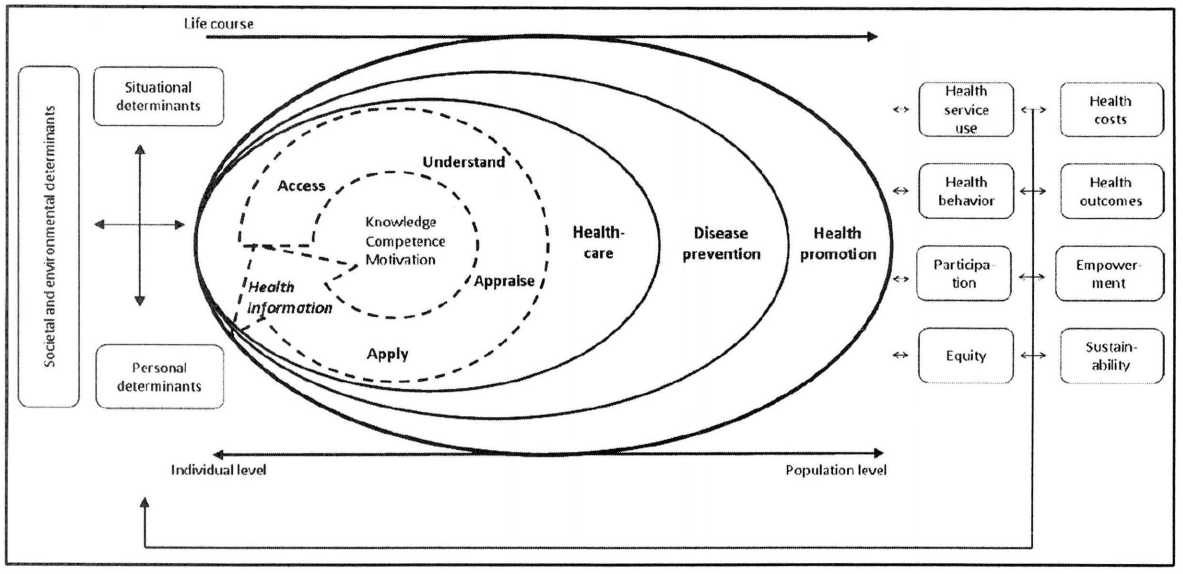

Figure 3. Integrated model of health literacy. From Sorensen et al., (2012). Health Literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health, 12*(80), p. 9. Reprinted from an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Studies of Medication Management Issues in Older Adults

Studies of the factors associated with medication adherence in older adults can be divided into three major categories: those investigating the problem from the points of view of the health care provider, the pharmacist, or another health professional. These studies vary widely in terms of their research design, ranging from qualitative interviews

(Swanlund et al., 2008) to quantitative cross-sectional surveys, questionnaires, and technology-assisted, pill-counting assessments (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008; Ho, Bryson, & Rumsfeld, 2009). Those studies relying on self-report may have been limited somewhat by inherent response biases (Ho et al., 2009), such as recall and/or social desirability bias. Despite this range of variation, some valuable insights into the factors associated with medication adherence and management still can be gleaned from them.

The Health Care Provider's Point of View

Both physicians and nurses have been interested in the issue of medication compliance in the elderly. Physician-driven studies of the problem of medication compliance in the elderly are seldom based within theoretical frameworks of social science and behavior change. Physicians have been known to rely on observation and clinical judgment in order to ascertain the incidence of medication nonadherence, and this objective, empirical approach is evident in many quantitative research studies of complex medication adherence interventions (Haynes et al., 2008). When physicians use behavior change theory as a theoretical framework, it is usually in the form of empirically obvious constructs, such as *self-efficacy* or *perceived susceptibility* (Bandura, 1986). As evidenced by the volume of literature in the field (Gazmararian et al., 2006; Haynes et al., 2008; Mann, 2009; Osborn, Paasche-Orlow, Bailey, & Wolf, 2011; Viswanathan et al., 2012; World Health Organization, 2003), physicians specializing in cardiovascular disease (CVD) have been particularly active in research studies directed toward

medication adherence. This is logical given the high rates of poor medication compliance and consequently increased morbidity and mortality in CVD-related conditions (Mann, Allegrante, Natarajan, Halm, & Charlson, 2007; Munger, Van Tassell, & LaFleur, 2007).

Quantitative studies of CV drug adherence by clinicians frequently use a self-report questionnaire to quickly assess patients' medication-taking behaviors; the underlying assumption here is that poor behavior indicates poor adherence (Mann, 2009). An example of such a survey is the "Morisky Medication Adherence Scale" (Morisky, Ang, Krousel-Wood, & Ward, 2008), or the "Hill-Bone Compliance Scale" (Kim, Hill, Bone, & Levine, 2000) for antihypertensive medication compliance. Using these and functional adherence ability assessments, such as mental status screening via the "Mini-Mental State Exam" (Benner et al., 2002) or the "Patient Health Questionnaire-9" (Kroenke, Spitzer, & Williams, 2001), clinicians have correlated adherence behaviors and adherence beliefs. From these types of studies a number of important risk factors have emerged which have been associated with medication noncompliance in older adults. A number of these risk factors will be discussed here.

Some factors complicating medication management scenarios in adults are considered common knowledge in the field, as evidenced by their repetition in the literature. Chief among these are impaired cognition and memory, inadequate comprehension of the medication's effects on the desired health outcome, the presence or absence of a caregiver or social support, difficulty accessing the medication (including distance issues, formulary restrictions, expense, and healthcare system navigation

problems), impaired overall health status and/or manual dexterity, and specific beliefs pertaining to barriers or susceptibility (Mann, 2009; Ownby, 2006). The following section will discuss several experimental studies that have expanded upon aspects of these medication management factors.

Memory impairment, or other type of cognitive impairment, such as depression, has been postulated as impinging upon medication adherence in older adults. The Cohort Study of Medication Adherence among Older Adults (CoSMO) assessed a very large (N < 2200) cross-section of independently-living older adult hypertension patients (mean age 75 years, predominantly Caucasian, approximately two-thirds female). This study found that depressed patients were two times more likely to exhibit noncompliance with anti-hypertensive medication both at baseline (AOR = 1.96, 95% CI = 1.43, 2.70) and at one-year follow-up (AOR = 1.87, 95% CI = 1.32, 2.66), respectively. However, neither formal diagnosis nor duration of depressive symptoms was determined, begging the need for further studies in this regard (Krousel-Wood et al., 2010).

The deleterious effects of inadequate comprehension of a medication's purpose or instructions for use was shown in a large study (N > 600) by Persell and colleagues in 2004. Middle to older -aged (mean age 52 ± 17 years) ambulatory care patients were found to be more likely to lack knowledge of indications for taking their medication as their age increased. In this study, every 10-year increment in age increased the multivariate adjusted odds ratio for misunderstanding by 1.67 (95% CI 1.38, 2.02; p <0.003) (Persell et al., 2004).

Related to decreased comprehension, miscommunications between the patient and the health care provider, such as receiving conflicting information, has been theorized as a barrier to appropriate medication management. In 2009, Carpenter and colleagues studied chronic vasculitis patients as part of the Accessing Social Support in Symptom Treatment (ASSIST) study. This novel, Internet-based, cross-sectional survey used statistical mediation modeling with a nonparametric bootstrap methodology (Preacher & Hayes, 2008) to evaluate the roles that conflicting information, self-efficacy (SE), and other factors might have on medication compliance. In a middle-aged population (N > 200, mean age 51 years, predominantly female and Caucasian), findings showed that conflicting information had a direct association with medication noncompliance (Point estimate 0.0619 [SE 0.0279], $t = 2.22$, $p < 0.03$; adjusted $R^2 = 0.25$). This direct effect was not mediated by outcome expectations or SE. Unfortunately, the low recruitment response rate in this study presupposes the existence of a possible selection bias, which is logical given the Internet venue used for both the original and 3-month follow-up questionnaires (Carpenter et al., 2009). Such bias limits the external validity of this study, especially to older adults with limited access and inclination to Internet use on the other side of the so-called "grey digital divide" (Morris, 2007, p. 1).

Lack of social support, such as in living by oneself, or not having access to a caregiver (Ownby, 2006) has been theorized to impact medication compliance. In the CoSMO study mentioned previously, Krousel-Wood and colleagues (2010) also demonstrated that having lower levels of social support was associated with lower

medication adherence for hypertension drugs (AOR = 1.27, 95% CI = 0.98, 1.65) at baseline and AOR = 1.30, 95% CI = 0.98, 1.72 at 1 year follow-up).

Healthcare system navigation problems have been postulated as a significant influencing factor for medication management activities in older adults (Mann, 2009). In 2007, Paasche-Orlow and Wolf stated that, even though there was no quantitative data published yet demonstrating the impact of navigation in this regard, the extreme complexity of the American health care system made this issue a significant one for HL frameworks. Navigation skill was therefore included as a patient factor on par with SE and perceived barriers in their 2007 model detailing a putative causal pathway between HL and health outcomes (such as medication management). A seminal study in this area, unusual for it use of qualitative methodology by a physicians' group, was that conducted by Baker and coworkers in 1996. A small population (N = 60, predominantly African-American and Latino, no gender data given) of adult public hospital patients with marginal and poor HL skills were interviewed, both individually and in focus groups. These participants reported difficulty navigating multiple forms of health care interactions, including "accessing the health care system, understanding recommended treatments, and following the instructions of providers… [including making] serious medication errors" (Baker et al., 1996, p. 329).

Several authors have posited that a patient's personal health belief system is a major influencing factor on his or her medication compliance (Langer, 2008; Mann, 2009; Ownby, 2006). A rare prospective, longitudinal survey of patients (N > 70, mean

age 61 years, predominantly male, ethnically diverse) at a regional Veterans Administration Medical Center was conducted by Mann, Allegrante, Natarajan, Halm, and Charlson in 2007. Their findings underscored the importance of various pre-existing beliefs to medication management activities. In multivariate regression of repeated measures, this study found strong, predictive associations between self-reported *non*adherence to statin medication therapy and patients' beliefs in the potentially curative effects of that therapy (expressed as an anticipated short duration of said therapy (OR = 3.6, 95% CI = 1.4, 9.4). In addition, patients with a lowered perception of their own heart attack risk were three times more likely to be nonadherent, (OR = 3.1, 95% CI = 1.1, 8.7), and those concerned about statin side effects were two and a half times more likely to be nonadherent (OR = 2.5, 95% CI = 1.0, 6.3) (Mann et al., 2007).

New work by Sirey and coworkers (2013) has corroborated previous studies on the importance of both logistical barriers and belief perceptions in relation to medication adherence. In a moderately large (N < 300) cross-sectional survey of independently-living older adults (mean age approximately 76 years, two-thirds Caucasian, predominantly female) attending community-sponsored meals, multivariate logistical regression showed that both manual dexterity issues (OR = 2.16, 95% CI = 1.3, 3.6) and the perception of a lower risk to benefit ratio for medication-taking (OR = 0.73 [95% CI = 0.6, 0.94]) were independently associated with the lack of medication compliance (Sirey, Greenfield, Weinberger, & Bruce, 2013).

Of note is a particularly innovative study in the annals of HL research, which was conducted in 2011. Here Osborn, Paasche-Orlow, Bailey, and Wolf sought to statistically validate the HL and self-care pathways described in the earlier proposed causal framework of Paasche-Orlow and Wolf (2007). Their cross-sectional study assessed hypertensive adult patients (mean age approximately 54 years, two-thirds female, three-quarters African American) in four primary care clinics covering three states. The authors found weakly positive but statistically significant pathway links from HL to knowledge ($\rho = 0.22$, $P < 0.001$), from knowledge to SE ($\rho = 0.13$, $P < 0.01$), from SE to physical activity (the latter construct was used as a marker for self-care; ($\rho = 0.17$, $P < 0.01$), and from physical activity to health status ($\rho = 0.17$, $P < 0.01$). These results thereby delineated a potential path for the mediating effects of HL on health outcomes. The findings were of good quality; the parsimonious model exhibited strong data fit ($\chi^2(3$ N = 330) = 5.42, $p = 0.14$, Comparative Fit Index [CFI] = 0.99, Root Mean Error of Approximation [RMSEA] =0.05 [90% CI = 0.00, 0.11], where CFI > 0.90 and RMSEA < 0.08 suggest a reasonable fit of the model to observed data (Rigdon, 1996). Furthermore, the sample size (N = 330) was sufficiently powered to detect large effects. Thus, Osborn and coworkers (2011) have finally helped to capture the empirical relationship postulated among these variables in the HL literature through their utilization of a path analytic modeling system. However, while statistically significant, the elucidated effects were somewhat small. In addition, due to the cross-sectional nature of this study, it cannot be

construed to propose causal relationships, because by its very nature it is limited to an examination of construct associations, not causality.

While physicians have tended to approach the problem of elders' medication management from an empirical point of view, nurses have turned to classic nursing theory for an explanation. In 2008, Swanlund and colleagues utilized Orem's classic Self-Care Deficit Nursing Theory (Orem, 2001) as the theoretical framework for a qualitative study using interviews to explore the experience of successful, everyday medication self-management from the perspective of responsible, independently living elders in retirement facilities. According to Orem's theory, the construct of *self-care agency* is defined as "the ability to engage in self-care practices to meet the requirements for health" (Swanlund et al., 2008, p. 240). *Self-care agency* is mediated by the individual's health status, health behaviors, sociodemographic and psychosocial characteristics, and interactions with both larger family and societal systems. Thus, *self-care agency* is derived from the social science constructs of *self-efficacy* and *personal agency* (Bandura, 2006), as well as from the construct of *perceived control* from the Integrated Behavioral Model (Montano & Kasprzyk, 2008). In an analysis of audio-recorded interviews, Swanlund and colleagues discovered three key patterns or themes among study participants: "successful self-management of medications, living orderly, and aging well" (Swanlund et al., 2008, p. 238). The first theme, *successful self-management of medications*, included activities of:

> ... establishing habits, adjusting routines (such as use of special travel pill cases), tracking (using unique visual cues), simplifying (such as locating medications in a central location, using 7-day pillboxes, and employing pharmacy delivery services), valuing medications, collaborating (with physicians) to manage (medications' effects), and managing costs (Swanlund et al., 2008, p. 241).

