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Comparison of Home Medication Adherence in Adults Age 65 and Older After Completion of Standardized Discharge Medication Education or Non-Standardized Discharge Medication Education

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Executive Summary

Comparison of Home Medication Adherence in Adults Age 65 and Older After Completion of Standardized Discharge Medication Education or Non-Standardized Discharge Medication Education

Problem

The older patient (age 65 and older) is at higher risk of medication induced illness because of numerous co-morbid conditions treated with multiple medications, a standardized approach to medication education at hospital discharge can reduce adverse medication events for this at risk population (Esposito, 1995; Jack et al., 2009). The primary driving force for this project is the limited number of research studies published to date that include this specific age bracket and setting. It is clear the aging population is at risk for adverse medication events (Esposito, 1995; Holloway, 1996; Jack et al., 2009; Laugaland et al., 2012). What is unclear is what the most effective approach to meeting the educational needs of the aging population is.

Purpose

Based on this identified problem, the PICO (P, population, I, intervention, C, comparison, O, outcome) question served to focus the Capstone Project, for adults aged 65 and above, would a standardized discharge education program for medication management versus no standardized program be effective in increasing patient adherence to home medication regimen, as measured by telephone questionnaire at one week and again at three to six weeks post discharge.

Goals

The general project focus was to create a standardized discharge medication education program for older adults. The specific focus was to improve patient compliance with their complex medication regimen. The expectation, is with improved compliance there will also be a decrease in adverse events, improvement of patient self-efficacy, increase patient understanding of their medication regimen, and subsequently reduce hospital readmission rates and resource utilization.

Objectives

The primary project objective was to increase patient adherence of home medication regimen by 25% in the intervention group as evidenced by improvement in scores using a modified CASE adherence index.

Plan

The study was a two group design interventional study, one group receiving "standard" hospital discharge medication education and an "intervention" group. Participants were a convenience sample of hospital patients, chosen by chance. The education program for the intervention group included three facets of "tactile" information combined with verbal education. A pill dispenser was provided to the participants of the intervention group. A phone questionnaire was performed at one week and three to six weeks post discharge for all participants, using the modified CASE adherence index to determine medication compliance.

Outcomes, Results, and Recommendations

The intervention did not make a statistically significant difference between two group total scores overall. Question one, week one and three, showed the most improvement ($p = .334$ and $p = .031$ respectively) indicating the participants are taking their medications correctly and retaining the education at three weeks post discharge for this sample. This project provides a framework for additional research on this topic with a larger sample size and longer data collection period.

Acknowledgments

I would like to take this opportunity to thank the people in my life who have contributed to my success, not only in this program, but life as well. First, I would like to thank my mother, for always pushing me to be my absolute best. She did so as she believed my opportunities to excel in life were limitless, should I only set my mind to the task. Her love, support and confidence in my ability continue to push me to achieve great things. I would also like to thank my brother, who has always given me an alternate perspective on life and taught me to accept its bumps and bruises as part of the journey. Lastly, thank you to the family I was blessed with rather than born with. Their unconditional encouragement, love and support have made me the person I am today.

I would also like to thank my mentors who supported and guided me throughout this journey. Much appreciation to Cris Finn, PhD, RN, FNP, MS, MA, FNE, my DNP capstone chair, for her support and encouragement. Without her guidance (and patience), none of you would be reading this article.

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As medications play a large role in the treatment of many medical conditions, adherence to those medications is vital. This capstone project discusses adults age 65 and older, identified as a vulnerable population, and the benefits of a standardized approach to discharge medication education program in a hospital setting.

Problem Recognition and Definition

Individuals older than 65 years are the most active consumers of health care, and this group continues to incr projected population of people 65 and older in 2050 is 88.5 million, compromising 20 percent of the total US population at that time (United States Census Bureau, 2012). Patient medication education is a large component of discharge planning and one of many standards necessary for a hospital to attain accreditation (The Joint Commission, 2015). However, there is often a lack of patient education and information regarding medication, resulting in patients being discharged with inadequate preparation (Holloway, 1996). The purpose of this project was to demonstrate improved medication compliance in adults age 65 and older, with the use of a standardized discharge medication education program.

The older patient (age 65 and older) is at higher risk for a medication induced illness because of numerous co-morbid conditions treated with multiple medications, prescribed by multiple providers (Esposito, 1995; Jones, Treiber, & Jones, 2014). A standardized approach to medication education at hospital discharge can reduce adverse medication events for this at risk population (Jack et al., 2009). Based on this identified patient care issue, the PICO (P, population, I, intervention, C, comparison, O, outcome) question that served as the basis for this research project, for adults aged 65 and above, would a standardized discharge education program for medication management versus no standardized program be effective in increasing

patient adherence to home medication regimen, as measured by telephone questionnaire at one week and again at three to six weeks post discharge? This was a standardized quality improvement initiative, not intended to develop new knowledge or be generalized outside of the agency. The project was an evidence-based practice (EBP) project in which a quality improvement plan, educational, and standard of care intervention will be completed. A pre-test/post-test evaluation assessed the effect of the intervention. The project will be internal to an agency and will inform the agency of issues regarding health care quality. The results of this project were not meant to generate new knowledge or be generalizable across settings but rather seek to address a specific population, at a specific time, in a specific agency. This project translated and applied the science of nursing to the greater health care field.

This project utilized the acronym "PICO", rather than stating a formal research hypothesis. The acronym stands for: Population or Disease (P), Intervention or Issue of Interest (I), Comparison group or Current Practice (C), and Outcome (O) and is usually framed as a question (Melnyk & Fineout-Overholt, 2011, p. 31). The question this study seeks to address is:

P: Older adults, aged 65 and above

I: Developing a standardized discharge education program for medication management

C: No standardized discharge education program in place

O: Increased compliance with home medication regimen evidenced by results of phone questionnaire performed at one week and again at three to six post discharge.

The PICO question is: Would standardized discharge medication education improve home medication adherence in adults age 65 and older compared to non-standardized discharge medication education?

The topic of patient education is paramount to any nursing field, specifically the advanced practice role. As an advanced practice nurse, prescription medications and their subsequent adherence are part of the complexity involved when speaking to disease management. Appropriate and comprehensive education has potential to improve patient compliance, subsequently improving patient health and well-being. The benefit of a solid education program is not limited to only one practice, or hospital setting. In the author's opinion, a program of this type has the ability to be used universally throughout the medical community (Jones et al., 2014; Miner, 2015). The role of an advanced practice nurse, or doctorate prepared nurse, is unique in its dual role as nurse and provider. Duality leads to increased potential for choices made to impact the nursing profession as well as the patient population.

There are numerous advanced practice nursing outcome measures the project addressed: care, patient, and performance related (Kleinpell, 2013). The general project focus was to create a standardized discharge medication education program for older adults. The specific focus was to improve patient adherence with their medication regimen. The expectation was, with improved adherence, there would also be a decrease in adverse events, improvement of patient self-efficacy, increased patient understanding/knowledge of their medication regimen, and subsequently reduced hospital readmission rates and resource utilization.

Theoretical Framework

Perhaps the most important theoretical foundation for this practice issue was Adult Learning Theory by Malcolm Knowles. This theory is based on the principle adults need certain considerations to successfully learn (Syx, 2008). The six primary concepts are:

1. Adults need to know why they need to know something before they start
2. As adults mature they become more self-directed and less dependent in their actions

3. Personal experience is a large resource for learning new information
4. Adults are problem oriented learners
5. An adults time frame changes from postponed action to immediate action
6. Adults are primarily motivated by a need to solve immediate and practical problems (McEwen & Wills, 2011; Syx, 2008)

These principles were intentionally incorporated in this project. This was accomplished by clearly outlining each item within the consent form and discussion with each participant of the project. To be effective patient educators, one must be familiar with the appropriate theoretical foundation to optimize learning. Theories provide a framework that can be adapted to each patient's needs. A healthcare provider can educate their using a combination of theories. Through this process arises the opportunity for the achievement of optimal patient outcomes. Having an effective grasp of these concepts will assist in making any educational effort more successful.

