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Addressing Adherence to Bisphosphonate Medication Using a Systems-Based Approach

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Primary non-adherence (PNA) to bisphosphonate medications has been recently identified to be as high as 30% in patients with osteoporosis or who are at risk for hip fracture. It is known that taking a bisphosphonate is the main course of defense in lowering patient risk and decreasing the hip fracture rate by 50%. However, if patients do not take their medication, they will not receive the benefit of fracture risk reduction that comes with it. This paper explored the testing and implementation of a protocol designed to improve the PNA rate and thus improve patient outcomes. This protocol used evidenced-based information that improved the provider-patient relationship through a telephone outreach protocol aided by a computer system that identified patients who had not picked up their medications from the pharmacy. The nurse practitioner (NP) coordinator targeted each patient and then worked the list of patients at risk until all patients had been contacted. The goal was to lower the PNA rate by 20% by targeting those patients who had not picked up their medications and by changing their behavior to develop an intention to pick up and take their bisphosphonate medication. This goal was reached as the PNA rate was reduced to 3.2%, although it might have been a combination of contributing factors that led to the decrease in rate and not the telephone outreach alone. The

protocol was successful and was accepted into practice to be replicated throughout all of the medical centers within the organization.

TABLE OF CONTENTS

CHAPTER I. INTRODUCTION 1

Statement and Background of the Problem 1
Population/Intervention/Comparison/Outcome/Time Statement 3
Background and Significance of the Problem 3
National Statistics 8
Financial Impact 11
Theoretical Framework 12
Literature Review 18
Summary 46

CHAPTER II. STUDY DESCRIPTION AND OBJECTIVES 48

Study Description 48
Objectives of the Study 48
Study Design 49
Description of the Knowledge Builder Tool 52
Ethical Considerations 55
Goal of the Study 57
Desired Outcomes of the Study 58
Budget and Financial Disclosures 65
Primary Non-Adherence Workflow Process for Telephone Outreach 66
The Study and Agency Strategic Plan 68
Timeline of Study Phases 69
Descriptive Statistics 72
Data Collection Method 73
Summary 75

CHAPTER III. STUDY EVALUATION PLAN 76

Exclusion Criteria 77
Measureable Objectives 78
Additional Necessary Resources 84
Summary 85

CHAPTER IV. RESULTS AND OUTCOMES 86

Objectives of the Study 86
Study Population 87
Participant Exclusion 88
Implementation of the Telephone Protocol by the Nurse Practitioner 88
Telephone Outreach Protocol Tool 91
Characteristics of the Prescriber 99
Summary 103

CHAPTER V. DISCUSSION 105

Systems Level 106
Provider Level 108
Patient Level 110
Timetable to Completion 112
Work Flow Process/Project Activities 112
Recommendations and Implications for Practice 115
Barriers and Unintended Consequences 119
Framework of the Organization's Strategic Plan 122
Contribution of the Project to the Attainment of Personal Leadership Goals 124
How the Project Compares to the Solution 125
Summary 126

REFERENCES 128

APPENDIX A. UNIVERSITY OF NORTHERN COLORADO INSTITUTIONAL REVIEW BOARD APPROVAL 140

APPENDIX B. CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH 142

APPENDIX C. INSTITUTIONAL REVIEW BOARD APPROVAL FOR KAISER PERMANENTE 145

APPENDIX D. MEMORANDUM OF UNDERSTANDING 147

APPENDIX E. NURSE PRACTITIONER QUESTIONNAIRE 150

APPENDIX F. TELEPHONE PROTOCOL 156

APPENDIX G. LETTER TO PATIENT AND PROVIDER 158

APPENDIX H. PATIENT INTAKE AND PATIENT RESPONSE FORMS 160

LIST OF TABLES

1. Timeline of Phase Implementation 70
2. Reasons for Participant Exclusion 88
3. Adherence Rates Before and After Telephone Outreach Call 93
4. Descriptive Statistics of Telephone Outreach Protocol 94
5. Reasons for Not Picking Up Medication 95
6. One Call Versus Two Calls to Pick Up Medication in the Telephone Outreach Adherent Group 96
7. Calls Made to Primary Non-Adherent Patients 97
8. Reasons for Not Picking Up Medication 98
9. Prescriber Characteristics for Non-Adherent Patients 100
10. Prescriptions Written by Nurse Practitioner 102
11. Prescriptions Written by Another Prescriber 103