The second theme, *living orderly*, incorporated activities of "ordering and organizing daily routines, maintaining order despite complexity ... and physical limitations, and integrating medications into daily life" (Swanlund et al., 2008, pp. 242-243). The third theme, *aging well*, contained activities of purposefully "being active and perceiving one's self as healthy" (Swanlund et al., 2008, p. 243), which included medication-taking as part of an overall healthy lifestyle to accommodate for age-related health changes. The authors found that variations of these experiences were all factors associated with successful medication adherence and its integration with a healthy lifestyle for older adults.

Qualitative studies of medication adherence from nursing professionals have, like those of their physician counterparts, tended to rely on studies within a particular diagnostic group of patients, especially among those living independently. Most recently, an innovative randomized controlled trial in Australia (Williams & Manias, 2013, abstract) used motivational interviewing telephone calls to explore the medication-taking experience of a small group of adult outpatients (N = 39) with multiple comorbidities (hypertension, chronic kidney disease, and diabetes). Findings were coded using the

theoretical lens of the Health Belief Model framework (Janz & Becker, 1984; Rosenstock, 1974). Their results bolstered the conclusions of Mann (2009) and Ownby (2006) that complex medication regimens become an overwhelming and constant occupation for patients with comorbid conditions. Beliefs were found to be particularly important to this population, in that the perceived benefits of medication adherence were seen to be superseded by the barriers of managing polypharmacy. Unfortunately, as of this time, this study has not yet been published in full (Williams & Manias, 2013, abstract).

Quantitative nursing studies, while smaller in number, have also informed health care providers' research into medication compliance in the elderly. Most recently, Ingram and Ivanov (2013) examined a variety of predisposing, reinforcing, and enabling factors for self-reported antihypertensive medication compliance in a moderately sized ($N > 120$) population of community-living African American patients (mean age 60 ± 7.94 years, approximately equal gender distribution). Confirming a minor trend seen in some studies of age and compliance, multivariate regression here showed that *younger* age ($\beta = -0.247$, $P < 0.01$), rather than older age, was significantly predictive of antihypertensive *non*compliance. Correlation analyses with Spearman's rho found that lower educational attainment ($r = -0.200$, $p < 0.05$) and poorer health status ($r = -0.267$, $p < 0.01$) also correlated with decreased adherence, but HL status was *not* found to correlate directly with adherence (Ingram & Ivanov, 2013). This last finding, and that of the correlation between higher age and better compliance, may perhaps reflect the enhanced motivation

and coping characteristics of more middle-aged participants, and highlight the dangers involved in extending study population generalizations too widely based on age.

The Pharmacist's Point of View

Most recently, pharmacy-driven studies of medication nonadherence have focused on technological interventions to assist medication compliance through improved packaging and/or objective compliance monitoring (Swanlund et al., 2008). Such objective measures obviate concerns with use of self-reported adherence rates, but are not foolproof, and are not frequently encountered in real-life scenarios (McDonald-Miszczak, Maris, Fitzgibbon, & Ritchie, 2004).

Another avenue of research interest has been that of pharmacist counseling interventions to improve adherence (Morrow, Weiner, Steinley, Young, & Murray, 2007). This approach has been successful in some cases when an intervention targets a single disease state (Viswanathan et al., 2012). In 2006, Lee, Grace, and Taylor conducted a moderately large (N >350) prospective, randomized controlled trial of a comprehensive pharmacy counseling intervention for medication adherence in community-living elders (mean age 78 years, predominantly male, taking an average of nine medications). At 6 months follow-up, results showed medication compliance had improved from 61.2% at baseline to 96.9% (SD = 5.2%; $P < 0.001$), and was accompanied by actual health outcomes improvement, as reflected in both systolic blood pressure (from 133.2 [SD = 14.9] to 129.9 [SD = 16.0] mm Hg; $P = 0.02$), and in Low Density Lipoprotein-C levels (from 91.7 [SD = 26.1] to 86.8 [SD = 23.4] mg/dL; $P =$

0.001). Improved adherence persisted at an additional 6 months follow-up in a randomized subset of the original participants. At this later endpoint, medication adherence dropped to 69.1% (SD = 16.4%) among participants in the control group (without extended pharmacy counseling), while those with continued counseling dropped their adherence rate only slightly, to 95.5% (SD = 7.7%; P <0.001) (Lee et al., 2006).

In a randomized controlled trial rated as 'good quality' by the AHRQ in a systematic review (Berkman et al., 2011), Murray and coworkers (2007) tested yet another complex pharmacy-led intervention for medication compliance improvement (and subsequent cost savings) in ambulatory indigent heart failure patients (mean age 57 years, N > 300, predominantly female; ethnically diverse). This study showed decreases in emergency care and hospitalizations of 19.4% (0.82 incidence rate ratio, 95% CI = 0.73, 0.93) among intervention participants when compared to the control group. However, the authors did not stratify their results according to levels of HL, only reporting that approximately 29% of participants were not health literate as assessed by the TOFHLA. The authors also did not provide the discrimination cutoff points used for the distinction between health literate and not health literate categories, making any estimation of the link between HL and the effects of the intervention on health care costs difficult. Furthermore, medication adherence improvements between the two experimental groups were nonsignificant by the end of the three month follow-up period (Murray et al., 2007).

For patients with multiple chronic comorbidities, pharmacist counseling has not been as successful at improving medication compliance as it has in single disease process conditions (Viswanathan et al., 2012). An example is that of the 2003 study of Taylor, Byrd, and Krueger, which examined a small sample of older adult, comorbid patients ((N < 70), mean age approximately 66 years, predominantly female, three-fifths Caucasian) in a highly underserved, rural population at several family medicine outpatient clinics. Here, an intensive one-year pharmacy-led counseling intervention to improve medication adherence found no significant difference in self-reported medication adherence scores between experimental groups at 12 months follow-up (Taylor et al., 2003).

An embedded qualitative component in the study conducted by Taylor and colleagues (2003; described above) showed that regimen complexity in the face of multiple comorbidities, as well as expense, issues reading or comprehending directions, and difficulty in remembering, were each barriers to medication adherence that were singularly worthy of mention in exit interviews. Each of these factors has been noted by other sources (Mann, 2009; Ownby, 2006).

In a 2004 review, Murray and colleagues proposed a pharmacist's conceptual model of medication adherence for congestive heart failure drugs in older adults, thereby uniting both quantitative and qualitative findings in a more comprehensive framework. This framework was based on the behavioral health care utilization model of Phillips, Morrison, Anderson, and Aday (1998) and on the medication adherence and aging model of Park and Jones (1997). In this composite pharmacist's conceptual model (2004),

Murray and coworkers posited a *medication use system* domain as the target for medication adherence interventions. This *medication use system* contained three subunits: *patient characteristics*, *medication adherence*, and *health outcomes*. Upon inspection, social science and behavior change theories were evident in the formulation of the *patient characteristics* subunit, within which three major determinant subsets were proposed: *predisposing characteristics*, *need*, and *enabling resources*. *Predisposing characteristics* included determinants such as "knowledge, attitudes, beliefs, and expectations" (Murray et al., 2004, p. 39), and thus were heavily informed by the constructs of *behavioral intention* in the Theory of Reasoned Action (Fishbein & Ajzen, 1975), and of *perceived behavioral control* in the Theory of Planned Behavior (Ajzen, 1991). In addition, *need* determinants within the *patient characteristics* subunit include *perceptions of illness severity and outcome*, which were informed by the constructs of *perceived susceptibility* and *perceived severity* in the Health Belief Model (Strecher & Rosenstock, 1997).

Utilizing this pharmacy-developed framework, specific *patient characteristic* determinants or factors have been associated with medication nonadherence. These factors are: suboptimal attitudes toward health professionals' advice; impaired medication access due to financial or transportation problems; "lack of understanding of the role their medications play in managing their disease (including over-the-counter [OTC] and herbal medications), inability to manage and reliably self-administer multiple medications" (Murray & Callahan, 2003, as cited by Murray et al., 2004, p. 37),

packaging constraints which challenge elders' manual dexterity and visual discrimination (also confirmed by Sirey et al., 2013), inappropriate perceptions of disease severity or suboptimal medication efficacy beliefs (as described by Park & Jones, 1997), and inadequate HL and cognitive and perceptual disorders (Murray, et al., 2004).

Other Health Professionals' Point of View

Health education/promotion specialists, public health practitioners, and psychologists (in the fields of motivation and memory) make up the majority of investigators in the third and final category of research into self-care activities among elderly populations. A subset of these studies looks at medication compliance. Within these fields, *patient activation*, *self-efficacy*, *perceptions of health belief*, and *locus of control* were the most commonly used constructs.

According to Hibbard and colleagues (2004), *patient activation* is a health-behavior specific extension of the constructs of *self-efficacy*, *locus of control*, and *readiness to change*, and serves as a specific measure of "patient readiness to be engaged in their care" (Rask et al., 2009, p. 623). *Patient activation* and *self-efficacy* have been used in research on various diabetic populations, as described previously in this chapter (Hibbard et al., 2007; Mosen et al., 2007; Rask et al., 2009). In these studies, higher patient activation scores generally have been associated with higher levels of appropriate self-care behaviors, usually including medication compliance.

As has been shown, quantitative studies addressing the relationship between *perceptions of health belief*, *locus of control*, and medication adherence in the elderly

frequently have been cross-sectional in nature, utilizing self-reported surveys (Gazmararian, Baker, Parker, & Blazer, 2000) such as the "Beliefs Related to Medications" (BERMA) survey (McDonald-Miszczak et al., 2004), the "Multidimensional Health Locus of Control Scale" (MHLC; Wallston, Wallston, & DeVellis, 1978), the "Hill Bone Compliance Scale" (predominantly used for antihypertensive medication compliance; Kim, Hill, Bone, & Levine, 2000), and the Beliefs about Medicines questionnaire (BMQ; Horne, Weinman, & Hankins, 1999). The BERMA survey, devised by psychologists, was based on the "Meta-Memory in Adulthood" questionnaire, which "include[d] a *self-efficacy* factor that primarily consist[ed] of *perceived capacity..*, *perceived change*..., and anxiety" (Hultsch, Hertzog, Dixon, & Davidson, 1988, as cited by McDonald-Miszczak et al., 2004, p. 595). The MHLC scale assessed whether a patient's *perceived health beliefs* are primarily related to an internal source of control, a powerful external source of control, or chance (Armstrong, 2007), and at what degree or level *perceived control* was attributable to these loci (Sarkar, Fisher, & Schillinger, 2006).

Self-report measures such as these have revealed a number of relationships between medication adherence in the elderly and various mediating factors. Within this genre, some findings concerning the relationship between medication beliefs and self-reported rates of medication adherence have varied, however. In 2004, McDonald-Miszczak and colleagues pilot-tested the BERMA survey for development of validity and reliability data. In a convenience sample of community-living, urban, older adults, factor

analysis found a significant correlation between self-reported medication adherence and memory for medications ($\rho = 0.36, p < 0.001$), as well as between reported adherence and belief in the importance of adherence ($\rho = 0.45, p < 0.01$). However, the BERMA study did not find any significant association between adherence and other medication beliefs. While comparisons with other studies are difficult to make in this regard, due to the wide variation in the form of self-report adherence measures used (McDonald-Miszczak et al., 2004), it is possible to note that these results somewhat contradicted the earlier work of Horne, Weinman, and Hankins in 1999. In the earlier study, Horne and coworkers carried out a criterion- related validity assessment of the BMQ through factor analysis, showing that belief in the perceived need for medication (a *perceived susceptibility* construct) correlated weakly with greater adherence ($\rho = 0.19$; $N = 210, p < 0.01$). Their data also showed that concerns about the suitability of present therapy were negatively correlated with adherence ($\rho = -0.28$, $N = 210$; $p < 0.001$), and weakly negatively correlated with the belief that medications could be omitted without harm ($\rho = -0.19$; $N = 210$; $p < 0.01$; Horne et al., 1999).

Obviously, variability among research methodologies hampers efforts to draw comparative conclusions from across these studies. The two major problems in this area are the lack of participant homogeneity in regard to sociodemographic and gender variables, and the wide variation in types of assessment measures used. However, most of these studies enrolled participants who were over the age of 55, and some broad patterns can be discerned – most notably, that patients must expend considerable effort to

integrate successful medication-taking into their everyday lives, that certain structural obstacles (such as physical health and healthcare system factors) can pose major barriers to the medication adherence/management process, and that a patient's pre-existing beliefs and self-efficacy can further impact this process in significant ways.

CHAPTER III

METHODOLOGY

The research design used for this study was a pre-experimental, within-subjects, one-group, pretest-posttest design (Leedy & Ormrod, 2005). Health literacy (HL) researchers have reached the consensus that motivation, volition, and skill sets are each appropriate target constructs for improving medication-taking within the generalized domain of patient self-care (Paasche-Orlow et al., 2005; Rothman et al., 2004; Sorensen et al., 2012). Because most studies in this area have been disease-specific (von Wagner et al., 2009), there is a need to assess the role of these constructs in general population health. As older adults represent an especially vulnerable population in regard to the domain of low HL (NPSF, 2008) and medication-taking, and as brief interventions are increasingly of interest (Schonfeld et al., 2010) due to their potential to lower various health education barriers (Mihalko et al., 2006; Rejeski & Brawley, 2006), this pilot study examined the effects of a brief, single-stage, tailored educational intervention on both volition (in the form of self-efficacy) and skill (in the form of knowledge) with regards to medication management in a low HL-vulnerable population of independently-living older adults.