The Theory of Self-Care Management for Vulnerable Populations by Dorsey and Murdaugh (2003) was additionally applicable to this practice issue. They define a vulnerable population as "social groups who experience disparities as a result of a lack of resources and increased exposure to risk" (Dorsey & Murdaugh, 2003, p. 43). The major concepts noted include contextual factors, vulnerability, intra-personal factors, self-care management, health status, and quality of life (Dorsey & Murdaugh, 2003). The older patient is vulnerable largely due to the number co-morbid conditions treated with multiple medications, which are prescribed by multiple providers (Esposito, 1995; Jones, Treiber, & Jones, 2014). This alone places the patient at risk for adverse complications, increased hospital utilization, and death. The theory posits people with a chronic illness encounter both modifiable and non-modifiable factors that

may increase their vulnerability. Effective management of chronic disease thus would assist in the control of this modifiable factor. Therefore, one could surmise that a comprehensive education program offers the patient the best chance at effective management of their medication regimen consequently increase patient control of their health and quality of life.

Prevention as Intervention by August-Brady (2000) is the method through which one acts to accomplish the goal of client/system stability. Three concepts exist within the Prevention as Intervention Theory: a) assessment of actual or potential stressors; b) Prevention strategies-primary, secondary, tertiary; and c) health-client system stability (August-Brady, 2000). The prevention strategies in this model can be used synchronously or individually to achieve the desired outcome. This theory correlates closely with Adult Learning Theory and the educational program being designed as the education provided was a prevention strategy designed to prevent complications from mismanagement of medications and/or worsening disease states.

The Health Belief Model, developed in the 1950s by Hochbaum and colleagues, also provided framework to the foundation of this education program. There are three major premises noted: individual perceptions, modifying factors, and likelihood of action (Syx, 2008). This theory was developed with the idea people fear disease, and their health actions are based upon that fear, as well as, the benefit attained from making healthy choices (McEwen & Wills, 2011). This model works well with this practice issue, as education about consequences of not adhering to prescribed medication regimen are included in the program and supportive of Adult Learning theory.

Pender's Health Promotion Model was applicable to this practice issue, as the plan was to promote compliance with medication regimen utilizing a thorough education program. Major concepts of this model are "individual characteristics and experiences, behavior-specific

cognition and affect, and behavioral outcomes" (McEwen & Wills, 2011, p. 225). Personal experiences affect behaviors, which in turn will affect outcomes (Syx, 2008). Giving the patient a positive educational experience can increase their chance of applying education in an effective manner.

Systematic Review of Evidence: Literature Review

A systematic literature review of 150 articles was completed. After review, 36 articles were chosen to provide a foundation of reference material related to the project. Data was obtained from CINAHL database using keywords: discharge medication education, discharge summary, aged, drug prescriptions, educational intervention, drug therapy, drug toxicity, patient compliance, patient non-adherence, compliance, elderly, hospital readmissions, adherence, inappropriate prescribing, treatment review, patient education, resident education, transitional care, hospital discharge summary, discharge planning, resident training, communication, electronic medical record, collaboration, medication error, self-care, self-management, and self-medication. The data reviewed included one interventional trial, one survey, four randomized controlled trials, eight literature reviews, one ethnographic study, one expert opinion, one practice report, three prospective intervention studies with retrospective controls, three quasi-experimental designs, three single descriptive studies, four qualitative studies, two prospective randomized parallel-group open-label trials, two observational studies, one retrospective cohort, and one quality improvement project. The literature was narrowed to support the topic of the aging population and discharge education regimens (Appendix A).

The underlying theme noted within each article reviewed was that standardized education, to some degree, improves patient outcomes (Doggrell, 2010; Esposito, 1995; Holloway, 1996; Martens, 1998). The data documented various modalities to educate patients

about their home medication regimen. One randomized, controlled trial evaluated the clinical effects of implementing a reengineered discharge program for patients admitted to a general medical service (Jack et al., 2009). This trial decreased readmissions and hospital utilization within 30 days of discharge by 30% among study participants (Jack et al., 2009). One survey concluded the participants had insufficient knowledge and information concerning their discharge medications (Holloway, 1996). An interventional trial, specifically focused on the older adult (>65 years old), presented the participants who had a medication schedule given to them upon discharge had a reduced incidence of medication error than to those who did not have the intervention (Esposito, 1995).

A literature review to categorize interventions designed to improve patient safety at discharge among the elderly found that simple tools were most effective to reduce readmission rates and decrease adverse drug events. These tools include the use of structured discharge reports, verbally verified checklists, education performed by pharmacy staff, and post hospital discharge follow up by medical staff (Laugaland, Aase & Branch, 2012). A prospective intervention study with retrospective controls exhibited the use of a prescription report at discharge decreased the need for medical care post-discharge due to medication errors (Midlov, Deierborg, Holmdahl, Hoglund, & Eriksson, 2008).

While patient education was performed using varying methodologies the outcomes appeared similar. A standardized and multi-faceted approach to discharge medication education for the older adult can decrease adverse events and improve patient outcomes.

Market/Risk Analyses

SWOT

A Strength, Weakness, Opportunities, and Threat (SWOT) analysis was performed to further objectify the project outcomes (Fortenberry, 2010).

Strengths of the project included:

1. A large potential group of participants to draw from in this setting was desired.
2. The author estimated 80% of current practice population was > 65 years of age
3. Of those patients, 90% or more left the hospital setting with a new prescription
4. Lastly, the lack of benchmark studies pertaining to this particular age group (Jack et al., 2009).

Weaknesses of the project included:

1. Data obtained from single medical center
2. Small sample size
3. Data obtained using a convenience sample
4. Results are not generalizable
5. Complexity of the participants medication regimen
6. Patient education level
7. The relationship of the patient with their primary care provider.

Opportunities found within the project included:

1. Increase number of the "aging" population in medical settings
2. Limited time for proper patient education using "dated" or unstructured techniques
3. The ability to be adapted at any facility/setting for minimal out-of-pocket cost.

Threats to the success of the project included:

1. Financial limitations

2. Transportation issues to obtain medications
3. Interaction with a home health agency
4. Family support
5. Patient medication compliance (Appendix B)

The primary driving force for this project was the limited number of studies performed to date that included this specific age bracket and setting. There are no benchmarks to draw upon. There are no reference points to begin with. It is clear the aging population is at risk for adverse medication events (Esposito, 1995; Holloway, 1996; Jack et al., 2009; Laugaland et al., 2012). What is unclear is what the most effective approach to meeting the educational needs of the aging population with a standardized discharge medication education regimen. The restraining forces of the project were the financial limitations of the project developer as well as the generalizability of the study findings.

The need for a project of this type has been clearly defined by the lack of studies specific to this patient population (Esposito, 1995; Holloway, 1996; Jack et al., 2009; Laugaland et al., 2012). Resources necessary to complete this project were few. The project designer performed the patient education at discharge as well as the follow-up telephone calls to the project participants. The author spent approximately three hours per week providing education to participants and completing follow-up phone calls to perform the survey questionnaire. The author calculated the results of the study using IBM SPSS version 23. The author purchased the monthly medication pill dispensers to distribute them to the appropriate study participants. The sustainability of the study was very manageable, as the project length was short, participants limited by the hospital census, and minimal cost to complete the study. The sustainability for a hospital to institute the project into the daily nursing care are limited to the costs of the

medication dispensers (should they ultimately be provided by the facility), as the nursing staff is already budgeted for patient care.

Project Team and Stake Holders

The project team includes the author and her capstone chair at Regis University, Dr. Christine Finn; Kristie Agee RN, BSN mentored throughout the project, providing insight and alternative viewpoints; and Jackie DeSouza, Chief Executive Officer at Research Medical Center, granted approval for project completion. The stakeholders included the medical facility staff and providers where the project was completed, to include nursing staff and patients, as it could prove to be an improvement to their current discharge practice.