LIST OF FIGURES

1. The fracture pyramid 23

2. Flow diagram of how the theory of planned behavior effects change in attitudes and behavior of patient and nurse practitioner 60

3. Timeline for protocol 67

4. Framework for program evaluation 832

5. Prescriptions by nurse practitioner versus other clinician for study telephone protocol primary non-adherent versus adherent 100

6. Results of telephone outreach protocol 104

CHAPTER I

INTRODUCTION

Statement and Background of the Problem

Major advancements in the pharmaceutical management of osteoporosis have contributed to drastic reductions in osteoporosis and related fractures. Therapeutic results of medication treatment for osteoporosis can reduce the risk of hip fracture by 47% (Ensrud et al., 1997). The primary treatment of choice for osteoporosis is a class of medications called bisphosphonates. Evidence has shown that patients could have up to a 50% reduction in their fracture risk if this medication is taken properly (Black et al., 2000). The impact of osteoporosis related fractures is significant in terms of poor outcomes for the patient as well as being tremendously costly to the healthcare system. Medication adherence is essential for reducing morbidity and mortality in patients with or at risk for osteoporosis. Accomplishing medication adherence requires a system of care that addresses the individual needs of patients with osteoporosis and provides a method for tracking patient data through information technology to identify non-adherence. Combining these into a model of care that provides strategies targeting adherence at both the individual and systems levels is needed to reduce osteoporosis-related fractures with decreased morbidity and mortality in this population. While strategies are needed at both levels to positively impact outcomes of patients with osteoporosis, efforts to accomplish this have met with limited success.

Management of osteoporosis, as with any chronic disease, is based on the ability of health care providers to (a) identify patients at risk for fractures and (b) implement evidence-based treatment regimens that will lead to improved patient outcomes, thereby reducing morbidity and mortality. Improved patient outcomes can only occur if patients adhere to treatment. While adherence to treatment can occur at many levels, primary non-adherence (PNA) occurs when patients do not pick up their prescriptions within 60 days of receiving the prescription (Reynolds et al., 2013). Utilizing information technology at the system level to identify those patients who are non-adherent in obtaining their medication is one method of alleviating non-adherence and potentially impacting outcomes.

This project focused on answering the following research question:

Q1 Will a telephone outreach protocol based on the theory of planned behavior (TPB) be effective in lowering the primary non-adherence rate (PNA) to bisphosphonate medication by 20% in a large Health Maintenance Organization (HMO)?

Thus, a protocol designed to increase patient adherence in taking medications was implemented and evaluated in a practice setting. The project included data analysis to monitor the activities of patients who had a new prescription for a bisphosphonate and whether or not they picked the prescription up from the pharmacy within 60 days. The project investigated whether a protocol that included individual nurse practitioner (NP) and system strategies could impact primary non-adherence in patients at risk for or who have osteoporosis.

Population/Intervention/Comparison/ Outcome/Time Statement

Population/Intervention/Comparison/Outcome/Time (PICOT) is the method used in addressing clinical questions related to PNA. According to Melnyk and Fineout-Overholt (2011), the components of a PICOT question include patient population, intervention, outcome, and timeline to goal completion. The population for this project included men and women over the age of 55 years with primary non-adherence to bisphosphonate medication. The PICOT question answered in this paper was as follows: Will the implementation of a practice protocol impact patient primary non-adherence (PNA) within 60 days of a new bisphosphonate prescription? As part of an osteoporosis disease management program, NP specialists in osteoporosis disease management utilized a protocol that focused on interventions to address and improve the rate of PNA.

Background and Significance of the Problem

This section begins with a brief description and definition of terms unique to and used consistently throughout this paper.

Definitions

The National Osteoporosis Foundation (NOF; 2013b) defines osteoporosis as a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures, especially of the hip. Osteoporosis is known as a silent disease because bone loss can occur without symptoms until a fracture event occurs, making the condition more challenging to prevent and treat (NOF, 2013a). To date, bisphosphonates are proven to be the best medication to treat osteoporosis and prevent subsequent fractures (Black et al., 2000).

Primary non-adherence (PNA) of a bisphosphonate occurs when patients do not retrieve their new prescription from the pharmacy within 60 days of the date of the prescription. This is also referred to as non-fulfillment. Secondary non- adherence (SNA) describes non-persistence of a medication and occurs when the patient fails to refill their medication from the pharmacy after it was initially filled. This definition of secondary non-adherence was included because it is important to understand both of the concepts of primary and secondary non-adherence; only PNA was followed for the purpose of this paper.