Population and Sample

This study targeted the English-speaking independently-living older adults (greater than 65 years) residing at a non-profit retirement facility in the suburbs of a North Texas metroplex. The intervention was presented as a single informational session within an established monthly health education seminar series, thereby capitalizing on pre-existing cues to action (Janz & Becker, 1984) for series attendance already present within this population. This approach necessitated the use of a nonrandomized, purposive convenience sampling frame, which initially numbered 18 volunteer residents. This retirement facility is non-profit and run by a Christian church-based foundation. Its residents are overwhelmingly White, female, and of higher socioeconomic status (as evidenced by the facility's census and information on its pricing structure). This facility runs a monthly HL improvement program called the "To Your Health" series. The facility also has a pre-existing Wellness Center onsite, with a director whose job duties include encouraging healthy strategies for aging. The presence of these two factors influenced the researcher's decision to carry out this pilot study at this particular location.

Cognitive impairment is known to interfere with HL status (Baker et al., 2002). For this reason, data from residents having apparent problems with executive function (such as lack of orientation to time, place, or person; Luggen, 2004) were removed from data analysis under the exclusion criteria for this study. Blindness was an exclusion criteria, as well. However, no such participants were encountered. Subsequent to the data collection process, data from three participants was removed from consideration for

analysis because the testing materials were not fully completed. In addition, one participant withdrew consent one week after the intervention session. The remaining 14 participants met the eligibility requirements. Of the 14, one completed all assessment materials except for the self-efficacy post-test. Thus, this participant's data was used for the knowledge and HL assessments (N = 14), but was deleted from the self-efficacy data set (N = 13).

Of the 14 participants, all were White, and only one was male. All participants were 65 years or older. The mean age of the participants was 84.06 years. One participant was between the ages of 65 and 69 years, two were between 70 and 79 years, and 11 were between 80 and 87 years of age.

Protection of Human Participants

This study collected data in the form of basic demographic information, a small number of open-ended and close-ended intervention satisfaction questions, and knowledge and self-efficacy assessments taken before and after the medication management intervention. HL assessment scores were also taken before the intervention commenced. The Texas Woman's University (TWU) Institutional Review Board (IRB) approved this study (see Appendix A for approval letter), deeming the collection of this data to be of no more than minimal risk to the study's target population. Senior adults are not considered a vulnerable population by the TWU IRB. In compliance with the TWU IRB's guidelines, this researcher compiled the pre- and post-intervention testing instruments, post-testing satisfaction questionnaires, and the demographic survey sheets

into stapled Pre- and Post-test booklets. Each booklet was identified using the participants' first and last initials. This was logistically feasible due to the small number of participants in this pilot study. After the booklets were filled out by the participants, they were collated, and the investigator randomly anonymized the initials used as identifiers by converting to coded identification numbers. The coded numbers were used as indirect identifiers throughout the rest of the data analysis phase. The final anonymized data was reported in aggregate.

Demographic profile sheets containing participants' actual initials and their equivalent coded identification number were stored in a locked filing cabinet in the researcher's office. Only the researcher and her statistical advisor had access to these sheets. This method was chosen in order to limit the possibility that any participant's individual responses could be linked back to the original resident. The data were stored on an encrypted USB drive using AES-256 bit encryption, and will be destroyed five years after the end of this study.

Data Collection Procedures

The researcher obtained permission from the facility's parent entity to conduct this pilot study at one of their senior adult campuses. This agency approval letter is found in Appendix B. Participants were recruited through the use of activity calendars, a flyer, and brochures situated throughout this campus's independent living facility. The pilot study intervention session was held during one of the facility's regularly scheduled monthly "To Your Health" informational sessions. At this session, the researcher read

out loud a verbal script using the low HL- and older adult-tailored "Plain Language Companion Guide to the Informed Consent Form" (shown in Appendix C) in order to introduce the purpose of the research study and the need for a formal informed consent process (Lowenhaupt, 2011). Immediately thereafter, this researcher verbally went over the "TWU Consent to Participate in Research" informed consent form (shown in Appendix D), and obtained written informed consent from the participants. The goals and objectives of the intervention were briefly introduced, and then the Pre-test booklet assessments were administered. In addition to the researcher, two facility staff members remained with the group throughout the intervention. Participants were twice encouraged to ask questions at any time during the data collection or the intervention, and twice reminded that they could discontinue participation at any time during the session without penalty.

The Pre-test booklet contained a 10-item pre-intervention knowledge test and a 13-item, pre-intervention "Self Efficacy for Appropriate Medication use Scale" (SEAMS; Risser, Jacobson, & Kripalani, 2007), as well as the 6-item "Newest Vital Sign" (NVS) validated health literacy assessment tool (Weiss et al., 2005), and a short demographic questionnaire (shown in Appendix E). All of the instruments in the Pre-test booklet were administered in written form. In addition, the NVS tool was read aloud to the group by the investigator, as its designers had intended (Weiss et al., 2005). After the Pre-test booklet was completed, a 10 minute break was given to minimize the potential risk of fatigue for this age group. Upon the participants' return, a 45 minute interactive, low HL

and older adult-tailored educational session (CDC, 2009b; Doak et al., 2006; Plain Language Action and Information Network, 2010; Ridpath, Greene, & Wiese, 2009; Robert Wood Johnson Foundation, 2005; Seligman et al., 2007; Weiss, 2007) on medication management (Hawthorne, 2003a, 2003b, 2003c; Rudd, Soricone, Santos, Zobel, & Smith, 2005; Seligman et al., 2007) was provided via PowerPoint. A copy of this presentation is shown in Appendix F. Educational content was presented using both anecdotal and game show formats. At the close of this portion of the session, another 10 minute break was given. Upon participants' return, the Post-test booklet instruments were completed (shown in Appendix G). This booklet contained a post-intervention knowledge test and a SEAMS self-efficacy evaluation, and a short Participant Satisfaction Questionnaire (PSQ). Upon completion, the participants submitted their booklets to the researcher (or to the attending facility staff members), and were encouraged to ask questions and/or to view additional handouts on the session's topics if they so desired.

Instrumentation

This study collected new, primary data in the form of:

1. Quantitative pre-intervention/baseline HL scores on a validated, published, 6-item written instrument called "the Newest Vital Sign" (Weiss et al., 2005).

2. Quantitative pre- and post-test scores of medication management knowledge on a 10-item true/false quiz designed specifically for this study.

3. Quantitative pre- and post-test scores of self-efficacy for appropriate medication management on a validated, published, 13-item written instrument called the "Self-Efficacy for Appropriate Medication use Scale" (Risser et al., 2007).

4. Quantitative written post-intervention satisfaction questionnaire of participants, with a small, embedded qualitative component (Creswell, 2009) composed of open-ended questions. Both sections were designed specifically for this study.

5. Quantitative written questionnaire of participant demographic characteristics designed specifically for this study.

These instruments and their respective measurement categories are summarized in the table shown on the following page. It must be noted that the self-efficacy measurements were treated as continuous ratio data because they met the criteria of having 5 to 7 levels of measurement, and of possessing an innate order between the levels (Johnson & Creech, 1983; Zumbo & Zimmerman, 1993). Also, while race was surveyed, 100% of participants were White, so this categorical demographic covariate became a degenerate variable because it was constant.

Table 1

Instruments and their Respective Measurement Categories

Concept or Construct (Dependent Variable)	Measure	Reference	Measure-ment Level	Collection Method	When Collected
Health literacy	Newest Vital Sign (NVS)	Weiss et al., 2005	Continu-ous ratio	Written tool	Baseline only
Knowledge of medication management	Knowledge Test	Hawthorne, 2003a, b, & c Rudd et al., 2005	Continu-ous ratio	Written tool	Pre- and post-interven-tion
Self-efficacy for appropriate medication management	Self-Efficacy for Appropriate Medication Use Scale (SEAMS)	Risser, Jacobson, and Kripalani, 2007	Continu-ous ratio	Written tool	Pre- and post-interven-tion
Participant satisfaction	Participant Satisfaction Question-naire (PSQ)	N/A	Interval and qualita-tive open-ended questions	Written questionnaire	Post-interven-tion only
Participant characteristics: a. Age b. Gender c. Education d. Race	Participant Demograph-ic Profile	N/A	 a. Ratio b. Nominal c. Ratio d. Nominal	Written questionnaire	Pre- and post-interven-tion

Qualitative Assessment

An embedded qualitative component was included in this study to provide data triangulation for enhancing instrument validity for the Participant Satisfaction Questionnaire (PSQ). The embedded qualitative component consisted of four open-ended questions at the end of the PSQ, which followed the ten quantitative Likert-type questions on satisfaction (these latter questions were discussed in the preceding section entitled "Relationship between Intervention Satisfaction and HL Level").

The PSQ was designed to assess the following attributes of participant satisfaction: appropriateness of the intervention program for the target audience, facilitator competency (in this case, that of the researcher), and participant satisfaction with the intervention program's content, delivery, and setting. The four open-ended questions used to elicit these attributes were:

1. What part of today's presentation did you like the most? Why?
2. What part of today's presentation did you like the least? Why?
3. What part of today's presentation was the most useful for you? Why?
4. Please tell us if there is anything else you want us to know about today's presentation.

Data analysis showed that the participants' answers to these questions were not specific to the questions being asked; therefore, participants' responses were reviewed for thematic grouping without referencing the specific questions to which they referred.

Review of the entire data set necessitated use of "constant comparison analysis" (Leech & Onwuegbuzie, 2007, p. 565), also known as coding, in which:

> … the researcher first reads through the entire set of data… After doing so, the researcher chunks the data into smaller meaningful parts. Then, the researcher labels each chunk with a descriptive title or a "code." The researcher takes pains to compare each new chunk of data with previous codes, so similar chunks will be labeled with the same code. After all the data have been coded, the codes are grouped by similarity, and a theme is identified and documented based on each grouping (Leech & Onwuegbuzie, 2007, p. 565).

Validity and Reliability

The overriding criteria for choice of instruments in this intervention were 1) brevity, and 2) validity. The geriatric target population of this study can become fatigued easily. Imposing an undue burden on these participants by using overly detailed assessment measures might well reduce "the percentage of people consenting to participate in the evaluation" (Grembowski, 2001, p. 221).

Baseline levels of HL were assessed by the NVS tool, published by Weiss and colleagues in 2005. With only 6 items, this instrument is the shortest multi-item validated instrument found to date (Berkman et al., 2011) for evaluating HL comprehension (Ryan et al., 2008). It is based on a simple nutritional label, is estimated to take only 3 minutes to complete, and is said to be "suitable for use as a quick screening test for limited literacy" (Weiss et al., 2005, p. 514) in a variety of health care settings.

Because this tool utilizes a nutritional label format, it also evaluates numeracy skill, an important and often overlooked component of the overall construct of HL (Rudd, 2009). The NVS has a published cutoff of 4 correct items out of 6 total for the differentiation of limited versus not limited health literacy status (Weiss et al., 2005).

The NVS tool has been partially validated in both English and Spanish (Berkman et al., 2011). Summary likelihood ratios for determining inadequate or marginal HL versus adequate health literacy were found to be 5.4 for 0-1 correct answers, 1.2 for 2-3 correct answers, and 0 for 4-6 correct answers (Weiss et al., 2005). Similarly, in 2010, Powers, Trinh, and Bosworth found the NVS had summary likelihood ratios of 3.2 for 0-1 correct answers, 0.77 for 2-3 correct answers, and 0.08 for 4-6 correct answers. The NVS has been compared successfully to the "Test of Functional Health Literacy in Adults" (TOFHLA; Weiss et al., 2005), to the "Rapid Estimate of Adult Literacy in Medicine" (REALM; Osborn et al., 2007), and to the "Short-TOFHLA" (S-TOFHLA; Osborn et al., 2007). Cronbach's alpha for internal consistency reliability on the NVS was found to be > 0.76 by Weiss and colleagues (2005), to be 0.71 by Osborn and coworkers (2007), and to be 0.80 by Miser, Jeppesen, & Wallace (2013). Concurrent criterion validity for the NVS (compared to the TOFHLA) was moderately positive at Pearson's $r = 0.59$ (Weiss et al., 2005) and Spearman's rho = 0.62 (Miser et al., 2013). Pearson's r was moderately positive (at 0.41) against the REALM (Osborn et al., 2007), and strongly positive at $r = 0.61$ against the S-TOFHLA (Osborn et al., 2007).

The NVS originally was designed to be used in a primary care setting (Weiss et al., 2005). Its use expanded from there, and has included both a mixed ethnicity, middle-aged population receiving aid from Canadian community centers for low HL-vulnerable populations (Donelle, Hoffman-Goetz, Gatobu, & Arocha, 2009), as well as private practice and public health department clinics for adults of all ages (Miser et al., 2013; Ryan et al., 2008). This study offered the opportunity to evaluate the use of the NVS in an ambulatory, community-living retirement facility, which has not yet been done. (The NVS tool is not shown in the Pre-test booklet found in Appendix E due to copyright restrictions.)

Pre-test and post-test instruments for knowledge of medication management were developed designed by this researcher, based upon curriculum modified from *Medication Management Lessons 1-3* from the University of Georgia "Elderly Nutrition Program" (Hawthorne, 2003a, b, & c), and from Lessons 3-4 on "How to manage your medicines" and "How to take your medicines on time" from the National Center for the Study of Adult Learning and Literacy (NCSALL; Rudd et al., 2005). These sources provided complete lesson plans covering the major concepts addressed by this intervention - namely, knowledge and self-efficacy for medication management. Each source has been informally validated through its development process and widespread use. *Medication Management Lessons 1-3* have been used in populations of ambulatory elders at Senior Nutrition Centers throughout Georgia (Hawthorne, 2003a, b, & c), while the NCSALL

Lessons 3 and 4 have been used in adult basic education classes for learners of all ages (Rudd et al., 2005). The latter:

> ... were developed as part of the Health Literacy Study Circles Series – program facilitation guides created for professionals responsible for continuing education courses for adult educators.... These guides were distributed to all state adult education offices and are posted online. They have been piloted and used in cities and states throughout the country (Soricone, Rudd, Santos, & Capistrant, 2007, preface, para. 3).