Cost Benefit Analysis

A brief cost-benefit analysis indicates a 28 day pills dispenser cost approximately $5.00. This was calculated using an average of cost for dispensers found at two local retail pharmacy stores. The cost of medical care varies state to state, as does the cost of emergency room visits and hospital stays. As such, the actual dollars "saved" by preventing adverse drug events cannot be quantified. However, recent studies indicate 11% of hospital admissions in the greater than/equal to 65 age group are a result of medication errors with this number increasing to 26% in those over age 75 (Doggrell, 2010). An average cost for a hospital stay for a patient 65 or older nationally is estimated to be a mean of $10,000 per stay (HCUP, 2013)

Project Objectives

The Vision of the project was to have a positive effect on patient outcomes with an easy to use, standardized discharge medication education regimen with minimal financial burden to the patient/client. The primary project objective was to increase patient adherence of home medication regimen by 25% in the intervention group as evidenced by improvement in scores

using a modified Center for Adherence Support and Evaluation (CASE) adherence index (Appendix C).

Logic Model

The author could not find a benchmark. There is no nationally accepted standardized discharge medication education regimen (Esposito, 1995). However numerous clinical trials and clinical studies have been performed addressing a standardized discharge medication education program. These studies and clinical trials address general patient education, as well as education specific for older adults (Appendix A).

One randomized clinical trial reviewed utilized a nurse discharge advocate who worked with patients during their hospital stay to coordinate follow-up appointments, confirm accurate medication reconciliation, and perform patient education with an individualized instruction booklet sent to their primary care provider (Jack et al., 2009). A clinical pharmacist then called patients two to four days after discharge to reinforce the discharge plan and review medications (Jack et al., 2009). The control group of patient's received "usual" care upon discharge, with no follow up phone call from any staff of the facility. The intervention group demonstrated a decrease in hospital readmission rates and emergency room (ER) visits 30 days after discharge (Jack et al., 2009).

An additional study by Esposito (1995) utilized as a comparison benchmark of sorts, specific to the "elderly" population. This study was chosen for reference, despite the age, as it was the only study that was demographically similar to the current project. It was an intervention study to evaluate educational protocols to see which would be more effective in increasing medication compliance rates with an elderly population. Forty-two patients were randomized into four groups. Group one received a standard education protocol, group two received the

standard education and 30 minutes of verbal instruction, group three received the standard education and a medication schedule, and group four received the standard education, a medication schedule, and 30 minutes of verbal instruction. The intervention was accomplished on the day of hospital discharge. Home visits were made two weeks, one and two month's post-hospital discharge. Results of the visits revealed that groups one and two had higher rates of errors with medications than groups three and four. The groups with a medication schedule had higher compliance rates (Esposito, 1995).

There are numerous advanced practice nursing outcome measures this project addresses, including care-, patient-, and performance related (Kleinpell, 2013). However, the specific focus is to improve patient compliance with their medication regimen. Most health care professionals know how difficult this can be, and how it varies from patient to patient. Society is getting "older"(Doggrell, 2010). Often times, a myriad of medications are needed to control co-morbid conditions. The goal of the project, is with improved compliance there will also be a decrease in adverse events, improvement of patient self-efficacy, increase patient understanding/knowledge of their medication regimen (the why and the how or what they are taking), and subsequently reduce hospital readmission rates and resource utilization (Kane & Radosevich, 2011).

Through a thorough systematic review of supporting literature, the author was optimistic to create a successful education program using components of various studies that demonstrated positive outcomes. Below is a conceptual logic model that served as a foundation for the project (Zaccagnini & White, 2014). The project was the creation of a standardized discharge medication education program for adults age 65 and older. The model identified the problems the aging adult can face upon hospital discharge when sub-optimal medication education is dispensed. Problems include adverse medication events, increased hospital re-admission rates,

lack of patient medication education, incorrect medication intake, increased financial/medical burden and death.

Numerous resources impacted the identified problem. These resources include staff participation, complexity of the patient's medication regimen, compliance/time for hospital staff to perform education, and patient education level. Outside of the hospital setting resources impacting the problem include the patient's relationship with their PCP, financial limitations, transportation to obtain medications, interaction with a home health agency and family support.

Next identified were the activities, or interventions, that would affect the success of the program. The activities within a conceptual model include the processes, techniques, tools, and planned actions within a proposal (Zaccagnini & White, 2014). Activities included staff education of the project goals. Also, delivery of pill dispenser, creation of an individualized medication calendar and medication educational handouts for participants in the intervention group. Additionally, patient education was performed at discharge for those in the intervention portion of the project. Project completion occurred with a follow up phone call one week and three to six weeks post discharge for all project participants.

The outputs in a conceptual model reflect the direct result of the programs activities (Zaccagnini & White, 2014). The outputs in this project included the number of patients educated, education materials distributed, program participation rates, and time spent with each participant.

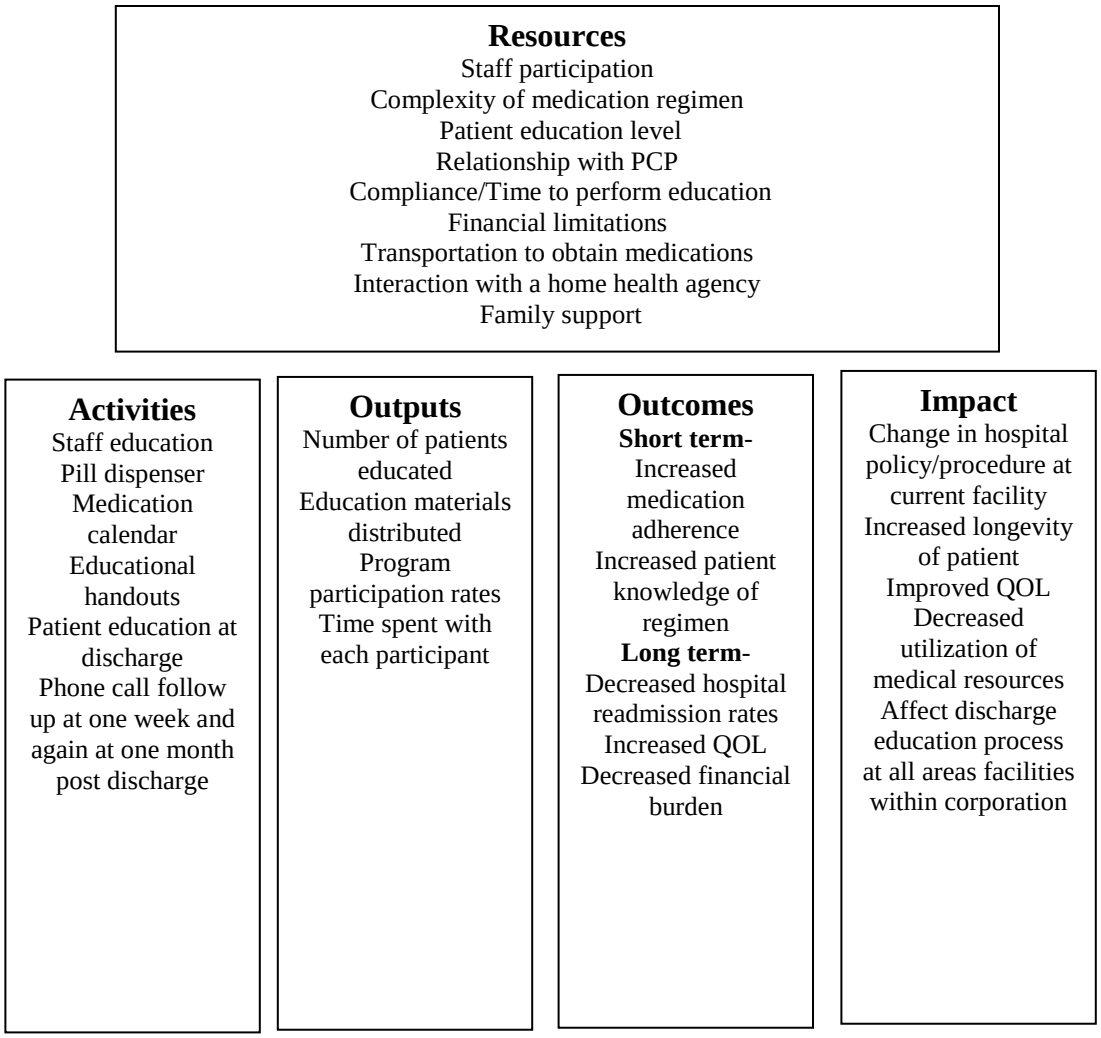
The final two portions of the logic model show the outcomes, as well as the impact of the project. Logic Models show short and long term goals that address the specific changes in attitudes, behaviors, skills, or knowledge that result from the program implementation (Zaccagnini & White, 2014). The short-term goals of this proposal included increased patient

medication adherence and increased patient knowledge of medication regimen. Long-term goals included decreased hospital readmission rates, increased quality of life and decreased financial burden.