The Knowledge Builder Tool is an information technology (IT) tool embedded into the electronic medical record (EMR) that assists the nurse practitioner (NP) in identifying patients who are not picking up their bisphosphonate medications from the pharmacy. The NP then monitors the treatment to meet program hip fracture reduction goals based on national guidelines established by the National Osteoporosis Foundation (2013a).

Statement of the Problem

Each year in the United States, two million people have an osteoporosis-related fracture. Of these fractures, 300,000 are hip fractures--the most serious of all fractures. Primary non-adherence is a major problem in the treatment of patients with osteoporosis. Reynolds et al. (2013) stated that 29.5% of patients in a large health care organization who were prescribed a bisphosphonate for osteoporosis did not pick up the medication, take it, or gain any benefit from it. Other authors have also shown both PNA and SNA to be a problem in the treatment of osteoporosis; this is discussed further in the literature review section of this paper.

In clinical trials, the use of bisphosphonate treatment has led to a 50% reduction in hip fractures (Black et al., 2000). When not taken correctly, the rate of hip fracture increases (Silverman & Gold 2008; Siris et al., 2006). No intervention other than medication adherence has shown this level of success in hip fracture reduction (Siris et al., 2006). Solutions to addressing this barrier are needed to improve treatment rates and patient outcomes. Although clinical and evidence-based guidelines are available to guide treatment, high rates of fractures continue, perhaps due to difficulties in primary non-adherence of patients who have been prescribed bisphosphonate anti-osteoporosis medications.

The significance of PNA spans three levels: the individual patient, the provider, and the system. All three contribute differently to the outcome of PNA and adherence to bisphosphonate medications. Even though health care providers have access to clinical care guidelines, there is no assurance they are followed in managing care of patients. Historically, published guidelines alone have generally been ineffective in changing provider behavior (Grol & Grimshaw, 2003). In fact, many factors related to knowledge, attitudes, and behaviors contribute to a stagnation in implementation of guidelines. Cabana et al. (1999) described six barriers: (a) lack of awareness or familiarity with the desired change, (b) disagreement with specific guidelines or guidelines in general, (c) doubt that following the guideline will lead to desired outcomes, (d) an inability to overcome existing practice habits, (e) patient factors such as preferences, and (f) environmental factors such as lack of time or resources.

Problem at patient level. Even when there is a system in place for early identification and treatment of patients at risk for a hip fracture, if the patient does not

pick the medication up from the pharmacy, they will not benefit from the medication's fracture reducing action (Silverman, Schousboe, & Gold, 2011). Silverman et al. (2011) identified that patients are not always truthful when asked to self-report the reasons for not picking up or taking their medications. Often times, they report that they simply forgot. It is also known that patient decisions to take or not to take medications might be transient and could change with time (Sale et al, 2011). Patients who do not pick up their medications from the pharmacy have made a conscious choice not to do so for many different reasons (Silverman et al., 2011).

Problem at provider level. The provider has a responsibility in PNA as well as the patient and the system itself. Lack of communication on the part of the provider regarding the diagnosis and the need for medication contributes to non-adherence. If a patient is prescribed a bisphosphonate and the provider does not actually diagnose the patient with osteoporosis by dual energy X-ray absorptiometry (DXA) or other means and does not discuss the diagnosis with the patient, this decreases the likelihood the patient will actually take the medication (Giangregorio et al., 2008). Without a diagnosis or discussion about his/her individual fracture risk and the importance of the medication, the patient may not be aware of the necessity to take the medication (Giangregorio et al., 2008). Since osteoporosis is usually asymptomatic until the fracture event, the patient is less likely to take the medication; more likely, he/she will take a medication to relieve uncomfortable symptoms (Giangregorio et al., 2008). Without open communication between the provider and the patient and a mutual agreement and awareness that the patient needs to take a medication, the likelihood for PNA is increased (Giangregorio et al., 2008). These authors found that healthcare providers might contribute to the problem

of non-adherence through poor communication and lack of making and discussing the actual diagnosis with the patient.