The development process for intervention knowledge assessment in the current study consisted of two steps:

1. Designing an interactive, culturally tailored, single medication management session for older adults centered on medication adherence and memory aid strategies, using the above-referenced resources.
2. Developing short pre- and post-tests in a true/false format to assess simple Level I knowledge in the Cognitive domain (Clark, 2010; Overbaugh & Schultz, n.d.) from this curriculum.

These knowledge assessment tools are found in the Pre- and Post-test booklets shown in Appendices E and G, respectively. The key for these instruments (which are identical to each other) is shown in Appendix H.

The "Self-Efficacy for Appropriate Medication Use Scale" (SEAMS) was published by Risser, Jacobson, and Kripalani in 2007. This instrument was selected

because it is a validated, behavior change theory-based tool (Risser et al., 2007) that has been used in other medication adherence interventions described in the literature (Kripalani et al., 2007). This 13-item tool has a 3-point response scale, where 3 is coded as 'very confident', 2 as 'somewhat confident', and 1 as 'not confident'. Lack of response was coded as 0, and a maximum of 39 points was possible.

The SEAMS has been used previously for assessment of:

1. Urban African-Americans patients with coronary heart disease in a non-classroom setting (mean age 64 years; Kripalani et al., 2007)
2. Ambulatory, urban, middle-aged African-Americans using pharmacies predominantly serving the indigent in a non-interventional study design (Gatti, Jacobson, Gazmararian, Schmotzer, & Kripalani, 2009), and
3. Adult vasculitis patients in an online, non-interventional experiment concerning contradictory medication information (Carpenter et al., 2010).

Most pertinent to the current study, the SEAMS has been validated previously for older patients (mean age of 64 years) with "coronary heart disease [CHD] and other comorbid conditions" (Risser et al., 2007, p. 203). The CHD population has several significant similarities to the population addressed by the current study – namely, older age, the use of polypharmacy, and prevalence of the aforementioned multiple comorbidities. In the CHD population, the SEAMS earned an excellent internal consistency rating with a Cronbach's alpha of 0.89 (Risser et al., 2007; Cronbach, 1951). Criterion-related validity for this scale was assessed as acceptable "by comparing

composite self-efficacy scores against the [previously published and validated] Morisky adherence scale using Spearman's rho" (Morisky, Green, & Levine, 1986; Risser et al., 2007, p. 207). Test-retest reliability also was found to be moderate with Spearman's rho at $p = 0.0001$ (Risser et al., 2007). The SEAMS tool is found in the Pre- and Post-test booklets shown in Appendices E and F, respectively.

The Participant Satisfaction Questionnaire (PSQ) also was developed by the researcher for this current study, based upon prior experience developing student satisfaction surveys. This 14-item instrument was a generalized, mixed-methods tool consisting of two parts: a 10-item Likert-type scale, and a 4-item set of qualitative, open-ended questions. The Likert-type items had a 7-point response scale, where 1 was coded as 'strongly agree', 4 was neutral, and 7 was 'strongly disagree'. Lack of response was coded as 0, and a maximum of 70 points was possible. In order to maximize content validity, these questionnaires included items relating to the following attributes of client satisfaction: appropriateness of program for target audience, client satisfaction with program content, delivery, and setting, and facilitator competency. This tool is shown in the Post-test booklet in Appendix G.

The Participant Demographic Profile was developed after a review of a number of published studies on medication adherence and HL (Berkman et al., 2011; Haynes et al., 2008; Sorensen et al., 2012). Gender, age, race, and educational attainment were included because they are common items of demographic data used as potential

dependent variables in these studies. This tool is found in the Pre- and Post-test booklets shown in Appendices E and G, respectively.

Data Analysis

The current study is a pilot test for feasibility utilizing a small sample population (N = 14). As such, nonparametric statistics were most suitable for data analysis (Steinberg, 2011) concerning relationships between the dependent variables. First, however, descriptive statistics were generated to determine the frequencies and percentages of the demographic categorical variables of gender and educational attainment, the means and standard deviations (SDs) of the demographic continuous variables of age and baseline health literacy, and the means and standard deviations of the dependent continuous variables of Pre-test knowledge, Post-test knowledge, knowledge change, Pre-test self-efficacy, Post-test self-efficacy, and self-efficacy change. Change in knowledge, change in self-efficacy, and satisfaction were created variables.

Relationships among demographic variables were assessed by determining frequencies and percentages between the categorical demographic variables of gender and educational attainment, using cross-tabulations. Then, means and SDs of the continuous demographics of age and baseline HL were evaluated by each of the categorical demographics, gender and educational attainment, using the Mann-Whitney U test and the Kruskal-Wallis test. The Mann-Whitney U test is considered the nonparametric equivalent of the two-sample t test, while the Kruskal-Wallis test for intergroup differences is considered the nonparametric equivalent of the one-way analysis

of variance (Zar, 1984). Last, Spearman correlation coefficients between the continuous demographics of age and baseline HL were performed.

Additional preliminary analyses included evaluation of the relationships between dependent variables, namely the investigation of correlations between continuous dependent variables of Pre- and Post-test knowledge, and Pre- and Post-test self-efficacy. Next, relationships between demographics and dependent variables were assessed, using:

1. Means and SDs of the continuous dependent variables Pre- and Post-test knowledge, knowledge change, Pre- and Post-test self-efficacy, and self-efficacy change, by each of the categorical demographics of gender and educational attainment. This was done using the Mann-Whitney U test and the Kruskal-Wallis test.

2. Correlations between the continuous demographics of age and baseline HL, and the continuous dependent variables of Pre- and Post-test knowledge, knowledge change, Pre- and Post-test self-efficacy, and self-efficacy change. This was done using Spearman's correlation coefficient.

Research Question One

The first question proposed by this study was, "Does this tailored HL intervention increase participants' knowledge related to medication management strategies in a population of independently living older adults?" In order to answer this question, the researcher hypothesized that there would be no significant difference in participants' knowledge scores of medication management strategies after the tailored health literacy intervention. Thus, the dependent variables of Pre-test knowledge and Post-test

knowledge were compared using the nonparametric Wilcoxon paired sample test to examine the significance of the difference between pre- and post-test distributions.

Research Question Two

The second question proposed by this study was, "Does this tailored HL intervention increase participants' self-efficacy related to medication management strategies in a population of independently living older adults?" In order to answer this question, the investigator hypothesized that there would be no significant difference in participants' self-efficacy scores related to medication management strategies after the tailored health literacy intervention. Thus, as with research question one, the dependent variables of Pre-test self-efficacy and Post-test self-efficacy were compared using the nonparametric Wilcoxon test to examine the significance of the difference between pre- and post-test distributions.

Research Question Three

The third question proposed by this study was, "Can change in knowledge and self-efficacy scores before and after the tailored HL intervention be related to age, educational attainment, and/or baseline HL in a population of independently living older adults?" In order to answer this question, the researcher hypothesized that there would be no statistically significant association between change scores for knowledge and self-efficacy and participants' age, educational attainment and baseline HL. Thus, the independent variables of age, educational attainment, and baseline HL scores, and the

dependent variables of knowledge change and self-efficacy change, were analyzed as follows:

1. Spearman's nonparametric correlation coefficient was run to examine the relationship between knowledge and self-efficacy change scores with age and baseline HL scores.

2. The Kruskal-Wallis nonparametric one-way analysis of variance by ranks test was run to examine the difference in knowledge and self-efficacy change scores based on educational attainment.

Research Question Four

The fourth research question proposed by this study was, "Can participant satisfaction with this tailored health literacy intervention be related to baseline health literacy in a population of independently living older adults?" In order to answer this question, the investigator hypothesized that there would be no statistically significant association between participants' satisfaction scores with the intervention on the first 10 Likert scale-type questions of the PSQ, and baseline HL scores. Thus, the dependent variable of satisfaction and the independent variable of baseline HL were compared using the nonparametric Spearman's correlation coefficient to examine the relationship between these two variables.

Qualitative Analyses

Lastly, the embedded qualitative component of this study consisted of four open-ended questions on the PSQ. This data was summarized by inductively grouping the responses to these questions into categories based on themes (Leedy & Ormrod, 2005).

Summary

This pilot study of a low HL- and older adult-tailored educational intervention for medication management investigated the relationships between baseline HL levels and the dependent variables of pre- and post-intervention scores for knowledge and self-efficacy. Post-intervention program satisfaction also was examined. Age, gender, and educational attainment were also investigated for their effects on the above-mentioned dependent variables. This study used a convenience sampling frame of 14 independently-living older adults residing in a nonprofit retirement facility in suburban North Texas. Texas Woman's University Institutional Review Board approval was obtained, and all participants took part in the informed consent process and gave formal written informed consent. In order to minimize cognitive burden, five brief instruments were utilized: a knowledge test, the validated NVS and SEAMS tools, a Participant Satisfaction Questionnaire (PSQ), and a Participant Demographic Profile. Data from these assessment tools were analyzed using both descriptive and nonparametric statistics, in keeping with the small sample size of the study population. Results of these analyses are discussed in detail in the following chapter.

CHAPTER IV

RESULTS

This small pilot study examined the effects of a brief intervention in medication management on the knowledge and self-efficacy of community-living older adults, and evaluated their baseline level of health literacy (HL). These constructs were chosen as the major dependent variables for study because they are postulated to be important mediators of HL in the integrated HL conceptual model of von Wagner and colleagues (2009). The current study also evaluated a minor embedded qualitative component concerning this population's satisfaction with the intervention.

Descriptive Statistics

Table 2 displays frequencies and percentages for the categorical demographic variables of gender, race, and education. As shown, the majority of participants in this study were female (83.3%), all participants were White, 8 participants had only completed high school (44.4%), 5 participants had completed junior college or trade school (27.8%), and another 5 participants had completed 4-year college or held a university degree (27.8%). Of the 17 participants assessed by the NVS, 4 had 'not limited HL' status, while 13 had 'limited' HL status (comprised of aggregated low and marginal HL status categories). This yielded a point prevalence of 76.5% for limited HL in this sample population.

Table 3 displays descriptive statistics for the continuous variables of age and baseline HL. Ages for participants in the study ranged from 65 to 94 years, with a mean age of 84.06 (SD = 6.49). Moreover, baseline HL scores ranged from 0 to 6, with a mean of 2.24 (SD = 1.99).

Table 2

Frequencies and Percentages for Demographic Variables of Gender, Race, and Education

	Frequency	%
Gender		
Male	3	16.7
Female	15	83.3
Race		
White	18	100.0
Education		
Completed High School	8	44.4
Completed Jr. College or Trade School	5	27.8
Completed College or University	5	27.8

Table 3

Means and Standard Deviations for Demographic Variables of Age and Baseline Health Literacy

	N	Mean	*SD*	Min	Max
Age	18	84.06	6.49	65	94
Baseline Health Literacy	17	2.24	1.99	0	6

Relationships between Demographic Variables

Pearson's chi-square analysis demonstrated that the relationship between participants' education and gender (Table 4) was not significant, χ^2 (2) = 3.600, p = .165. Tables 5 and 6 display the means and standard deviations for the continuous variables of age and baseline HL, based upon gender and education. No significant relationships were found between these variables (p-values ranged from .176 to .870).

In Table 7, Spearman's rank correlation coefficient is displayed for the relationship between the continuous variables of age and baseline HL. This test indicated a statistically insignificant relationship (ρ = -.291, p = .258).

Table 4

Frequencies and Percentages (Crosstabs) with Pearson's Chi-Square for Education and Gender

	Male		Female			
	n	%	*n*	%	χ^2	*p*
Education					3.60	.165
Completed High School	0	0.0	8	53.3		
Completed Jr. College or Trade School	1	33.3	4	26.7		
Completed College or University	2	66.7	3	20.0		

Table 5

Means, Standard Deviations, and Mann-Whitney U Scores for Age and Baseline Health Literacy by Gender

	n	Mean	Mdn	*SD*	*U*	*p*
Age					11.5	.129
Male	3	87.00	87.0	1.00		
Female	15	83.47	86.0	6.99		
Baseline Health Literacy					25.0	.183
Male	2	.50	.5	.71		
Female	15	2.47	2.0	2.00		

Table 6

Means, Standard Deviations, and Kruskal-Wallis Chi-Square Scores for Age and Baseline Health Literacy by Education

	n	Mean	Mdn	*SD*	χ^2	*p*
Age					.28	.870
Completed High School	8	82.63	86.0	9.38		
Completed Jr. College or Trade School	5	85.20	85.0	2.39		
Completed College or University	5	85.20	87.0	3.49		
Baseline Health Literacy					.87	.648
Completed High School	8	2.25	2.0	1.39		
Completed Jr. College or Trade School	4	1.50	1.0	1.92		
Completed College or University	5	2.80	1.0	2.95		

Table 7

Spearman's Correlation between Age and Baseline Health Literacy

	Age
Baseline Health Literacy	-.291

Dependent Variable Scores

Table 8 displays descriptive statistics for the dependent variables in this study: Pre-test, Post-test, and change-in-test (or change) scores on knowledge and self-efficacy. As shown, Pre-test knowledge scores ranged from 1 to 7 with a mean of 3.93 (SD = 1.82), and Post-test knowledge scores ranged from 4 to 10 with a mean of 8.43 (SD = 1.65). Change scores on knowledge ranged from 2 to 9 with a mean of 4.50 (SD = 2.35). Regarding self-efficacy, Pre-test scores ranged from 18 to 36 with a mean of 27.07 (SD = 6.22), and Post-test scores ranged from 18 to 32 with a mean of 25.85 (SD = 4.98). Self-efficacy change scores ranged from -6 to 5 with a mean of -.69 (SD = 3.57).