In conclusion, the model presents the impact of the project. The impact goal of this project included change in hospital policy/procedure at facility of project implementation, increased longevity of patient, improved QOL, decreased utilization of medical resources, and the potential to affect discharge education process at all areas facilities within the corporation (Table 1).

Table 1: Logic Model

Problem Identification
Adverse medication events Hospital re-admission rates Lack of patient medication education Incorrect medication intake Financial/medical burden Death



Methodology

The study was a quasi-experimental two group design interventional study, one group receiving “standard” hospital discharge medication education and the second an “intervention” group. Participants for the project were drawn from a convenience sample of hospital patients,

chosen by chance. The independent variable associated with this practice issue was the implementation of a standardized discharge education program for medication management. No study has evaluated a standardized discharge intervention that included patient education, comprehensive discharge planning, and post-discharge telephone reinforcement in a general medical population since the Jack et al. (2009) study. Geriatric education centers have identified a lack of communication by the health care provider as a contributing factor to medication errors by the patient (Esposito, 1995). A simple solution to this issue was the creation of a standardized medication education program that all facilities can use at discharge.

The education program had three facets of "tactile" information combined with verbal education :

1. Each patient was given a monthly or weekly pill dispenser, ensuring that it was easy to open and manipulate by the patient.

2. A weekly/monthly calendar was furnished to the patient, plotting out the times of day all medications were to be taken. If a drug was to be dosed in intervals, these days were shaded a different color, i.e. Monday, Wednesday, Friday dosing of warfarin were shaded blue on the calendar (Jack et al., 2009; Martens, 1998). (Appendix E)

3. Medication information handouts listing how and when to take each medication, as well as general information about each drug. Benefits of adhering to medication regimen as prescribed were included as well. These handouts were written at an eighth grade reading level with 18 point font size (Appendix F)

The dependent variable associated with the practice issue was increased compliance with home medication regimen evidenced by results of phone questionnaire performed at one week and again at three to six weeks post discharge. Understanding compliance does lie primarily with

the patient; health care providers can provide numerous adjuncts to further assist the process. Improved compliance with medication regimens are associated with:

1. Simple clear instructions, reviewed periodically
2. Written instructions
3. Assessment of cognitive function prior to education
4. Development of a routine for taking medications
5. Construction of a chart when multiple medications are taken (Esposito, 1995, p. 936).

Laugaland, Aase, and Branch (2012) found a review of the data demonstrated a positive correlation between the independent and dependent variables by use of simple tools. The less complex the intervention, the higher probability the patient will be receptive and successful. Successful interventions reduce hospital readmission rates, adverse drug events, health care utilization, medication induced illness, increased patient/family satisfaction, and decrease cost (Esposito, 1995; Holloway, 1996; Laugaland et al., 2012).

Potential antecedent variables to this practice issue included age, number of chronic medical conditions requiring medication (co-morbidities), complexity of medication regimen, patient education level, relationship with primary care provider, and compliance. Potential moderator variables included age, culture/ethnicity, past experience with similar programs, financial limitations, gender, compliance, dexterity, education level, and hearing/visual/auditory impairment. Extraneous variables included financial limitations, transportation issues to obtain medications, interaction with a home health agency, family support, and compliance (Esposito, 1995; Holloway, 1996; Laugaland et al., 2012).

Patients were selected from the hospital admission roster for the selected practice at the selected facility. Patients were not excluded from the selection process due to number of

medications taken daily or number of medical conditions. Extra time was allotted for participants with greater than five daily medications, as a review of their medications occupied more time than a patient who only takes one medication daily. As there is no cost to the patient to participate, financial limitations were not issue, as they were given the necessary elements for the project free of charge. Antecedent and moderator variables were further addressed by evaluating participants for enrollment in the study using the following inclusion criteria:

1. Age 65 or older
2. Hospitalized for at least 24 hours, but no longer than three days due to time constraints of the project
3. Patient must be oriented to person, time, and place
4. Discharged to home
5. Ability to self-administer medications or take with minimal assistance
6. No cognitive impairments
7. Able to comprehend instructions written in English, at an eighth grade reading level (Esposito, 1995).

The participants were drawn from a convenience sample of hospital patients who were discharged and meet the inclusion criteria. Figuring the lowest possible number of participants necessary to maintain a confidence level of 95% with a confidence interval of five, a minimum of 26 participants total was necessary for power in this project (http://www.gpower.hhu.de/en.html). Thus, the sample size was 26, or n= 26. A sample size of 100 was sought through the facility's institutional review board (IRB) for the purposes of this study. Participants were identified by their age (target group age equal to or greater than 65 years old) and approached regarding participation in the project. During the explanation about the

project, the participant was assessed regarding inclusion criteria. Exclusion criteria included patients with dementia or other disorders affecting cognitive impairment, those receiving hospice/palliative care, those patients undergoing active chemotherapy or radiation therapy, patients less than 65 years of age, and those with a hospital stay greater than three days.

This project involved protected data of a vulnerable population. The surveyor had access to participant medications and basic demographics for use in the data collection process. No names or participant identifiers were included in the project summary, only alpha characters assigned to each participant at the beginning of the project were recorded.

Regarding protection of human subjects, all project team members, including the author and project lead chair, successfully completed the Collaborative Institutional Training Initiative (CITI). The expiration dates for current certification expires in 2017. Responsibilities to the participants included protecting their medical and personal information, fully disclosing the purpose of the project, and assuring that their medical care would not be affected regardless of their consent to participation in the project (Appendix D). The project did not involve any testing on individuals or manipulation of their medications. The main purpose was only collecting data as it pertained to participant compliance or adherence to their prescribed regimen. As such, exempt status was obtained from the Regis IRB.

Participants for the project were drawn from a convenience sample of hospital patients, chosen by chance. On the day(s) the project was performed, each patient name that met the inclusion criteria was listed on a single piece of paper. The total number of participants was tallied and divided in half. All of the paper with the patient name was folded in half then placed into a box. A single piece of paper at a time was drawn from the box and placed in the control

folder, until half of the names were drawn. The remaining names in the box were placed in the intervention folder.

Once the participants were divided into their respective groups, and prior to categorizing data, all participants were given a letter associated with their profile. Control group members had a single alpha character, and the intervention group members had a double alpha character. Profile information included name, age, and gender. This particular set of patient data was kept in a secure locked office area to prevent violations of patient privacy. For the purposes of this project, a secure area was defined as a password protected computer and/or a locked file cabinet in the project lead's home office. A spreadsheet was then created to categorize data. Along the left side of the spreadsheet, the participants names were listed as their "letter" identifier, along the top of the spreadsheet had each question listed. Two separate spreadsheets were created for the control group and the intervention group. Once information was entered, a score was calculated and listed in the final column of the spreadsheet.

Project Variables, Design, and Data Collection Plan

The proposed project was a two group design interventional study, chosen by chance, one group of participants received "standard" hospital discharge medication education and an "intervention" group received additional verbal education, instructional handouts, and a medication dispenser. Non-parametric, descriptive statistics were used to evaluate the ordinal and nominal data (Polit & Hungler, 1995). Bivariate analysis was used to determine the relationship between the control and intervention group (Polit & Hungler, 1995). The data were analyzed with Statistical Package for the Social Sciences (SPSS) version 23.0 Grad Pack for Windows and displayed in the final study report using frequency tables and pie charts to compare data values (SPSS inc., Chicago IL).

The measure of compliance was deduced using a modified CASE adherence index (Mannheimer et al., 2006). The original author reported it may be reproduced and/or used for research, teaching, and private study purposes (Mannheimer et al., 2006). The questionnaire was modified, making it more applicable to the project, by omitting the word HIV in the questions. The project mentor and Capstone chair agreed this would not affect the reliability of the tool (Appendix C). The answers to the three question survey were allocated numbers. Once the survey was completed, the numbers were summed and an adherence score was attached to said number. A score of greater than 10 indicated "good" adherence, and a number less than or equal to 10 indicated poor adherence (Mannheimer et al., 2006).