Problem at system level. Calls to action by professionals in the field have described and advocated for effective nurse practitioner-led models of care to improve the care and treatment of osteoporosis and prevention of related hip fractures (Eiseman et al., 2012; Marsh et al., 2011). Addition of the electronic medical record (EMR) and information technology tools are solutions to meet focused goals and more efficiently and effectively remedy this problem (Marsh et al., 2011). Marsh et al. (2011) used criteria composed of 13 parameters, called the best practice framework and global campaign, which outlined the qualities a successful fracture liaison service (FLS) program must possess. According to the Centers for Disease Control (CDC; Crum, 2012), it is essential that disease management programs adopt more information technology decision support capabilities. These programs need to incorporate effective systems-based, preventive healthcare strategies that will improve the quality and quantity of care needed to meet the demands of a growing population.

Healthcare delivery systems of the near future will need to expand their capacity to care for the growing needs of a diverse, chronically ill, and aging population (Crum, 2012). These systems will need to consider the needs of the patient as a member of the healthcare team. If the patient is not a member of the team, he/she cannot be involved in understanding the importance of taking the needed medications (Giangregorio et al., 2008). The patient's desire to cooperate is essential if program goals are to be met.

The computer can assist by bringing together the responsibility of the patient, provider, and the system in the role of improving PNA because it can be used as a tool

that can help with improving compliance through early identification of patients with PNA and assisting the NP provider to contact the patient to intervene. Early identification and access to pharmacy information can help the NP coordinate the care of difficult patients. Management of PNA by hand is nearly impossible to achieve in a paper-based system (Che, Ettinger, Johnston, Pressman, & Liang, 2005; Cheetham et al., 2013; Kates, O'Malley, Friedman, & Mendelson, 2012). Improving access to communication with the prescriber and pharmacy has lowered the rate of non-adherence to medications (Kates et al., 2012). The computer is the key to accomplishing this. Without a system in place, access to information and communication is less likely to be effective.

Other barriers to implementing new practice tools or evidenced-based guidelines also need to be addressed. Primary non-adherence is a major barrier in improving outcomes of patients at risk for or diagnosed with osteoporosis (Silverman et al., 2011). Methods to address this barrier need to include individual interventions targeting the individual patients as well as changes in provider behavior, healthcare models, and systems. Strategies to address PNA should focus on the use of information technology tools and electronic medical records to measure the effectiveness of these strategies. These strategies can assist the provider in easily accessing guidelines and patient and pharmacy information (Che et al., 2005; Cheetham et al., 2013).

National Statistics

Worldwide, osteoporosis causes more than 8.9 million fractures annually, resulting in an osteoporotic fracture every three seconds (NOF, 2013b). In spite of the fact that hip fractures are preventable in patients with osteoporosis and acceptable

treatment and prevention guidelines have been established, medical costs from fractures continue to rise. Experts in the field agree that total medical costs from fractures will rise by almost 50% to $25.3 billion in 2025 (Burge et al., 2007). Osteoporosis continues to be under diagnosed and under treated. Only one-third of American women and fewer men with osteoporosis ever receive treatment (Agency for Healthcare Research and Quality [AHRQ], 2014; Eiseman et al., 2012; Gallagher, Grelig, & Comite, 2002; Marsh et al., 2011; Solomon, Finkelstein, Katz, Mogun, & Avorn, 2003; Solomon, Patrick, Schousboe, & Losina, 2014). Patient adherence is very important if goals of fracture reduction are to be met. Brown and Busell (2011) stated that the number of patients who are non-adherent in taking their medications overall may be as high as 50%, which outlines a very clinically significant problem. One out of every two women and one in four men over 50 will have an osteoporosis-related fracture in their lifetime (National Institutes of Health Osteoporosis and Related Bone Diseases-National Resource Center [NIH], 2005). According to the National Institutes of Health (2005), osteoporosis and related bone diseases are responsible for more than two million fractures annually. As a result, the National Bone Health Alliance (NBHA; 2013) has launched a campaign to increase fracture awareness to the public (NOF, 2013b; NBHA, 2013). Hip fractures are the most devastating of all fractures; 25% of those who suffer from a hip fracture will die within one year. Additionally, hip fractures are associated with a 2.5 fold increased risk of future fractures (NBHA, 2013; NIH, 2005).

Cooperation and proactive behavior amongst medical professionals is essential in decreasing osteoporosis and subsequent hip fractures. Despite the recommendations and support for osteoporosis disease management programs by the Centers for Disease

Control (2010), National Osteoporosis Foundation (2013a), and Agency for Health Research and Quality (2014), osteoporosis screening and treatment rates remain low worldwide. Gallagher et al. (2002) found that only 12–34% of women at high risk for fracture in a managed care network were screened for osteoporosis. Jachna and Forbes-Thompson (2005) cited that less than 50% of 1,200 adults aged 60 years or older surveyed in the northeastern United States reported that their doctor even recommended osteoporosis screening.