Table 8

Means and Standard Deviations for Pre- and Post-test Knowledge, Knowledge Change, Pre- and Post-test Self-efficacy, and Self-efficacy Change

	N	Mean	*SD*	Min	Max
Pre-test Knowledge	14	3.93	1.82	1	7
Post-test Knowledge	14	8.43	1.65	4	10
Knowledge Change	14	4.50	2.35	2	9
Pre-test Self-efficacy	14	27.07	6.22	18	36
Post-test Self-efficacy	13	25.85	4.98	18	32
Self-efficacy Change	13	-.69	3.57	-6	5

Relationships between Dependent Variables

Table 9 displays Spearman's rank correlation coefficient for Pre-test and Post-test knowledge and self-efficacy scores. Coefficients ranged from -.089 to .784. The only significant correlation was between Pre-test and Post-test self-efficacy scores ($\rho = .784$, $p = .001$). Participants who scored high on the Pre-test also tended to score high on the Post-test.

Table 9

Spearman's Correlations between Pre- and Post-test Knowledge and Pre- and Post-test Self-efficacy

	Pre-test Knowledge	Post-test Knowledge	Pre-test Self-efficacy
Post-test Knowledge	-.089		
Pre-test Self-efficacy	.087	.248	
Post-test Self-efficacy	-.149	.468	.784*

Note. *p = .001

Relationships between Dependent and Demographic Variables

Table 10 displays means, medians, standard deviations, and Mann-Whitney U values for Pre-test, Post-test, and change scores on knowledge and self-efficacy for both male and female participants. As displayed in the table, no significant relationships exist between any of the mentioned variables and gender (p-values ranging from (.097 to 1.000).

Tables 11 and 12 display the relationship between the aforementioned dependent variables of knowledge and self-efficacy, and education. Once again the chi-squares from the Kruskal-Wallis test for nonparametric analysis of variance failed to confirm any significant relationship (p-values ranging from .273 to .990).

Table 10

Means, Standard Deviations, and Mann-Whitney U Scores for Pre- and Post-test Knowledge, Knowledge Change, Pre- and Post-test Self-efficacy, and Self-efficacy Change by Gender

	n	Mean	Mdn	*SD*	*U*	*p*
Pre-test Knowledge					11.0	.258
Male	1	2.00	2.0	-		
Female	13	4.08	4.0	1.80		
Post-test Knowledge					13.0	.097
Male	1	4.00	4.0	-		
Female	13	8.77	9.0	1.09		
Knowledge Change					11.5	.204
Male	1	2.00	2.0	-		
Female	13	4.69	4.0	2.32		
Pre-test Self-efficacy					7.0	.125
Male	1	26.00	26.0	-		
Female	13	27.15	26.0	6.47		
Post-test Self-efficacy					6.0	1.000
Male	1	26.00	26.0	-		
Female	12	25.83	26.5	5.20		
Self-efficacy Change					5.0	.789
Male	1	.00	.0	-		
Female	12	-.75	-1.5	3.72		

Table 11

Means, Standard Deviations, and Kruskal-Wallis Chi-Square Scores for Pre-test Knowledge, Post-test Knowledge, and Knowledge Change by Education

	n	Mean	Mdn	*SD*	χ^2	*p*
Pre-test Knowledge					2.59	.273
Completed High School	6	4.67	5.0	1.97		
Completed Jr. College or Trade School	4	2.75	2.5	1.71		
Completed College or University	4	4.00	4.5	1.41		
Post-test Knowledge					.77	.680
Completed High School	6	8.50	8.5	1.05		
Completed Jr. College or Trade School	4	9.00	9.5	1.41		
Completed College or University	4	7.75	8.5	2.63		
Knowledge Change					2.10	.349
Completed High School	6	3.83	4.0	1.84		
Completed Jr. College or Trade School	4	6.25	7.0	3.10		
Completed College or University	4	3.75	3.5	1.71		

Table 12

Means, Standard Deviations, and Kruskal-Wallis Chi-Square Scores for Pre- and Post-test Self-efficacy, and Self-efficacy Change by Education

	n	Mean	Mdn	*SD*	χ^2	*p*
Pre-test Self-efficacy					1.18	.554
Completed High School	6	25.67	27.0	6.22		
Completed Jr. College or Trade School	4	29.50	31.0	7.90		
Completed College or University	4	26.75	26.0	5.38		
Post-test Self-efficacy					2.50	.287
Completed High School	6	24.83	25.0	6.18		
Completed Jr. College or Trade School	4	29.00	30.5	3.37		
Completed College or University	3	23.67	24.0	2.52		
Self-efficacy Change					.02	.990
Completed High School	6	-.83	-1.5	1.94		
Completed Jr. College or Trade School	4	-.50	-.5	5.80		
Completed College or University	3	-.67	.0	4.04		

Table 13 displays Spearman's rank correlation coefficient for Pre-test, Post-test, and change-test scores on knowledge and self-efficacy, based on the continuous variables of age and baseline HL. A strong positive relationship was revealed for pre-test knowledge scores and baseline HL scores ($\rho = .646, p = .012$), but all other correlations were found to be statistically insignificant (p-values ranged from .216 to .933).

Table 13

Spearman's Correlations for Pre- and Post-test Knowledge, Knowledge Change, Pre- and Post-test Self-efficacy, and Self-efficacy Change with Age and Baseline Health Literacy

	Age	Baseline Health Literacy
Pre-test Knowledge	-.201	.646*
Post-test Knowledge	.302	.079
Knowledge Change	.319	-.353
Pre-test Self-efficacy	.229	-.025
Post-test Self-efficacy	.056	-.043
Self-efficacy Change	-.096	-.152

Note. $*p < .05$

Nonparametric Paired Sample Test for Differences between Pre- and Post-Dependent Variables

Table 14 displays the results from a Wilcoxon signed-rank test, which was used to examine if changes in Pre-test to Post-test knowledge and self-efficacy scores were statistically significant. (The Wilcoxon test is considered the nonparametric equivalent of the paired sample t test; Zar, 1984.) As shown, Pre-test knowledge scores ($M = 3.93$, SD = 1.82) were significantly lower than Post-test scores ($M = 8.43$, SD = 1.65; $W = 105.00$,

$p = .001$). No significant difference was observed between Pre-test and Post-test self-efficacy scores ($W = 30.00, p = .478$).

Table 15 displays Spearman's rank correlation coefficients for knowledge and self-efficacy change scores, and the continuous variables of age and baseline health literacy. None of the coefficients were found to be statistically significant (p-values ranging from .216 to .756).

Table 16 displays the means and standard deviations for knowledge and self-efficacy change scores based on different levels of education. Results from the Kruskal–Wallis test for intergroup differences (a nonparametric analysis of variance; Zar, 1984) revealed no significant relationship between the two measures and education ($p = .349$ and $p = .990$).

Table 14

Wilcoxon Z Scores for Pre- and Post-test Knowledge and Pre- and Post-test Self-efficacy

	n	Mean	Mdn	*SD*	*Z*	*p*
Knowledge					105	.001**
Pre-test Knowledge	14	3.93	4	1.82		
Post-test Knowledge	14	8.43	9	1.65		
Self-efficacy					30	.478
Pre-test Self-efficacy	14	27.07	26	6.22		
Post-test Self-efficacy	13	25.85	26	4.98		

Note. $*p < .05$, $**p < .01$, $***p < .001$

Table 15

Spearman's Correlations for Knowledge Change and Self-efficacy Change with Age and Baseline Health Literacy

	Age	Baseline Health Literacy
Knowledge Change	.319	-.353
Self-efficacy Change	-.096	-.152

Table 16

Means, Standard Deviations, and Kruskal-Wallis Chi-Square Scores for Knowledge Change and Self-efficacy Change by Education

	n	Mean	Mdn	*SD*	χ^2	*p*
Knowledge Change					2.10	.349
Completed High School	6	3.83	4.0	1.84		
Completed Jr. College or Trade School	4	6.25	7.0	3.10		
Completed College or University	4	3.75	3.5	1.71		
Self-efficacy Change					.02	.990
Completed High School	6	-.83	-1.5	1.94		
Completed Jr. College or Trade School	4	-.50	-.5	5.80		
Completed College or University	3	-.67	.0	4.04		

Relationship between Intervention Satisfaction and HL Level

Table 17 displays the Spearman's rank correlation coefficient between scores of participant satisfaction and baseline HL. The data failed to confirm a significant relationship between these two variables (ρ = -.416, p = .139).

Table 17

Spearman's Correlation between Satisfaction and Baseline Health Literacy

	Baseline Health Literacy
Satisfaction	-.416

Qualitative Findings

Common themes that emerged inductively from the Participant Satisfaction Questionnaire (PSQ) fell into two major groups, which were classified as positive and negative. Positive themes were found to consist of comments relating to subthemes of either general or specific intervention content, while negative themes were found to relate to subthemes of either interventional time constraints or content-related issues. Positive themes occurred more than four times as often as negative themes.

Within the framework of positive themes, the first main subtheme of general intervention content comprised feedback on the overall presentation (including, "It was all very interesting and informative", "All was very helpful", "Most useful, all of it", "All parts were important", and "It was so well presented"). A second subcategory,

comprehensibility, also emerged here. This theme was represented by the comment that the intervention was "… understandable in all the areas presented".

Within the framework of positive themes, the second main subtheme of specific content elicited the vast majority of participant feedback. Most prevalent were comments concerning the information relating to accidental over-administration of Tylenol ("Learning results of overdoing certain medicine" [*sic*], and "Tylenol interactions"). Also noted positively were the intervention content items of general medication interactions and medication side effects ("Different medicine [*sic*] cause very serious harm to parts of the body"), and general medication-taking guidelines ("Label reading and comprehensation" [*sic*], "Medication consumption", and "How to take my meds. Now I'm more aware"). The question and answer session at the close of the intervention, and the utility of the medication worksheet shown in the session, were each cited specifically and fell into this subtheme, as well.

Within the framework of negative themes, the subtheme of time constraints elicited one comment each concerning the length of the introductory informed consent phase ("too long") and that of the question and answer period at the end of the session ("needed more time"). The subtheme of content-related issues elicited one comment concerning the need for a written version of the presentation; such a handout was intentionally omitted by the researcher in an attempt to reduce the paper burden upon the participants. Additional comments in the area of negative content-related issues included one on the need for more information on all of the intervention's topics, and two on the

dislike of the use of the Newest Vital Sign (NVS; Weiss et al., 2005) HL assessment. It is important to note that verbal mention of dislike for the NVS was quite strong; approximately half of the participants voiced such a concern. The cognitive burden of the NVS tool for this participant population apparently is substantial.

Summary of Results

As expected, participants who scored high on the self-efficacy Pre-test also tended to score high on the Post-test. Additionally, there was a significant relationship between baseline HL and Pre-test knowledge, where participants with high HL scores at baseline also scored high on the knowledge Pre-test.

Primary Analyses

Research question one. For the research question, "Does the tailored health literacy intervention increase participants' knowledge related to medication management strategies in a population of independently living older adults?", the non-parametric Wilcoxon's signed rank was used to see if the distribution of Pre-test and Post-test knowledge tests were significantly different from each other. The results confirmed that Post-test scores were indeed significantly greater than Pre-test scores (M = 8.43, Mdn = 9.00, SD = 1.651 compared to M = 3.93, Mdn = 4.00, SD = 1.817; p-value = .001).

Research question two. For the research question, "Does the tailored health literacy intervention increase participants' self-efficacy related to medication management strategies in a population of independently living older adults?", the non-parametric Wilcoxon's signed rank test was used to see if the distribution of Pre-test and Post-test

self-efficacy scores were significantly different from each other. The results revealed no significant difference.

Research question three. For the research question, "Can change in knowledge and self-efficacy scores before and after the tailored health literacy intervention be related to age, educational attainment, and/or baseline health literacy in a population of independently living older adults?", the non-parametric Spearman's correlation coefficients were calculated between knowledge and self-efficacy change scores and the continuous variables of age and baseline HL. Neither of the coefficients was found to be statistically significant. The Kruskal-Wallis test was then used to determine if knowledge and self-efficacy change scores differed by education. The results revealed no significant difference in test score changes by education levels.

Research question four. For the research question, "Can participant satisfaction with the tailored health literacy intervention be related to baseline health literacy in a population of independently living older adults?", the Spearman's correlation coefficient was calculated to assess the relationship between satisfaction scores and baseline HL. The results revealed no statistically significant association between satisfaction and baseline HL.

Qualitative Results

Four open-ended questions at the end of the PSQ served as the embedded qualitative component in this study. Two major classes of themes, positive and negative, emerged from the responses to these questions. Positive subthemes related to general or

specific intervention content (namely overall curriculum presentation and curriculum content comprehensibility), while negative subthemes related to interventional time constraints or content-related issues. Positive themes occurred more than four times as often as negative themes. Dislike of the NVS HL assessment also was mentioned verbally by several participants, reinforcing its mention in this category on the written PSQ itself.

CHAPTER V

SUMMARY, DISCUSSION AND RECOMMENDATIONS

Summary

The purpose of this mixed methods study was to pilot-test a brief, low-health literacy (HL) tailored intervention for improving medication management knowledge and self-efficacy (SE) in independently-living older adults. A single-stage pre- and post-test study design was utilized to evaluate a brief curriculum covering elders' most common medication management issues. In addition to immediate changes in knowledge and SE, the convenience sample of participants from a non-profit suburban retirement facility was assessed for pre-intervention HL status, post-intervention satisfaction, and demographic characteristics. Significant results included a strong positive correlation between higher SE pre-test scores and higher SE post-test scores ($\rho = .784, p = .001$, Spearman's correlation), a strong positive correlation between pre-test knowledge scores and baseline HL scores ($\rho = .646, p = .012$, Spearman's correlation), and significantly higher post-test knowledge scores when compared with pre-test knowledge scores for all participants (10-point maximum, Post-test: $M = 8.43$, $Mdn = 9.00$, $SD = 1.651$; Pre-test: $M = 3.93$, $Mdn = 4.00$, $SD = 1.817, p < .001$). Embedded qualitative assessment for intervention satisfaction showed positive response themes four times as often as negative themes, with the NVS tool receiving most of the negative responses.