The modified survey was administered to all project participants to determine if the intervention group scores demonstrated increased medication compliance. The scores from the survey were compiled and calculated to create a percentage of patients who were in the "good" adherence category and those who fall into the "poor" adherence category. These numbers were compared between the two groups to determine if the intervention exhibited an increase in home medication compliance. The comparisons were made by taking the total scores for each group and then dividing that number by the number of participants in each group, control and intervention. Information gathered from these surveys was used to show effects of a standardized discharge medication regimen

A power analysis was performed for the proposed plan. Researchers typically use power analysis to solve for the sample size needed to increase the chance of showing significant results (Polit & Hungler, 1995). To solve for sample size, the researcher must specify the significance criterion, population effect size, and power (Polit & Hungler, 1995). Statistical power is critical to the design and planning of an outcomes study; therefore it should be conducted in advance

through a priori power analysis (Kane & Radosevich, 2011). Set standards for considering statistical power include setting the risk of type one error (or alpha) as 0.05, and a conventional standard for power (1-beta) as 0.8 (Polit & Hungler, 1995). Utilizing an online tool, the completed analysis has identified a total study sample of 26 (http://www.gpower.hhu.de/en.html). The participants were then divided into the control group and the intervention group, chosen by chance. The author determined to have a significance criterion (alpha) of 0.05 and a .80 power, a minimum sample size of 26 total for each group combined participants was needed for the project (Kane & Radosevich, 2011, Polit & Hungler, 1995). A sample size of 100 was sought for approval for completion of this project to ensure adequate sample.

Statistical research has varying levels of threats, including those of reliability and validity (Polit & Hungler, 1995). Threats to reliability were minimized by using a standardized survey instrument to report participant information. The sensitivity and specificity of the CASE Adherence Index with respect to three -day self-reported adherence was calculated at different cut-off scores by the original author. Based on this analysis, a cutoff score of 10 on the CASE Adherence Index was used to dichotomize the CASE Adherence Index to maximize the sensitivity and specificity of the index with respect to the three-day self-report set at 95% adherence. Threats to internal validity were limited by using four steps:

1. Ensured measurement or observation used standard instruments
2. Used an appropriate study design
3. Controlled bias
4. Accurate statistical analysis (Cullen, 2011)

The project used a standardized adherence rating questionnaire to decrease threat to internal validity. The study design was a two group design interventional study utilizing a convenience sample available within the author's primary medical practice. Discharge education is a highly variable event with many contributing factors. These factors can include time of day discharge is performed, patient comprehension level, caliber of staff nurse, pharmaceutical knowledge-base of staff nurse, cognitive barriers, and physical handicaps of the patient limiting comprehension. Having a sole investigator perform the education limited the variability of the education administered to study participants.

Potential threats to reliability or validity were participants reporting inaccurate data to avoid judgment or perceived threats to care, participants not returning calls after consenting to participate, mental status changes that occurred post discharge which affected cognition of the survey, and family assistance with complying with medication regimen. Bias was avoided using specific verbiage in the consent to participate in the program, including language to inform patients their care would not be affected in any way by participating in the project and they could withdraw at any time without change in care.

To mitigate threats, a maximum of three phone calls were made to the participants to obtain survey data. Participants were given verbal reinforcement during each call that their responses, or lack thereof, would in no way affect the medical care they received. Participants were encouraged during each call about the importance of reporting accurate data for the purposes of the project.

Careful selection of study data displays enhanced the understanding of the significance of study results and reduced all possibility of obscuring or misrepresenting the data (Freeman, Walters & Campbell, 2011). There were several considerations for displaying data in a way that

augmented the discussion of the study results. Data were displayed in the final study report in frequency tables and pie charts that compare data values (Figure I, Table II, Appendix F, and Appendix G). The modified CASE survey used in the study is included as Appendix C (Mannheimer et al., 2006).

Timeline

A timeline was a tool utilized to guide the forward progression of the project. The project was submitted for approval by capstone chair in November 2014, followed by institutional review board (IRB) application completed January 1, 2014. IRB submission/approval from project site and Regis University was obtained April 2015. Data collection was performed April 1 to June 8, 2015. Data analysis, final capstone project written paper, and oral capstone defense followed culminating into the submission to the library for publication in August 2015.

Budget

The expense for this project will vary between facilities and locations. Costs for the project included:

- $130.00 for pill dispensers, 26 dispensers at $5.00/unit
- $198 for SPSS program used to perform data analysis
- $1,000.00 for computer with MS Office software and locked filing cabinet
- $90,000.00 annual salary for advanced practice registered nurse, pro-rated for time necessary to complete project which was 4 months total.

Estimates were made from an average of products found in retail chain office supply stores. Actual salary for advance practice registered nurse used, can be pro-rated to time necessary for

project completion and varies location to location, this is an averaged salary estimate. The final cost therefore, was $31,328.

Data Analysis

The Sample

After review of 100 potential candidates for participation, 16 met inclusion criteria with a final N=16. Those 16 were divided equally into control and intervention groups (eight in each group), chosen by chance. The participants were admitted to the hospital between April 2015 and June 2015.

Data was entered and analyzed utilizing SPSS version 23. Descriptive statistics were used to examine the percentages of categorical variables (age) and comparison of data between control and intervention groups. Demographic data was analyzed for descriptive statistics including median, mode, and percentile range. Independent t-tests were performed for comparison of mean data between control and intervention groups.

The participants of the study were aged 66 to 82, with the mean age of 73.13 years (Figure I). Twenty-five percent of the participants were age 69 or less (Table II).

Figure I

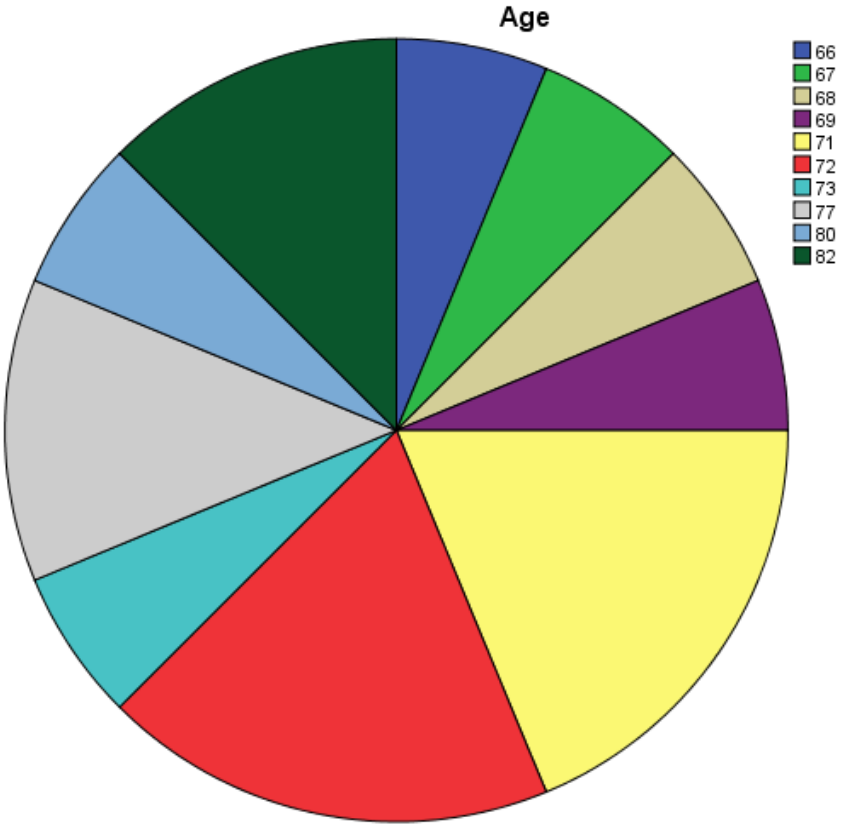

Age
66
67
68
69
71
72
73
77
80
82

Table II

Age

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	66	1	6.3	6.3	6.3
	67	1	6.3	6.3	12.5
	68	1	6.3	6.3	18.8
	69	1	6.3	6.3	25.0
	71	3	18.8	18.8	43.8
	72	3	18.8	18.8	62.5
	73	1	6.3	6.3	68.8
	77	2	12.5	12.5	81.3
	80	1	6.3	6.3	87.5
	82	2	12.5	12.5	100.0
	Total	16	100.0	100.0	

Protection of Human Subjects

This project involved protected data of a vulnerable population. The surveyor had access to participant medications and basic demographics for use in the data collection process. No names or participant identifiers were included in the project summary, only alpha characters assigned to each participant at the beginning of the project were recorded.