Developing methods for prevention and treatment of osteoporosis are critical to ensuring better detection and treatment of this disease before major complications occur. Heaney (2003) found there was inadequate participation of doctors in the proper screening, prevention, and treatment of patients with fractures. Patients were not receiving a DXA scan or treatment post fracture. Patients did not take their medications if they were not told they had osteoporosis and did not understand the risks of not taking their medications (Giangregorio et al., 2008). The American Society of Bone and Mineral Research has recommended the implementation of more fracture liaison service (FLS) programs to remedy this problem of patients not taking their medications (Eisman et al., 2012; Reynolds et al., 2013). Despite the endorsement of many professional organizations for FLS-type programs, treatment rates remain low. Lack of adherence to treatment is further compounded by the problem of PNA. Even those patients who have been prescribed treatment are non- adherent in obtaining or taking their medications (Reynolds et al., 2013).

Solomon et al. (2003) reported that roughly four out of five patients in one hospital system did not fill a prescription for an osteoporosis medication within six months after their

incident fracture. The problem of PNA is a significant barrier. Thus, Reynolds et al.'s (2013) research was the cornerstone and benchmark for this project, which calls for the development and implementation of a tool to decrease the incidence of PNA.

Financial Impact

According to the 2004 U.S. Surgeon General's Report on Bone Health (U.S. Department of Health and Human Services) and the National Osteoporosis Foundation (2013b), osteoporosis is a major public health threat in the United States and has an estimated cost of $18 billion each year (Burge et al., 2007). The cost of the Medicare program alone is projected to increase 50% from 2012 to the year 2020 (Eisman et al., 2012). This impacts the capacity of Medicare in financially supporting treatment in lieu of dwindling resources. Based on available evidence, Medicare spending on preventable hip fractures has sparked a concern to provide better, more cost-effective care (Eisman et al., 2012; Marsh et al., 2011; National Committee for Quality Assurance [NCQA], 2010). The majority of the costs of healthcare will be focused on providing services for older adults who are at risk of fractures (Mitchell, 2011; NOF, 2013b). Approximately 20% of patients who suffer a fracture due to osteoporosis will experience a repeat fracture in the next five years (Solomon et al., 2014). They represent the highest risk group who would benefit from treatment and lead to cost savings. Furthermore, Solomon et al. (2014) calculated a cost analysis for treating fractures versus preventing fractures with the use of an FLS program. They found that the FLS program reduced fractures and calculated that significant projected reduced costs would ensue mainly due to early and effective bisphosphonate treatment initiation. They stated that approximately 2.5 million osteoporotic fractures occur each year and estimated that if all the post-fracture patients

were cared for appropriately, the cost savings might equal as much as $16.7 million. The savings would come largely from patients taking their medications (Newman, Ayoub, Starkey, Diehl, & Wood, 2003; Solomon et al., 2014). According to recent data, the generic medication, Alendronate, costs $250 per year while the cost of treating one hip fracture is estimated to be $30,000 (CDC, 2010). This is a reduction from the previously reported cost by the Geissinger study (Newman et al., 2003), which showed the cost of hip fracture treatment was five times greater than the cost today for an oral bisphosphonate. With the availability of generic Alendronate in 2008, the cost was significantly reduced from previously brand named medication prices. By comparing the two costs, the savings are evident and worth implementing (Solomon et al., 2014). The steadily increasing cost of care and the work lost by those affected with osteoporosis and fracture add billions more to this figure. With an aging population, the number of hip fractures and related cost expenditures is expected to triple by 2040. The costliness of osteoporosis and other related complications further highlight the need for implementation of disease management programs (Burge et al., 2007).

Theoretical Framework

In applying a structured theory to practice, it is important to fully understand and integrate applicable concepts, which come from life or clinical experiences (Chinn & Kramer, 2010). According to Solomon et al. (2003), evidence alone is not a motivator in changing provider practice or patient behaviors. Patient compliance and cooperation with treatments are essential components to the success of any disease management program (Solomon et al., 2003). To overcome the barriers to change, a comprehensive model that incorporates theory and practice is needed. Information technology tools that focus on

improving compliance with medications have the potential to facilitate improvements in PNA and close care gaps (Kastner & Straus, 2009). According to the literature, the PNA care gap is not currently being addressed. A care gap is defined as a treatment or action that is not being appropriately applied.