The current study exists in a unique nexus formed by the overlapping fields of health literacy studies, educational intervention curriculum and assessment, medication management improvement, and the independently-living older adult population. As a result, direct comparison of findings from the current study with published reports is difficult, due to the multiplicity of research methodologies and intervention formats found in these four diverse areas. Nevertheless, in many cases the current findings can be related to broad trends within the literature.

As expected, Pre-test Self-Efficacy (SE) was strongly positively correlated with Post-test SE on the SEAMS (Risser et al., 2007), showing that participants who scored high on the Pre-test also tended to score high on the Post-test. Comparing these results to other pre- and post-intervention SEAMS evaluations is not possible, because the tool has been used primarily for single-stage evaluation of SE in medication management-related studies (Carpenter et al., 2010; Gatti et al., 2009; Pepper, Carpenter, & DeVellis, 2012).

Baseline HL scores on the NVS had a strong positive relationship with Pre-test Knowledge scores, such that participants with high HL scores at baseline also scored high on the knowledge Pre-test. These findings suggest that the NVS can readily identify high performers on HL-related knowledge assessments, and seems reasonable given the wide knowledge base that encompasses the construct of HL skill (Berkman et al., 2011). The ability of the NVS to discriminate between 'limited' and 'not limited' HL subpopulations was discussed in Chapter 3. A broader issue here is the degree to which HL ability is associated with general literacy/educational attainment (Freedman et al., 2009). This

question has been of major concern in HL studies, and has figured prominently in the development of comprehensive theoretical frameworks to position HL and its mediators with causative outcomes (Sorensen et al., 2012). One study, in which NVS scores were found to be "strongly associated with educational attainment" (Kirk et al., 2011, p. 537), utilized a large sample of ethnically diverse older adult diabetics (> 60 years; mean age not available). However, the current study used a smaller and more homogeneous sample, and did not reveal such an association. It might be inferred that the current results suggest the NVS could be used to predict pre-test knowledge of medication management topics. Such a hypothesis must be tested in a much larger sample population, however.

The answer to Research Question One, "Does the tailored health literacy intervention increase participants' knowledge related to medication management strategies in a population of independently living older adults?" was 'yes'. Wilcoxon's signed rank test showed the distribution of Pre- and Post-test knowledge scores were significantly different from each other, confirming that post-test scores were indeed significantly greater than pre-test scores (M = 8.43, Mdn = 9.00, SD = 1.651 compared to M = 3.93, Mdn = 4.00, SD = 1.817; p-value = .001). These findings showed that knowledge scores more than doubled in all participants (measured immediately after intervention). Such an increase is supported by the findings of the Florida BRITE project (Brief Intervention and Treatment for Elders). This large study (Schonfeld et al., 2010) demonstrated the ability of brief educational interventions (varying from 1 to 5 sessions

within a 30-day window) to effect change in medication management strategies for seniors (mean age 75 years). The BRITE project found an improvement in 32% of participants referred for prescription misuse, and in over 95% of participants referred for over-the-counter medication misuse.

Common themes emerging from the PSQ were coded as positive or negative. Participants expressed significant satisfaction with the intervention; four times as many positive responses were recorded as negative responses. Positive subgroups primarily related to satisfaction with intervention curriculum, especially that concerning the dangers of accidental acetaminophen overdose. Negative subgroups reflected the need for more curriculum, more time, more opportunity for questions, and dislike of the NVS tool.

The answers to Research Question Two, "Does the tailored health literacy intervention increase participants' self-efficacy related to medication management strategies in a population of independently living older adults?", to Research Question Three, "Can change in knowledge and self-efficacy scores before and after the tailored health literacy intervention be related to age, educational attainment, and/or baseline health literacy in a population of independently living older adults?", and to Research Question Four, "Can participant satisfaction with the tailored health literacy intervention be related to baseline health literacy in a population of independently living older adults?", were 'no'. This lack of change in pre- and post-SE is corroborated by a study in which the SEAMS was used for baseline and 3 months post-intervention evaluation of a

pictorial medication management educational aid. This study found only small, nonsignificant increases in SE (Kripalani et al., 2007).

In addition, the current study found no significant relationships among the demographic variables of gender, educational attainment, age, or baseline HL. No significant relationships were found among the dependent variables of pre-test and post-test knowledge and pre-test and post-test SE. Neither were any significant relationships found between the demographic variables and the dependent variables, other than those mentioned in the preceding section. Of the 17 participants assessed for HL status by the NVS tool, 13 were found to have *limited* HL status, while 4 were found to have *not limited* HL status. These results represented a point prevalence of 76.5% for limited HL in this population.

Discussion

Quantitative HL research on effective educational interventions, especially for vulnerable populations such as seniors, have been lacking in recent years. In particular, researchers need to evaluate the efficacy of various modes of HL intervention (McCray, 2005; OSG, 2007). Improved patient education is one form of HL educational intervention that warrants extended focus (Vernon et al., 2007). Recently, interest has increased in the use of brief educational interventions for this purpose (Martin, O'Connell, Inciardi, Surratt, & Beard, 2003; Mello et al., 2013; Zatzick et al., 2013). Von Wagner's comprehensive conceptual model of HL proposed knowledge and SE (in the form of attitudes and beliefs) as key mediators of the effects of HL on health

outcomes (2009). In the current study, this model was used to develop testable hypotheses concerning improvement of medication management knowledge and SE through the use of a brief, low HL-tailored intervention for independently-living older adults. Positive quantitative findings from the current study included strong positive correlation of Pre-test SE with Post-test SE on the SEAMS (Risser et al., 2007), strong positive correlation of baseline HL scores on the NVS with Pre-test Knowledge scores, and most importantly, a statistically significant doubling of knowledge scores from before and immediately after the intervention. The qualitative satisfaction assessment revealed four times more positive than negative responses, with NVS use recorded as a negative feature.

The importance of knowledge in HL conceptual construction was recently reinforced by a landmark paper, which performed content analysis on all of the extant published HL frameworks/models to date (Sorensen et al., 2012). This systematic review found that knowledge, in the form of both information and critical skills, composed two of the six major domains found in all HL frameworks. Such analysis lends credence to the view that knowledge is a vital component of HL interventions, and is reinforced by findings from the current study. Though small, the current study fulfills three of the seven goals of the recent *National Action Plan to Improve Health Literacy*, which can be summarized as developing appropriate, accessible, and actionable adult education interventions, and "increas(ing) basic research and … development, implementation, and

evaluation of practices and interventions to improve health literacy" (ODPHP, 2010, pp. 16-17).

Limitations

This project may have been limited by several factors. Lesser limitations included such issues as the prevalence of multiple comorbidities in the sample population. Exclusion criteria for cognitive impairment and blindness were in place for this study, but no participants meeting these criteria were encountered. Nevertheless, because of the nature of this population, intervention comprehension may have been diminished in a manner unknown by the researcher. As the current study site is strongly health promotion-oriented, a type of "diffusion of treatment" threat to internal validity (Cook & Campbell, 1979) might have occurred. The intervention was limited to a single-exposure format in order to reduce this threat. However, because the study site was health promotion-oriented, it is also possible the participant sample had more baseline medication management knowledge than the typical resident of an average independent-living facility. Such a difference could pose an additional threat to external validity in the form of an interaction of setting and treatment (Creswell, 2009), where other senior independent-living facilities without monthly HL improvement programs might not yield the same results as those from the current study site.

The major limitations of this study were small sample size and lack of randomization from the convenience sampling frame. Small sample size decreases the statistical power of a study (Newsom, 2013), and invalidates the use of parametric tests

for multilevel regression analyses. In the current study, nonparametric statistics were used to help ameliorate this problem. Convenience sampling of volunteers automatically engenders a selection bias (Creswell, 2009), thus limiting the generalizability of the final results. Nevertheless, purposive convenience sampling can be valuable when studying a "clearly defined and relatively limited group" (Columbia Center for New Media Teaching and Learning, 2003, Purposive Sampling section, para. 1), as is the case in this population. While small sample size (Schmader & Pepper, 2011) and convenience sampling frames are common methodological problems of pilot studies, they do not present insuperable obstacles to drawing valuable preliminary conclusions from a pilot test design, such as suitability of recruitment protocol, intervention curriculum, setting, and instrumentation (Schmader & Pepper, 2011).

Future Research/Implications

Brief educational interventions to effect changes in health behavior have received increased attention in recent years (Martin, et al., 2003; Mello et al., 2013; Schonfeld et al., 2010; Zatzick et al., 2013). Results from this study indicate that a brief educational intervention can significantly improve medication management knowledge scores of participants. However, SE scores were not significantly changed, pointing to the future need for long-term follow-up studies to determine the presence of delayed effects on SE or the need for additional skill-based methodology for medication management. Follow-up is also important to ascertain knowledge retention for long-term outcome evaluation. Future studies would be best served by using a research design consisting of a larger

population sampling frame. Such a design would allow repeated parametric analysis of variance for evaluation of long-term outcomes for knowledge and SE.

Because this study population is more likely to experience cognitive and physical fatigue, the current intervention was formatted as a single session to aid in recruitment and retention of participants. The ideal for future iterations of this project would be to reconfigure the single intervention curriculum into a number of smaller sessions, thus yielding more opportunity for questions, and allowing elaboration of the curriculum at the participants' direction. Shorter sessions would also limit fatigue as a negative outcome for participants. In addition, participant interviews might be considered as adjunctive post-test evaluation modalities, in order to enhance triangulation for instrument validity of the PSQ.

Future use of the NVS as a HL assessment in an older adult population poses certain problems. Participants in the current study voiced strong cognitive challenge to the researcher while using the NVS tool. These findings echo those of Miser and colleagues in 2013 (population mean age 53.8 years), for whom the NVS was found to be more challenging than the S-TOFHLA as a brief HL assessment. Similarly, the NVS was found to have the lowest completion rate (73%) for older adult (> 60 years) diabetics when compared to the REALM-SF (REALM Short Form; 85%), the S-TOFHLA reading section (85%) and the S-TOFHLA numeracy section (90%) (Kirk et al., 2011).

In addition, the NVS is recommended to take three minutes for administration to adults (Weiss et al., 2005). In the current study, the researcher anticipated the sample

population (mean age 84.1 years) would take at least twice as long as recommended to complete this instrument and this was found to be true. Based on difficulties voiced by the current participants (with a mean educational attainment of 13.7 years), an administration time of 10 minutes would be more realistic. This finding is corroborated by Patel and colleagues (2011), who determined that a clinic convenience sample of African-American seniors (mean age 73.2 years with a mean educational attainment of 12.3 years) needed an average of 11.7 minutes for NVS completion. While such a time limitation is not an insurmountable obstacle to NVS use in a geriatric setting, it must be taken into account when evaluating the expansion of this pilot study into a full-scale project.

Recommendations for Practice

Health education practitioners can utilize the findings of the current study as an addition to the published knowledge base concerning HL assessment tools, such as the NVS, in older adult populations. Based on the experience of administering the NVS to the current study population, this researcher concurs with the following suggestions cited by Miser and coworkers (2013) in their assessment of NVS difficulty, and recommends the following actions when using the NVS in both health education and research settings:

1. Immediate use of arithmetic skills is daunting; move the easier questions 5 and 6 to the beginning of the tool.
2. Make question 2 more specific by asking "How many cups of ice cream could you have?" instead of "How much ice cream could you have?"

3. Question 3 is too long; remove the first sentence.

4. For question 3, substitute the word "eating" for "consuming".

5. Make question 3 clearer by making all the verb tenses the same; i.e., substitute "If you stopped eating ice cream, how many grams of saturated fat would you then be consuming each day?" for "If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?"

6. For question 5, substitute the word "things" for "substances".

Results of the current study also imply that the NVS tool may be used to help predict pre-test knowledge of medication management topics in older adult populations, and help to provide a firm background for health educators utilizing the NVS in geriatric settings. Overall, the current study helps to elucidate effective practice strategies for geriatric HL educational interventions, and aids in evaluating HL's role in mediating public health efforts to improve geriatric medication management strategies. Thus, this research fills a unique gap in the literature, blending inquiries from the fields of HL, educational interventions, and medication management to address the needs of an important vulnerable population.

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APPENDIX A

Institutional Review Board Approval Letter

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Institutional Review Board
Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378 FAX 940-898-4416
e-mail: IRB@twu.edu

May 2, 2013

Ms. Carol L. Creech

Dear Ms. Creech:

Re: The "Medication Matters ... To You!" Educational Intervention Session: A Pilot Study to Improve Medication Management in Community-Living Older Adults (Protocol #: 17269)

The above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and appears to meet our requirements for the protection of individuals' rights.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. A copy of the approved consent form with the IRB approval stamp is enclosed. Please use the consent form with the most recent approval date stamp when obtaining consent from your participants. A copy of the signed consent forms must be submitted with the request to close the study file at the completion of the study.

This approval is valid one year from May 2, 2013. Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

Sincerely,

Rhonda R. Buckley

Dr. Rhonda Buckley, Chair
Institutional Review Board - Denton

cc. Dr. Gay James, Department of Health Studies
Dr. Kristin L. Wiginton, Department of Health Studies
Graduate School

APPENDIX B

Agency Approval Letter

MESQUITE, FORT WORTH, CUNTER
Christian Care Centers
TEXAS
"Caring As Our Calling"

February 1, 2013

Re: Texas Woman's University Doctoral research study

To Whom It May Concern:

Carol L. Creech has been given permission to recruit participants, post flyers, and conduct research for her dissertation project, *"The Medication Matters ... to You!" Educational Intervention Session: A Pilot Study to Improve Medication Management in Community-Living Older Adults"* at two of our facilities - the Lakewood Village campus in Fort Worth, Texas, and the Greenway Village campus in Mesquite, Texas. This permission is contingent upon research approval by the Institutional Review Board (IRB) at Texas Woman's University in Denton, Texas. The IRB approval letter must be made available to our facilities before the start of this research.