Once the participants were placed into their respective groups, and prior to categorizing data, all participants were given a letter associated with their profile. Control group members had a single alpha character, and the intervention group members had a double alpha character. Profile information included name, age, and gender. This particular set of patient data was kept in a secure locked file cabinet in a locked office area to prevent violations of patient privacy. For the purposes of this project, a secure area was defined as a password protected computer and/or a locked file cabinet in the project lead's home office.

All project team members, including the author and project lead chair, successfully completed the Collaborative Institutional Training Initiative (CITI). All information related to this project will be destroyed after five years. The data will be destroyed using a paper shredder.

Findings and Results Discussion

An Independent T-test compared participants who received "standard" discharge medication education and those who received an additional education that combined three facets of "tactile" information with verbal education. There was no statistically significant improvement in the cumulative scores of those who received "standard" discharge medication education and those in the intervention group. However, there was notable improvement when comparing the week one (all groups) and week three (all groups) scores pertaining to question one of the survey (Appendix G). Results demonstrated a change in significance from week one ($p = .334$) to week three ($p = .031$) respectively. Question two scoring showed no significant change from week one to week three. Question three did show a slight decrease in overall significance in comparing week one ($p = .215$) and week three ($p = .314$). The weakest points of the study were related to "missed" doses of the participant's medications evidenced in the cumulative scores from question two and question three and lack of change in overall significance (Appendix F).

Effect Size

The magnitude of a relationship in situations calling for independent group t-tests is most often communicated in the form of effect size, as it measures the strength of the relationship between variables in the population (Polit, 2010). This statistic is referred to as Cohen's *d*. The effect size, or Cohen's *d* was calculated for the individual questions and the total cumulative scores, comparing the control and intervention groups. The results include:

- The Cohen's *d* was .24 for week one and .56 for week three pertaining to question one.
- The Cohen's *d* was .00 for week one and .00 for week three pertaining to question two.
- The Cohen's *d* was .27 for week one and .22 for week three pertaining to question three.
- The Cohen's *d* was .28 for week one and .32 for week three for the cumulative scores.

According to Cohen's criteria, an effect size of .20 in a two-group mean-difference situation is considered small, .50 is medium, and .80 is large (Polit, 2010). Based on the data above the estimated effect size is small, with the exception of question one/week three. This question showed an estimated medium effect size, which was reflective of the results obtained from the independent t-test.

Reliability

When researchers are interested in assessing an instrument's stability over time, the test is administered on two separate occasions to determine test-retest reliability (Polit, 2010). The correlation coefficient between the total scores in week one and week three provide evidence of the instrument's reliability (Appendix F, Appendix G).

Utilizing a standardized questionnaire to document participant responses increased the reliability of the data obtained overall. However, discharge education is a highly variable event with many contributing factors that could impact the outcomes of the "standard" education group. These factors can include time of day discharge is performed, patient comprehension level, caliber of staff nurse, pharmaceutical knowledge-base of staff nurse, cognitive barriers,

and physical handicaps of the patient limiting comprehension. Having a sole investigator perform the education limited the variability of the education administered to the intervention group.

Threats to reliability were minimized by using a standardized survey instrument to report participant information. The sensitivity and specificity of the CASE Adherence Index with respect to three -day self-reported adherence was calculated at different cut-off scores by the original author (Mannheimer et al., 2006). Based on this analysis, a cutoff score of 10 on the CASE Adherence Index was used to dichotomize the CASE Adherence Index to maximize the sensitivity and specificity of the index with respect to the three-day self-report set at 95% adherence (Mannheimer et al., 2006).

The initial study used the data obtained from the survey and correlated the results to laboratory data. The published questionnaire had a reliability and validity published by the author reporting the CASE Adherence Index correlated strongly with the three-day self-reported adherence data ($p < 0.001$) and was more strongly associated with human immunodeficiency virus (HIV) outcomes ($p < 0.05$), and performed as well as the three-day self-report when predicting CD4 count status (Mannheimer et al., 2006). Participants with a CASE Index score >10 achieved a 98 cell mean increase in CD4 count over 12 months, compared to a 41 cell increase for those with scores ≤10 ($p < 0.05$) (Mannheimer et al., 2006).

Validity

The concept of validity refers to how close the measure is to actually measuring what was intended (Polit, 2010). Validity is the extent to which a conclusion or measurement is well-founded and corresponds accurately to the real world. This questionnaire at weeks one and three measured the participants' medication adherence. The published questionnaire had a reliability

and validity published by the author reporting the CASE Adherence Index correlated strongly with the three-day self-reported adherence data ($p < 0.001$) and was more strongly associated with HIV outcomes ($p < 0.05$) (Mannheimer et al., 2006).

Discussion

Although there was a change in the total scores between the control and intervention group, it was not statistically significant. However, statistically significant differences existed in the overall scoring of question one/week one and question one/week three. This theorizes participants were retaining information regarding the importance of medication adherence even after three weeks following education. The results of this small study could be used as a foundation for additional studies that support the creation of a "standard" discharge program. Even though this was a small sample size and did not reached the expected power, one could summarize based upon the published literature and the beginnings of movement to increased adherence that this is a study that warrants repeating using a larger sample size.

Discharge education is a highly variable event with many contributing factors. These factors can include time of day discharge is performed, patient comprehension level, caliber of staff nurse, pharmaceutical knowledge-base of staff nurse, cognitive barriers, and physical handicaps of the patient limiting comprehension. Having a sole investigator perform the education limited the variability of the education administered to study participants.

Evidence-based Practice Questions

Analysis was conducted of the question: Would a standardized discharge education program for medication management versus no standardized program be effective in increasing patient adherence to home medication regimen, as measured by telephone questionnaire at one week and again at three to six weeks post discharge. The study results did illustrate the additional

education components the intervention group received did have an impact on patient medication adherence, albeit not statistically significant. A clinically significant increase in adherence is important even if not statistically significant. Medication non-adherence is considered a threat to the physical, mental and economic health of the United States (Jones et al., 2014). Adverse health outcomes related to poor medication adherence can range from exacerbations of disease processes to premature death as well as resulting in increased utilization of healthcare resources thus patient safety continues to be a concern (Jack et al., 2009; Jones et al., 2014).

Theoretical Support

The data did display a notable improvement in the overall week one scores, despite the lack of significant changes in the overall scoring. This does support the Adult Learning Theory by Malcolm Knowles that recommends certain information be used to enhance/improve the educational experience of the adult learner. This theory is based on the principle adults need certain considerations to successfully learn (Syx, 2008).

1. Adults need to know why they need to know something before they start
2. As adults mature they are more self-directed and less dependent
3. Personal experience is a large resource for learning new information
4. Adults are problem oriented learners
5. An adults time frame changes from postponed action to immediate action
6. Adults are primarily motivated by a need to solve immediate and practical problems

Limitations

Limitations included a small sample size within one health care facility. Approval was sought for 100 participants total in the research project. However, only 16 participants met

inclusion criteria during the allotted time frame for data collection. This limitation decreases the ability of findings to be generalized outside of this setting. Limiting the study to the three months could also be consider at limitation as seniors are hospitalized during different seasons with varying diagnoses.

Contributions to Nursing Advanced Practice

Continuation of this education initiative would be of benefit to any healthcare facility. The results do illustrate there is increased retention of medication education at three weeks post discharge. There are numerous reasons a program such as this could potentially benefit seniors at any healthcare facility. With improved medication adherence, there would also be a decrease in adverse events, improvement of patient self-efficacy, increased patient understanding/knowledge of their medication regimen, increased patient well-being and subsequently reduced hospital readmission rates and resource utilization thus increased patient satisfaction and quality of life (Doggrell, 2010; Jack et al., 2009; Jones et al., 2014; Midlov et al., 2008).