Theoretical principles can be used to guide and improve the quality of practice. One theory that could accomplish this is the theory of planned behavior (TPB; Ajzen, 1991). Theory of planned behavior deals with the link between beliefs and behavior. The theory of planned behavior has been applied to studies that deal with attitudes, behavioral intentions, and behaviors in different professions such as advertising, public relations, and healthcare (Ajzen, 1991). According to Ajzen (1991), attitudes lead to behavioral intentions that then lead to carrying out a behavior. A person must have the intention to act upon it before it becomes a behavior. The TPB was created to predict health behavior at particular points in time, to discover the variables that determine health behavior, and to assess their ability to predict it. The theory adds to the concept of behavioral change and control, which began from self-efficacy theory (SET). Self-efficacy was proposed by Bandura in 1977 and has a foundation in social cognitive theory. The theory of planned behavior states that attitudes toward behavior, subjective norms, and perceived behavioral control, together, shape an individual's behavioral intentions and behaviors.

Theory of planned behavior provides the basis for understanding patient behavior change related to medication adherence. According to TPB, patients' attitudes and control beliefs (self-efficacy) determine their action regarding adherence (Ajzen, 1991). Interventions can be initiated that address patients' attitudes, control beliefs, and

perceived control, leading to changes in intention and behavior (Morisky, 2008). For example, when the NP calls that patient who has not picked up their medication, it is believed the telephone call and the NP acting as change agent will help the patient to develop a new intention and then a behavioral change will occur. The way TPB affects patient behavior is through the NP acting as change agent implementing the concepts of TBP. The NP has a strong belief in TPB and relays this positive belief in TPB to the patient during the telephone call. The patient is made aware of what is expected of him/her by the healthcare provider and the patient gains knowledge of the importance of taking the medication. The patient wants to do what is right—subjective norms, what is expected of them by others—social norms, and will act within their physical ability to make the change happen—perceived behavioral control.

Through TPB, the patient shall act of his/her free will, change the behavior, and pick up the medication from the pharmacy. The laws of social norms, perceived behavioral norms, and subjective norms (Ajzen, 1991) will be evidenced by the patient changing his/her behavior. The patient will also have a change to verbalize that it was the call that influenced his/her behavior due to the telephone outreach call. Theory of planned behavior uses various beliefs that influence the perceived behavioral control of the patient (subjective and social norms). In this project, a protocol for behavior change was based on normative beliefs of the system and subjective norms (beliefs supporting adherence of those interacting with patients). The system provided strong support for behavior change through its ability to record, collect, and report data related to medication adherence. Subjective norms were reflected through activities of the NP coordinator who acted as the change agent and implemented the protocol supporting the

change. The protocol focused on interventions based on normative beliefs of the system and subjective norms of the NP coordinator and other staff. The effect of the protocol on the patient's control beliefs, perceived control, and ultimately his/her behavior could then be measured. The perceived behavioral control and control beliefs of the patient were prerequisites to adopting adherent behaviors related to taking the medication. Utilizing a protocol that incorporated the concepts from TPB and addressed both perceived control and the patient's self-efficacy was necessary for behavior change to occur.

According to Fawcett (2005), outcomes can be predicted and measured by using an empirical referent. An empirical referent is defined as a concrete and specific instrument, experiment, or procedure used to measure a concept. In this case, the empirical referent was the Knowledge Builder Tool (KBT) computer system. The NP used the KBT to measure the concept of PNA through a telephone outreach program. According to Ajzen (1991), behavioral beliefs can determine the likelihood of how successful one can be in changing a behavior in order to facilitate adherence of a particular behavior. The stronger the belief that the NP would be effective in changing patients' behavior to pick up their medication from the pharmacy, the greater the perceived probability that the new behavior produced a given, desired outcome. The degree of belief about behavior change is directly connected to the favorable or unfavorable outcome, also known as belief strength. One must have the motivation to comply with the desired change (Ajzen, 1991). In this case, the change would be in the staff's belief that when the program was applied to their patients, it would result in the desired effect of change in patient behavior to lower PNA. Prior to this study, there was a baseline of 29.5% of patients who did not pick up their medications. This prior

behavior had no influence on the NP until the tool was applied to make change. The TPB has been used successfully to predict and explain a wide range of health behaviors and intentions including smoking, drinking, health services utilization, breastfeeding, and substance use.