Sincerely yours,

Phil Elmore
President / CEO
Christian Care Centers, Inc.

[redacted]
MESQUITE, TX 75150-0944
972.686-2400
www.christiancarecenters.org

APPENDIX C

Plain Language Companion Guide to the Informed Consent Form

Plain Language Companion Guide to the Informed Consent Form

Study Title: The "Medication Matters ... To You!" Educational Intervention Session: A Pilot Study to Improve Medication Management in Community-Living Older Adults

Why this Research Study is Being Done

- Carol Creech is doing research at Texas Woman's University (TWU) on ways that older adults manage their medicines.
- You are being asked to take part in this session because you are an older adult (over 65 years) who lives in the retirement apartments at Lakewood Village or Greenway Village.
- If you live at Lakewood Village, Carol needs participants to come to the June 24, 2013 *To Your Health* session in the Multi-Purpose room at that facility. She will give a program that day called *Medication Matters ... to You!* If you want to participate in the research, she will give you several paper test questionnaires before and after the program.
- If you live at Greenway Village, Carol needs participants to come early to the June 19, 2013 Book Review meeting in the Multi-Purpose room. If you want to participate in the research, she will give you several paper test questionnaires before and after the Book Review. (The Book Review is not part of the research.)

What Should I Do If I Want to Participate?

- Sign the formal TWU Consent Form that goes with this paper.
- You will be given a blank copy of the Consent Form now, so that you know who to call if you have questions. Within 7 days a copy of your original signed Consent Form will be put in your mailbox or mail folder for you to keep.
- Come to the June 24th *To Your Health* session at 2:00 pm if you live at Lakewood Village.
- Come to the June 19th Book Review meeting at 2:00 pm if you live at Greenway Village.

What Will We Do on June 24th at Lakewood Village?

- Carol will give you information on how to manage your medicines.
- Before and after Carol speaks you will be asked to fill out several paper test questionnaires about how you assess health information, and how you feel about managing your medicines. You will also be given time for a break.
- Martha Fiddes, Scott Dobbs, and Laura Myles also will be there to help, and to answer any questions you have with the questionnaires.

What Will We Do on June 19th at Greenway Village?

- Carol will give you a few short questionnaires to take before and after the regularly scheduled Book Review meeting.
- These paper test questionnaires will look at how you assess health information, and how you feel about managing your medicines. You will also have time for two breaks.
- Martha Fiddes, Mary Frances Zaby, and Chantel Dauster also will be there to help, and to answer any questions you have with the questionnaires.

Are There Any Risks to This Study?

- There is a risk of getting tired while filling out the questionnaires. You will have two scheduled breaks to help reduce this risk, and you may stop and leave the sessions at any time.
- Coercion is another possible risk in this study. You have the option to stay in your apartment, or go anywhere else in the facility (such as the Wellness Center, the dining room, etc.), at the time that the intervention and control group sessions are occurring.
- **You do not have to participate in either group.**
- Loss of confidentiality is another possible risk in this study.

- Electronic transmission of this information may be used. There is a potential risk of loss of confidentiality with any email, downloading, and internet transactions.
- Only Carol and her school advisor will be able to trace the study information directly back to you.
- The confidentiality of your information will be protected to the extent that is allowed by law.
- If the study results are reported in scientific magazines or journals, or presented at conferences, your name or any other identifying information will not be given out.
- You should let Carol know at once if you have a problem with the study, and she will help you. **Her phone number is ###-###-####.**

Do I Have to Participate?

- **NO.** Your participation in this study is entirely voluntary.
- You are free to refuse to be in either group. There is **NO** penalty for refusing to be in the study.
- If you do participate, you can stop anytime. Just stop filling out the forms, or leave the room if you want. There is no penalty for stopping.
- You can ask questions at any time during the study.

How Does This Study Benefit Me?

- About a third of all serious medication problems in independent older adults are preventable. Helping to reduce these problems might improve the quality of life for you and your friends.
- There are no direct benefits to this study.
- The educational program session given at Lakewood will be offered to Greenway residents once the data have been collected and the study is over.
- If you would like to know the results of this study, we can mail them to you when the study is over. Please fill out your name and address on the last page of the attached TWU Informed Consent form if you want to receive these results.
- If you have questions about your rights as a participant in this study, or about the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378, or via e-mail at IRB@twu.edu.

Thank you for considering taking part in my study!

Carol L. Creech, M.S., MT(ASCP)

APPENDIX D

TWU Consent to Participate in Research

TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: The "Medication Matters ... To You!" Educational Intervention Session: A Pilot Study to Improve Medication Management in Community-Living Older Adults

Investigator: Carol Creech, M.S. ccreech@
Advisor: K. L. Wiginton, Ph.D. klwiginton@

Explanation and Purpose of the Research

You are being asked to participate in a research study for Carol Creech's dissertation at Texas Woman's University (TWU). The purpose of this research is to determine how being a participant in the *Medication Matters ... to You!* health education program affects older adults' knowledge and feelings about managing their medicines, and to assess their baseline level of health literacy. (Health literacy is the ability to function successfully as a patient.)

You have been asked to participate in this study because you are an older adult (over the age of 65 years) who has indicated interest in attending the *Medication Matters ... to You!* program at Lakewood Village in Fort Worth, or the control group testing session held before and after a Book Review at Greenway Village in Mesquite.

Description of Procedures

As a participant in the intervention group of this study at Lakewood Village (LV), you will be asked to spend 2 hours at a special *To Your Health* session, called *Medication Matters ... to You!* As a participant in the control group of this study at Greenway Village (GV), you will be asked to spend 2 hours at a Book Review meeting. Both sessions are face-to-face classroom-based programs with the researcher, one or more facility staff members, and other program participants.

At LV, the researcher will give you information on how to manage your medicines effectively. Before the presentation begins, you will be

Initials

asked to fill out several questionnaires about your ability to interpret health information, and your knowledge and feelings about managing your medicines. The total time commitment for this study is 2 hours. At the end of the session, you will again be given several questionnaires that ask about your knowledge and feelings about managing your medicines.

At GV, the researcher will not give a presentation, but the questionnaires will be given before and after the regularly scheduled Book Review meeting .

Potential Risks

You may become fatigued while filling out the questionnaires. Two breaks will be provided to minimize this risk, and you may discontinue participation at any time.

Coercion is a possible risk in this study. You have the option to stay in your apartment, or go anywhere else in the facility (such as the Wellness Center, the dining room, etc.), at the time that the intervention and control group sessions are occurring. You may discontinue participation in the intervention or control group session at any time. The voluntary nature of your participation, as well as your ability to leave either session at any time, is specified in writing in the LV advertising brochure, the GV advertising flyer, the recruiting flyer, the Plain Language Companion Guide to the Informed Consent Form, and in this formal Informed Consent Form.

Loss of confidentiality is another possible risk in this study. Confidentiality will be protected to the extent that is allowed by law. The information from your questionnaires will be recorded first as your initials, and then converted to coded numbers. These coded numbers will be used as indirect identifiers throughout the rest of the study. No one but the researcher will know your real name. This information will be stored in a locked cabinet in the researcher's office. Only the researcher and her advisor will see this information. This information will be shredded within 5 years after the study is finished. Electronic transmission of this information may be used. There is a potential risk of loss of confidentiality in all email, downloading, and internet transactions. If the results of this study are

_____
Initials

reported in scientific magazines or journals, or presented at conferences, your name or any other identifying information will not be disclosed.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future relationships with Texas Woman's University or Christian Care Centers, Inc. You may withdraw from this study at any time without penalty. If you wish to stop your participation in this study for any reason. vou should contact the principal investigator, Carol Creech, at [redacted] You are free to withdraw your consent and stop participation in this research study at any time without penalty or loss of any benefits to which you may be entitled. You also may ask questions at any time during the study.

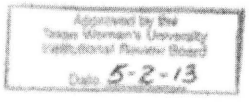
There are no direct benefits to this study. About a third of all serious medication problems in independent older adults are preventable. Helping to reduce these problems might improve the quality of life for you and your friends.

At the end of this study, Greenway Village residents will have the opportunity to hear the same educational session as that presented at Lakewood Village.

If you would like to know the results of this research study we can mail them to you within 6 weeks after the end of the study.* Please write your name and address on the last page of this form so we will know where to send them.

You should call Carol Creech (the principal investigator) if you have any questions, concerns, or complaints about the research.

Initials



Questions Regarding the Study

Within 7 days of signing, you will be mailed or given a copy of this signed and dated consent form to keep. Until then you will be given a copy of the blank form to keep in case you wish to contact the researchers.

If you have any questions about the research study you should ask the researchers; their phone numbers are at the top of this form.

If you have questions about your rights as a participant in this research, or about the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378, or via e-mail at IRB@twu.edu.

Participant Printed Name:

_____

_____

Participant Signature Date

*If you would like to know the results of this study, please tell us where you want them to be sent:

Mailing Address:

_____

_____

_____

_____

Thank you so much for your help with this project!

APPENDIX E

Pre-Test Booklet

PLEASE FILL

THIS OUT

BEFORE WE

START

YOUR FIRST INITIAL: _____ YOUR LAST INITIAL: _____

DIRECTIONS: Please tell us your opinions on managing your medicines. Circle TRUE **or** FALSE for each statement.

1. It is important for me to read the little warning labels on all of my medicine bottles. TRUE FALSE

2. Tylenol™ is the same thing as acetaminophen. TRUE FALSE

3. Nyquil™ contains Tylenol™. TRUE FALSE

4. Too much Tylenol™ can harm your lungs. TRUE FALSE

5. Aleve™ and Advil™ are completely different kinds of drugs. TRUE FALSE

6. Coumadin can interact with other drugs to make your blood too thin. TRUE FALSE

7. Cholesterol drugs can interact with orange juice. TRUE FALSE

8. It is a good idea to have all of my prescriptions filled at just one pharmacy. TRUE FALSE

9. Too much Aleve™ can harm your heart. TRUE FALSE

10. Night-time cold medicines can make you dizzy. TRUE FALSE

Ice Cream Label

DIRECTIONS: On the facing page are 6 questions about the label shown below. Please answer questions about them on the lines provided on the next page.

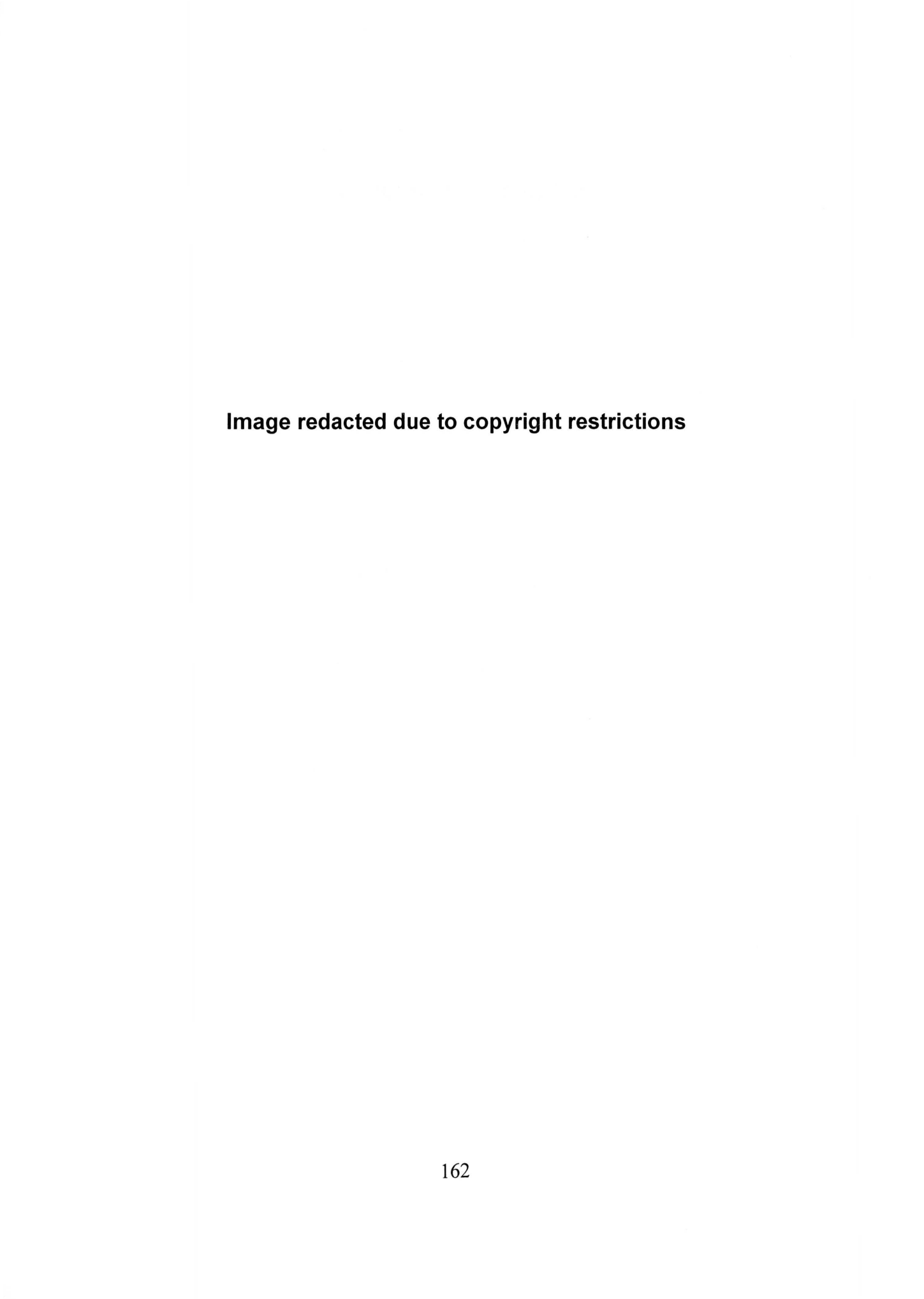


Image redacted due to copyright restrictions

Ice Cream Label Questions

Image redacted due to copyright restrictions

Self-Efficacy for Appropriate Medication Use Scale (SEAMS)

DIRECTIONS: We would like to ask you about your personal views about medicine-taking in general. Please indicate how much you agree or disagree with the following statements by circling the appropriate choice. There are no right or wrong answers. We are interested in your personal views. Thank you for your help!