Recommendation for Further Study

Despite a small sample size, the project does demonstrate a probable positive correlation between a standardized discharge medication regimen and improved medication adherence once discharged from a facility. A study with a larger sample size, a longer collection period, along with broadening the inclusion criteria could increase the ability to generalize these results. The weakest points of the study were related to “missed” doses of the participant’s medications. This indicates an educational opportunity for focused education about the importance of not only taking a medication on time, but also not missing doses of medications. There are a number of ways to improve upon this aspect of the study.

Additional measures could include written-information sheets, structured discharge medication education, medication calendars, supplementation of medication dispensers with up to four times daily dosing, increased verbal counseling, and increased utilization of additional resources (i.e. pharmacists or pharmacy technicians). Any, or all, of these additional processes might improve patient's understanding of their medication regimen, resulting in increased medication adherence and safer use of medications by the patient. When combined with current medication education practice, these additional measures can only benefit the health and safety of any patient, regardless of their age.

Implications for Change

Non-adherence to prescribed medication therapies has no predilection for age, gender or ethnicity. Non-adherence impacts the overall health and well-being, short and long-term, for anyone using prescription medication for a medical condition (Jones et al., 2014). Initiating a standardized medication education regimen in acute care settings is a beneficial tool to improve medication adherence thus leading to increase patient quality of health.

Conclusion

Education could be considered one of the most important duties a practitioner has to their patient. Generally speaking, the goal of patient education is for the patient to not only understand their health condition but also how to properly manage said condition(s). Management of a co-morbid condition is largely achieved with proper medication administration and this burden often lies with the patient or their family. A comprehensive medication education program is a logical solution for something that has potential to be so detrimental to a patient's health.

The findings of the project demonstrate a possible positive correlation between a standardized discharge medication regimen and improved medication adherence once discharged

from a facility. A study with a larger sample size, a longer collection period, along with broadening the inclusion criteria could increase the ability to generalize these results. With further research studies, a stronger positive correlation could be found between a standardized discharge medication education that could significantly impact patient's quality of life and health care understanding.

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Appendix A

Doggrell, S. A. (2010). Adherence to medications in the older-aged with chronic conditions. Does intervention by an allied health professional help?	**Esposito, L. (1995). The effect of medication education on adherence to medication regimens in an elderly population.**	**Holloway, A. (1996). Patient knowledge and information concerning medication on discharge from hospital.**	**Jack, B. W., et al. (2009). A reengineered hospital discharge program to decrease rehospitalization.**	**Laugaland, K., et al. (2012). Interventions to improve patient safety in transitional care-a review of the evidence.**	**Martens, K. H. (1998). An ethnographic study of the process of medication discharge education (MDE).**	
VII	III	VI	II	VII	VI	

Appendix B

SWOT analysis

Strength	Weakness
• Large potential group • Estimated that 80% of current practice population > 65 years of age • Of those 90% or more leave the hospital setting with a new Rx • As of 2009, no study has evaluated a standardized discharge intervention (Jack et al., 2009)	• Data obtained from single medical center • Convenience sample • Results not likely to be generalizable to public • Complexity of medication regimen • Patient education level • Relationship with primary care provider
Opportunities	**Threats**
• Increase number of the "aging" population in medical settings • Limited time for proper patient education using "dated", unstructured techniques • Can be adapted at any facility/setting for minimal out-of-pocket cost	• Financial limitations to obtain medications • Transportation issues to obtain medications • Interaction with a home health agency • Family support • Compliance

*SWOT analysis (Fortenberry, 2010)

Appendix C

CASE (Center for Adherence Support and Evaluation) Adherence Index questionnaire-modified

Please ask each question and circle the corresponding number next to the answer, then add up the numbers circled to calculate Index score.

A1. How often do you feel that you have difficulty taking your medications on time? By 'on time' we mean no more than two hours before or two hours after the time your doctor told you to take it.

4 Never
3 Rarely
2 Most of the time
1 All of the time

A2. On average, how many days per week would you say that you missed at least one dose of your medications?

1 Everyday
2 4_6 days/week
3 2_3 days/week
4 Once a week
5 Less than once a week
6 Never

A3. When was the last time you missed at least one dose of your medications?

1 Within the past week
2 1_2 weeks ago
3 3_4 weeks ago
4 Between 1 and 3 months ago
5 More than 3 months ago
6 Never

INDEX SCORE: _____

>10 =/good adherence
≤ 10 = poor adherence (Mannheimer et al., 2006)

Appendix D

CONSENT TO PARTICIPATE IN RESEARCH

Standardized discharge medication education program for adults age 65 and older

You are asked to participate in a research study conducted by Jill Weller, doctoral candidate, at Research Medical Center. You have been asked to participate in this study because you are aged 65 or older and being discharged home with medications that may or may not be new to you. Approximately 26 total participants will be involved in this study. You will receive in depth medication education at discharge, given educational handouts, and a pill dispenser. You will be contacted and asked a series of questions one week following discharge, and again in three to six weeks after discharge. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- **PURPOSE OF THE STUDY**

The purpose of the study is to determine if focused education at performed at hospital discharge regarding home medication use improves compliance.

- **PROCEDURES**

If you volunteer to participate in this study, and are in the intervention group, the education program will include the following:
1. You will be given a pill dispenser.
2. You will be given medication information handouts listing how and when to take each medication, as well as general information about each drug. These handouts will be written at an eighth grade reading level with large font size.
3. You will be given a weekly/monthly calendar, plotting out the times of day all medications are to be taken.

- **PARTICIPANT SELECTION**

Participants will be placed into two groups, the intervention group and the standard care group. All participants will be given a letter associated with their profile. Profile information will also include name, age, and gender.

- **POTENTIAL RISKS AND DISCOMFORTS**

This project involves protected health information. The principal investigator will have access to participant medications and basic demographics for use in the data collection process. No names or participant identifiers will be included in the final project.

The project will not involve any testing on individuals or manipulation of their medications. The primary purpose is collecting data as it pertains to participant compliance or adherence to their prescribed regimen.

- **ANTICIPATED BENEFITS TO SUBJECTS**

Improved understanding of home medication regimen, and/or improved medication compliance.

- **ANTICIPATED BENEFITS TO SOCIETY**

The vision of the project is to have a positive effect on patient outcomes with an easy to use, standardized discharge medication education regimen with minimal financial burden to the patient/client.

- **FINANCIAL OBLIGATION**

There is no financial obligation of the subject.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care);
- any threats that you make to harm yourself or others;
- information that a child has been subjected to abuse or neglect; or
- evidence of an infectious or contagious disease that endangers the public health will be reported to appropriate authorities.

Profile information will include name, age, and gender. Patient data will be kept in a secure area to prevent violations of patient privacy. For the purposes of this project, a secure area is defined as a password protected computer and/or a locked file cabinet in the project lead's home. No names or participant identifiers will be included in the final project. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Authorized representatives of the HCA-Midwest Health System IRB may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with Research Medical Center, or your right to health care or other services to which you are otherwise entitled. If you wish to withdraw from the study, you must do so in writing to the principal investigator, Jill Weller.

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at Research Medical Center.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The principal investigator, Jill Weller, will make the decision and let you know if it is not possible for you to continue.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad) that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **IDENTIFICATION OF INVESTIGATOR**

In the event of a research related issue, or questions about the research, please contact the principal investigator Jill Weller at (816) 678-8675.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact Larry D. Cordell, MD, Chair of the HCA-Midwest Health System Institutional Review Board at 816-246-3921.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Subject's name (print name)

Subject's Signature _____

Date: _____

FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject, discussed with the subject, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____
_____
Signature of Impartial Witness (if applicable) Date

Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. ***Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance***

SIGNATURE OF INVESTIGATOR/INTERVIEWER

I have explained the research to the subject or his/her legal representative and answered all of his/her questions.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subjects)

Appendix E

Weekly Medication Calendar

Monday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Tuesday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Wednesday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Thursday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Friday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Saturday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only
Sunday	Levothyroxine 150mcg 6AM- 30-60 minutes prior to breakfast Sertraline 50 MG 9AM Pravastatin 40mg 9PM Percocet 1-2 tablets 6AM, Noon, 6PM, Midnight as needed only

Appendix F

Sample Medication Education Handout (font size decreased for purposes of paper)

Drug #1

Sertraline: Sertraline is used to treat depression, panic attacks, obsessive compulsive disorder, post-traumatic stress disorder, social anxiety disorder, and a severe form of premenstrual dysphoric disorder. This medication may improve your mood, sleep, appetite, and energy level and may help restore your interest in daily living. It may decrease fear, anxiety, and the number of panic attacks. It may also reduce the urge to perform repeated tasks that interfere with daily living. Sertraline is known as a selective serotonin reuptake inhibitor (SSRI). It works by helping to restore the balance of a certain natural substance (serotonin) in the brain.