The TPB states that behavioral achievement depends on both motivation (intention) and ability (behavioral control). It is distinguished by three types of beliefs: behavioral, normative, and control. The TPB is comprised of six concepts broken down into three main areas; together, they represent a person's actual control over his/her own behavior.

The first of the six concepts is called attitudes--the degree to which a person has a favorable or unfavorable evaluation of the behavior of interest. The second is called behavioral intention--the motivational factors that influence a given behavior. Where there is strong intention to perform the behavior, the more likely the behavior will be performed. The third concept is subjective norms--the belief about whether most people approve or disapprove of the behavior. Subjective norms relate to a person's beliefs about whether peers and people around them of importance think he or she should engage in the given behavior. Subjective norms were very important to this project because the NP knew her actions were being observed so she would do her best to act in a way she believed was expected of her by her superiors. Next are social norms--the customary codes of behavior in a group; these might only apply to what the NP believed she should be doing in her scope of practice or what she believed should be applied to her tasks in order to assist the patient to change his/her behavior and pick up the medication. Next is perceived power--the perceived presence of factors that might facilitate or hinder

performance of a behavior. The NP must work within a framework and has to believe the time frame given, the environment, and the nature of the workload are reasonable. Perceived power contributes to a person's perceived behavioral control over each of those factors. The NP must believe she has some power over the situation in order to believe her action will make a difference. The last action is perceived behavioral control--a person's perception of the ease or difficulty of performing the behavior of interest. Perceived behavioral control is related to perceived power over one's environment. In this project, perceived behavioral control applied to the specific telephone protocol, which resulted in the patient exhibiting behavioral control to change his/her behavior and pick up his/her medication when previously, prior to the intervention, he/she did not have this intention.

Constructs of TBP and its application to this project were reduced to three main influences that were the focus of this project: behavioral beliefs, normative beliefs, and control beliefs. Behavioral beliefs are beliefs that the actions of the person would result in desired change. Normative beliefs are when the person knows he/she is being watched and so will want to perform in an acceptable way. Control beliefs involve the person's beliefs that he/she has some control over the environment and some control over the ability to make change. These concepts of the NP's beliefs in the context of the three influences of TPB were especially important for this project.

The method used to evaluate the program was called the CDC framework for program evaluation. The CDC (1999) framework for program evaluation is a systematic approach to ensuring that questions worth significance of the program were addressed; it

worked to engage stakeholders, described the program, evaluated the design, gathered credible evidence, justified conclusions, and shared lessons learned.

In summary, the TPB process flow began with behavioral beliefs, turned into normative beliefs, a development of an attitude toward the belief itself, and the person's perceived control that led to the formation of a behavior intention and ultimately the action itself. The person developed his/her own free intention to perform the change (Ajzen, 1991). It was very important that these three concepts be tied together and flow in a systematic way in order for them to be effective in changing beliefs, behaviors, and outcomes (Ajzen, 1991).

Literature Review

Osteoporosis and subsequent fracture affect millions of people in America and worldwide. Many people who sustain a hip fracture never regain their previous level of functioning (Burge et al., 2007; Eisman et al., 2012; Marsh et al., 2011). Although there is unanimous agreement from all major osteoporosis societies around the world that fragility fracture is preventable, efforts to date have not resulted in lowering the hip fracture rate. Experts in the literature agreed that a fracture liaison service (FLS) program is the most effective approach to fracture prevention. However, no one to date has been able to address all of the barriers to effectively closing persistent care gaps that result in increased fracture risk and subsequent fracture (Eisman et al., 2012; Marsh et al., 2011; Siris et al., 2006). The most important element of the FLS program for fracture prevention is the early identification and treatment of patients at risk for a hip fracture with a bisphophonate (Dell, 2011; Siris et al., 2006). Until recently, the problem of

primary non-adherence has not been known. There is little research to support the findings or solutions to PNA (Reynolds et al., 2013).

Bisphosphonates are the medications of choice for the treatment of osteoporosis (Eisman et al., 2012; Marsh et al., 2011; Siris, Boonen, Mitchell, Bilezikian, & Silverman, 2012; Siris et al., 2006). When osteoporosis is diagnosed by dual energy absorptiometry (DXA) scan or by fragility fracture, the patient will often suffer a subsequent fracture if not treated. Fifty percent of the time without adequate treatment after a fracture, the patient will go on to suffer a second fracture (AHRQ, 2014; Eisman et al., 2012; Marsh et al., 2011; NOF, 2013a).