How confident are you that you can take your medicines correctly. . .

1. When you take several different medicines each day?

Not confident Somewhat confident Very confident

2. When you take medicines more than once a day?

Not confident Somewhat confident Very confident

3. When you are away from home?

Not confident Somewhat confident Very confident

4. When you have a busy day planned?

Not confident Somewhat confident Very confident

5. When they cause some side effects?

Not confident Somewhat confident Very confident

6. When no one reminds you to take the medicine?

Not confident Somewhat confident Very confident

7. When the schedule to take the medicine is not convenient?

Not confident Somewhat confident Very confident

How confident are you that you can take your medicines correctly. . .

8. When your normal routine gets messed up?

Not confident Somewhat confident Very confident

9. When you are not sure how to take the medicine?

Not confident Somewhat confident Very confident

10. When you are not sure what time of the day to take your medicine?

Not confident Somewhat confident Very confident

11. When you are feeling sick (like having a cold or the flu)?

Not confident Somewhat confident Very confident

12. When you get a refill of your old medicines and some of the pills look different than usual?

Not confident Somewhat confident Very confident

13. When a doctor changes your medicines?

Not confident Somewhat confident Very confident

From: Risser, J., Jacobson, T. A., & Kripalani, S. (2007). *Journal of Nursing Measurement, 15,*(3), p. 215.

Please tell us about yourself:

First initial: _____ Last initial: _____

Gender (Circle one): Male Female Age: _____

Race (Circle one):

White Black Hispanic Asian Other

Please circle the phrase that describes the number of years of education you have completed:

primary school	high school	jr. college or trade school	college or university

You are finished with this booklet.

Thank you!

APPENDIX F

PowerPoint Presentation with Answers

Medication Matters ... to You!

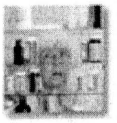
Lakewood Village
To Your Health series
Carol L. Creech, M.S., MT(ASCP)
Texas Woman's University

Introduction

- Carol Creech
- Background in allied health education
- Currently at Texas Woman's University
- [redacted]
- Research interest in 'health literacy'

Importance of Health Literacy

- How to "function successfully as a patient" [1,2]
- What's one of your biggest jobs as a patient?



Informed Consent Process

- Informal *Plain Language Companion Guide to the Informed Consent Form* to help you understand:
- Formal *Texas Woman's University Consent to Participate in Research* to be signed.

This session will be different ☺

- 1. It will be participatory, using both short stories and a quiz show format.
- 2. You will fill out the green booklets before our session.
- 3. You will fill out the red booklets after we are finished.

(You don't have to fill out the booklets if you don't want to.)

Let's look at the booklet with the green cover now.

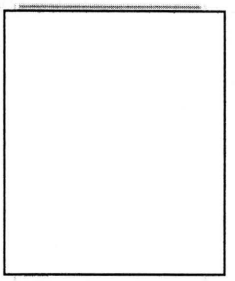
- 1. Please ask if you have questions.
- 2. If you need to leave the room, go ahead.
- 3. When we are finished doing the ice cream label questions as group, please go ahead and fill out the rest of the booklet.

On the booklet with the green cover …

- ❑3. Let's do pages 3 and 4 together first.
- ❑4. I'll read the questions on this item.
- ❑5. You'll have one minute for each question.

Ice Cream Label

DIRECTIONS: On the facing page are 6 questions about the label shown below. Please answer questions about them on the lines provided on the next page.



After you fill out the rest of the green booklet, take a break!

Importance of Medication Management

- ❑From 2000 – 2008, annual prescription costs went up 64%.[3]
- ❑The older we get, the likelier we are to take more medicine![4]
- ❑At least 1/3 of accidents involving medicines are preventable.[5]

What Should You Get Out of Today's Program?

- ❑ To find out your views on managing your medicines.
- ❑ To help you learn new strategies for managing your medicines.
- ❑ To help promote healthy aging.

Topic 1: Memory aids and strategies

Imogene's story

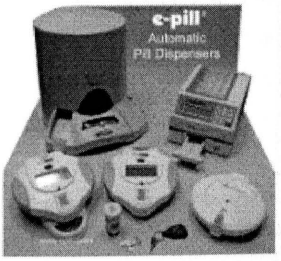
Strategies

- 1. My strategy
- 2. What are your strategies?

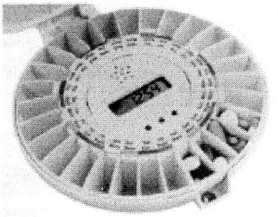
Pill Organizers

- 1. Simple
- 2. Super size
- 3. Recyclable
- 4. Fancy!

From http://www.epill.com/dispenser.html



I have info on some of these organizers if you would like to take a handout after today's session.



http://www.digitalworldtokyo.com.jpg

Questions so far?

Topic 2: Side effects and interactions

George's story

George's Story

- Tylenol with dinner at 5:30 pm
- Bedtime at 6:30 pm
- Takes Nyquil
- Takes Dristan Cold and Sinus
- What has he accidentally done?

George's Story

- Taken Tylenol (acetaminophen) 3 times!
- How could this hurt him? Liver damage or death!
- DO: read ingredients on multi-symptom meds to avoid 'doubling up'
- Duplication is the most common mistake made with medicines![7]
- Too much Tylenol is the #1 mistake adults make during cold and flu season![8]

Let's talk about George a little more

- Which of his medicines should he probably avoid entirely?
  - Tylenol or
  - Dristan Cold and Sinus or
  - Nyquil
- Nyquil!
- Why? Could make him sleepy and dizzy, and likely to fall if he gets up at night.

Topic 2: Side effects and interactions

Viola's story

Viola's Story

- Lunch at noon
- Takes Aleve at 2 pm
- 2:30 pm stomach-ache
- 3:00 pm takes Pepto-Bismol
- 5 pm feels fine and eats dinner
- 6 pm ready to play cards!

Viola's Story

- Two days later, same thing happens
- Lunch at noon
- Aleve at 2 pm
- 2:30 pm stomach-ache
- 3:00 pm takes Pepto-Bismol
- 5 pm feels fine and decides it must be a problem with the food in the dining room!

Viola's Story

- What could you have told her about Aleve?
- DO: Always take Aleve with food!
- Same for Advil, Motrin, Naproxen, Naprosyn, Celebrex, and Feldene
- What is another problem with this group of drugs?
- Liver damage, maybe even death if too many pills taken.[9]

The "Do You Know?" Quiz Show

- What over the counter medicines can work with Coumadin to make your blood too thin and increase bleeding risk?[10]
- Vitamin E
- Fish oil
- AND aspirin

The "Do You Know?" Quiz Show

- DO: read the warning labels on your pill bottles.
- If you take cholesterol drugs, you should avoid eating what breakfast food?
- Grapefruit or grapefruit juice![10]
- Do any other drugs interact with this food?
- Yes – check with your pharmacist[11]

Speaking of Strategies for Managing Medicines ...

Are these good ideas?[10]

1. Get all your medicines filled at the same pharmacy.
2. Throw out your medicines once they expire.
3. Know how to take each of your medicines (on an empty stomach, with food, etc.)
4. Know how to store each of your medicines.

Topic 3: What is the #1 way to ensure medication safety?

Know the names of all your medicines, and why you take them![10]

To help you remember medicine names and what they are for...

- **DO:** Write the name of the medicine and what it is for in big print on the side of the bottle with a Sharpie pen.
- Example: Digoxin and Heart
- Even better ....

Keep a Medication Summary Sheet![10]

- Bring it with you to the doctor.
- Keep a copy in your purse.
- Put a copy in the pocket on the back of your front door.
- Update it often.
- Take the handout,"Keep a Medication Summary"[10].

What did we learn today?

- Ways to remember to take your medicines. Such as?

What else did we learn?

- Most common mistake made in cold and flu season?
- Too much Tylenol/acetaminophen!
- Too much Tylenol can cause?
- Liver damage or even death!

What else did we learn?

- You may want to avoid night-time formula medicines. Why?

May make you dizzy

May increase risk for falling

What else did we learn?

- Take Aleve and Advil with what?
  Food!
- Too much Aleve or Advil can hurt what organs?
  Your stomach and liver

What else did we learn?

- What medicines should you avoid if you are on Coumadin?

- Vitamin E
- Fish oil
- Aspirin

And why?

Thin your blood too much; may cause bleeding.

What else did we learn?

- What should you avoid eating if you are on cholesterol medicine?
- Grapefruit or grapefruit juice
- How would you find this out?
- DO: read the warning labels on the sides of your pill bottles!

After we fill out our next booklet …

- Take a "Medication Use Checklist" handout from up front after we are done.[10]
- Fill it out later to see if you are having a problem managing your medicines.
- Share it with your doctor if you'd like.
- Questions?

Please take a break before you come back and fill out all of the red booklet.

Please fill out all of the booklet with the red cover now.

- 1. Please ask if you have questions.
- 2. If you need to leave the room, go ahead.
- 3. When you are finished, just turn the booklet over.

Thank you so very much for your help!

We all get by with help from friends, so thank you again!

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APPENDIX G

Post-Test Booklet

PLEASE FILL

THIS OUT

AFTER OUR

SESSION IS DONE

YOUR FIRST INITIAL: _____ YOUR LAST INITIAL: _____

Participant Satisfaction Questionnaire:

DIRECTIONS: We would like to know what you thought about today's presentation. Please indicate the extent to which you agree or disagree with these statements by circling the appropriate number. There are no right or wrong answers. We are interested in your personal views. Thank you for your help!

1. I enjoyed today's presentation.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

2. I heard useful information in today's presentation.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

3. I thought today's presentation was too long.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

4. I thought today's presentation was too short.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

5. I would recommend today's presentation to my friends and family.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

6. I thought today's presentation was appropriate for people like me.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

7. I liked using this room for today's presentation.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

8. I liked how Ms. Creech delivered the presentation.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

9. I think Ms. Creech is competent to speak about this topic.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

10. I think the handouts were helpful for people like me.

Strongly Agree 1 2 3 4 5 6 7 Strongly disagree

11. What part of today's presentation did you like the most? Why?

12. What part of today's presentation did you like the least? Why?

13. What part of today's presentation was the most useful for you? Why?

Please tell us if there is anything else you want us to know about today's presentation:

Self-Efficacy for Appropriate Medication Use Scale (SEAMS)

DIRECTIONS: We would like to ask you about your personal views about medicine-taking in general. Please indicate how much you agree or disagree with the following statements by circling the appropriate choice. There are no right or wrong answers. We are interested in your personal views. Thank you for your help!

How confident are you that you can take your medicines correctly. . . .

1. When you take several different medicines each day?

Not confident Somewhat confident Very confident

2. When you take medicines more than once a day?

Not confident Somewhat confident Very confident

3. When you are away from home?

Not confident Somewhat confident Very confident

4. When you have a busy day planned?

Not confident Somewhat confident Very confident

5. When they cause some side effects?

Not confident Somewhat confident Very confident

6. When no one reminds you to take the medicine?

Not confident Somewhat confident Very confident

How confident are you that you can take your medicines correctly. . . .

7. When the schedule to take the medicine is not convenient?

Not confident Somewhat confident Very confident

8. When your normal routine gets messed up?

Not confident Somewhat confident Very confident

9. When you are not sure how to take the medicine?

Not confident Somewhat confident Very confident

10. When you are not sure what time of the day to take your medicine?

Not confident Somewhat confident Very confident

11. When you are feeling sick (like having a cold or the flu)?

Not confident Somewhat confident Very confident

12. When you get a refill of your old medicines and some of the pills look different than usual?

Not confident Somewhat confident Very confident

13. When a doctor changes your medicines?

Not confident Somewhat confident Very confident

From: Risser, J., Jacobson, T. A., & Kripalani, S. (2007). *Journal of Nursing Measurement, 15,*(3), p. 215.

Please tell us about yourself:

First initial: _____ **Last initial:** _____

Gender (Circle one): **Male** **Female** **Age:** _____

Race (Circle one):

White **Black** **Hispanic** **Asian** **Other**

Please circle the phrase that describes the number of years of education you have completed:

primary school	high school	jr. college or trade school	college or university

You are finished with this booklet.

Thank you so much for your time!

APPENDIX H

Pre- and Post- Knowledge Test Key

Pre- and Post-Test KEY

Correct answers are highlighted in boldface type.

DIRECTIONS: Please tell us your opinions on managing your medicines. Circle TRUE **or** FALSE for each statement.

1. It is important for me to read the little warning labels on all of my medicine bottles. **TRUE** FALSE
2. Tylenol™ is the same thing as acetaminophen. **TRUE** FALSE
3. Nyquil™ contains Tylenol™. **TRUE** FALSE
4. Too much Tylenol™ can harm your lungs. TRUE **FALSE**
5. Aleve™ and Advil™ are completely different kinds of drugs. TRUE **FALSE**
6. Coumadin can interact with other drugs to make your blood too thin. **TRUE** FALSE
7. Cholesterol drugs can interact with orange juice. TRUE **FALSE**
8. It is a good idea to have all of my prescriptions filled at just one pharmacy. **TRUE** FALSE
9. Too much Aleve™ can harm your heart. TRUE **FALSE**
10. Night-time cold medicines can make you dizzy. **TRUE** FALSE