How to take: Take this medication by mouth as directed by your doctor, usually once daily either in the morning or evening. This medication may be taken with or without food.

Benefits of adherence: Since untreated mental/mood problems (such as depression, panic attacks, obsessive compulsive disorder, post-traumatic stress disorder) can be a serious condition, do not stop taking this medication unless directed by your doctor. It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor.

Side effects: Nausea, dizziness, drowsiness, dry mouth, loss of appetite, increased sweating, diarrhea, upset stomach, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Avoid alcoholic beverages.

Drug #2

Percocet: This combination medication is used to help relieve moderate to severe pain from your surgical procedure. It contains a narcotic pain reliever (oxycodone) and a non-narcotic pain reliever (acetaminophen). Oxycodone works in the brain to change how your body feels and responds to pain. Acetaminophen can also reduce a fever.

How to take: Take this medication by mouth as directed by your doctor. You may take this drug with or without food. If you have nausea, it may help to take this drug with food. Do not increase your dose, take the medication more frequently, or take it for a longer time than prescribed

Benefits of adherence: Pain medications work best if they are used as the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well. Along with its benefits, this medication may rarely cause abnormal drug-seeking behavior (addiction). This risk may be increased if you have abused alcohol or drugs in the past.

Side effects: Nausea, vomiting, constipation, lightheadedness, dizziness, or drowsiness may occur. Some of these side effects may decrease over time. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. To prevent constipation, eat a diet adequate in fiber, drink plenty of water, and exercise. Consult your pharmacist for help in selecting a laxative (such as a stimulant type with stool softener).To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Avoid alcoholic beverages. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes, severe stomach/abdominal pain, difficulty urinating.

Drug #3

Levothyroxine: Levothyroxine is used to treat an underactive thyroid (hypothyroidism). It replaces or provides more thyroid hormone, which is normally produced by the thyroid gland.
How to take: Take this medication by mouth as directed by your doctor, usually once daily on an empty stomach, 30 minutes to 1 hour before breakfast. Take this medication with a full glass of water unless your doctor directs you otherwise. If you are taking the capsule form of this medication, swallow it whole. Do not split, crush, or chew. People who cannot swallow the capsule whole should use the tablet form of the medication.
Benefits of adherence: Dosage is based on your age, weight, medical condition, laboratory test results, and response to treatment. Use this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time each day. Do not stop taking this medication without first consulting with your doctor. Thyroid replacement treatment is usually taken for life. There are different brands of levothyroxine available. Do not change brands without first consulting your doctor or pharmacist.
Side effects: Hair loss may occur during the first few months of treatment. This effect is usually temporary as your body adjusts to this medication. If this effect persists or worsens, tell your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious effects of high thyroid hormone levels occur (too much medication): increased sweating, sensitivity to heat, mental/mood changes (such as nervousness, mood swings), tiredness, diarrhea, shaking (tremor), headache, shortness of breath.
Note: Some products that may interact with this drug include: "blood thinners" (such as warfarin), digoxin, and theophylline.

Drug #4
Pravastatin: Pravastatin is used along with a proper diet to help lower "bad" cholesterol and fats (such as LDL, triglycerides) and raise "good" cholesterol (HDL) in the blood. It belongs to a group of drugs known as "statins." It works by reducing the amount of cholesterol made by the liver. Lowering "bad" cholesterol and triglycerides and raising "good" cholesterol decreases the risk of heart disease and helps prevent strokes and heart attacks.
How to take: Take this medication by mouth with or without food as directed by your doctor, usually once daily. For best results, take this medication in the evening. Dosage is based on your medical condition, response to treatment, age, and other medications you may be taking. If you also take certain other drugs to lower your cholesterol (bile acid-binding resins such as cholestyramine or colestipol), take pravastatin at least 1 hour before or at least 4 hours after taking these medications. These products can react with pravastatin, preventing its full absorption.
Benefits of adherence: Take this medication regularly in order to get the most benefit from it. Remember to take it at the same time each day. It is important to continue taking this medication even if you feel well. Most people with high cholesterol or triglycerides do not feel sick. It is very important to continue to follow your doctor's advice about diet and exercise. It may take up to 4 weeks before you get the full benefit of this drug.
Side effects: Many people using this medication do not have serious side effects. A very small number of people taking pravastatin may have mild memory problems or confusion. If these rare effects occur, talk to your doctor. Rarely, statins may cause or worsen diabetes. Talk to your doctor about the benefits and risks. **This drug may infrequently cause muscle problems**

(which can rarely lead to very serious conditions called rhabdomyolysis and autoimmune myopathy). Tell your doctor right away if you develop any of these symptoms during treatment and if these symptoms persist after your doctor stops this drug: muscle pain/tenderness/weakness (especially with fever or unusual tiredness), change in the amount of urine. This medication may rarely cause liver problems. If you notice any of the following rare but serious side effects, tell your doctor immediately: yellowing eyes/skin, dark urine, severe stomach/abdominal pain, persistent nausea/vomiting.

Appendix G

Group Statistics

	Control or Intervention	N	Mean	Std. Deviation	Std. Error Mean
Question one week one	Control	8	3.63	.518	.183
	Intervention	8	3.75	.463	.164
Question one week three	Control	8	3.63	.518	.183
	Intervention	8	3.88	.354	.125
Question two week one	Control	8	5.88	.354	.125
	Intervention	8	5.88	.354	.125
Question two week three	Control	8	5.88	.354	.125
	Intervention	8	5.88	.354	.125
Question three week one	Control	8	5.38	1.768	.625
	Intervention	8	5.75	.707	.250
Question three week three	Control	8	5.50	1.414	.500
	Intervention	8	5.75	.707	.250
Total score week one	Control	8	14.88	2.031	.718
	Intervention	8	15.38	1.408	.498
Total score week three	Control	8	15.00	1.690	.598
	Intervention	8	15.50	1.414	.500

Appendix H

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Question one week one	Equal variances assumed	1.000	.334	-.509	14	.619	-.125	.245	-.652	.402
	Equal variances not assumed			-.509	13.829	.619	-.125	.245	-.652	.402
Question one week three	Equal variances assumed	5.744	.031	-1.128	14	.278	-.250	.222	-.725	.225
	Equal variances not assumed			-1.128	12.365	.281	-.250	.222	-.731	.231
Question two week one	Equal variances assumed	.000	1.000	.000	14	1.000	.000	.177	-.379	.379
	Equal variances not assumed			.000	14.000	1.000	.000	.177	-.379	.379
Question two week three	Equal variances assumed	.000	1.000	.000	14	1.000	.000	.177	-.379	.379
	Equal variances not assumed			.000	14.000	1.000	.000	.177	-.379	.379

Question three week one	Equal variances assumed	1.690	.215	-.557	14	.586	-.375	.673	-1.819	1.069
	Equal variances not assumed			-.557	9.184	.591	-.375	.673	-1.893	1.143
Question three week three	Equal variances assumed	1.089	.314	-.447	14	.662	-.250	.559	-1.449	.949
	Equal variances not assumed			-.447	10.294	.664	-.250	.559	-1.491	.991
Total score week one	Equal variances assumed	.186	.673	-.572	14	.576	-.500	.874	-2.374	1.374
	Equal variances not assumed			-.572	12.465	.577	-.500	.874	-2.396	1.396
Total score week three	Equal variances assumed	.044	.837	-.642	14	.531	-.500	.779	-2.171	1.171
	Equal variances not assumed			-.642	13.577	.532	-.500	.779	-2.176	1.176