The literature stated that it is necessary to use the electronic medical record (EMR) and incorporate information technology (IT) such as the Knowledge Builder Tool (KBT) to further investigate non-adherence to bisphosphonate medication and the causes of it (Dell, 2011). Patients who do not take their medication cannot receive the fracture risk reduction a bisphosphonate provides. A bisphosphonate has been shown to be the best way to reduce fracture risk by 50% (Ensrud et al., 1997). Studies (Burge et al., 2007; Eisman et al., 2012; Ensrud et al., 1997; Marsh et al., 2011; Sirris et al., 2006; Solomon et al., 2014) supported the early initiation of bisphosphonate treatment in lowering the hip fracture rate and lowering the huge economic burden of osteoporotic fractures when the problem is not addressed properly and secondary fractures result. Subsequent fracture incidences cause increased care costs due to the severe morbidity and mortality associated with fracture. Without control, this problem and associated costs are predicted to increase dramatically in the future (Burge et al., 2007).

Research studies such as one conducted by Marsh and colleagues (2011) and articles written by Eisman et al. (2012); Dell, Greene, Schelkun, and Williams (2008); Dell, Greene, Anderson, and Williams (2009); and Dell (2011) all added to the body of knowledge and provided evidence that has helped to further develop fracture liaison service (FLS) programs, care pathways, risk assessment models, and calculators. These authors indicated the importance of early identification and treatment using a dedicated NP coordinator and a systems-based approach that includes initiation with a bisphosphonate medication as critical to lowering the hip fracture rate.

This evidence was the foundation upon which this capstone project was built. Morbidity and mortality rates related to hip fracture are high--up to 25% of patients die within the first year following a hip fracture. Less than half of those who survive the hip fracture regain their previous level of function (Center, Bliuc, Nguyen, & Eisman, 2007). Silverman et al. (2011) and Silverman and Gold (2008) showed that PNA is a major problem, resulting in continued hip fracture regardless of other factors. Implementation of an FLS program and the process of continuous quality improvement could identify and set new goals to meet fracture reduction goals. The FLS program uses continuous quality improvement and information technology tools to monitor progress and identify new problems that need to be addressed (AHRQ, 2014; Dell, 2011); progress is measured and monitored by the program NP coordinator through documentation of performance goals and outcomes. This information is shared between medical centers. Friendly competition helps each medical center meet their bench mark and shows how each program is progressing (Dell et al. (2009). The program with a systems approach allows for continuous feedback that keeps the program aware of which goals are being met,

which measures are not being met, and what might be needed to address the problem or make changes (Dell, 2011; Eisman et al., 2012; Marsh et al., 2011; Reynolds et al., 2013). Currently, PNA is a major barrier compounding the problem of missed opportunities for fracture reduction (Reynolds et al., 2013; Silverman & Gold, 2008). The only way to meet fracture reduction goals and see cost savings is through the implementation of an FLS program that uses a dedicated program coordinator such as an NP (Eiseman et al., 2012; Reynolds et al., 2013; Silverman & Gold, 2008).

Reynolds et al. (2013) investigated the Kaiser Permanente Healthy Bones Program (KPHBP) Southern California pharmacy database and reviewed records of 8,454 women who were prescribed a bisphosphonate treatment for post fracture care. Results revealed that 29.5% of the women who had been prescribed medication did not pick up the medication for 60 days. These women fulfilled the criteria for being non-adherent based on the authors' definition of PNA. Reynolds et al.'s study was used as a benchmark because it was the only study to date that identified and quantified the incidence rate of PNA in bisphosphonate use.

Another prospective observational study (Dell, 2011) evaluated the changes of osteoporosis disease management in the Kaiser Southern California Health-Maintenance Organization (HMO) for the years 2002 to 2006 inclusively. The Kaiser Permanente electronic medical record (EMR) called HealthConnect was used to gather data on anti-osteoporotic medication prescriptions written, dual x-ray absorptiometry scans (DXA), demographic information, and information related to hip and other fragility fractures in more than 620,000 patients. The results revealed that through a team approach using a NP champion to provide leadership in a disease management program, the fracture rate

was reduced by greater than 40%, saving millions of dollars and preventing hip fracture (Dell & Greene, 2010; Dell et al., 2008; Greene & Dell, 2010; Newman et al., 2003).

Burge et al. (2007) discussed the impact of the lack of fracture management on the skyrocketing costs of fracture care in the United States and world-wide. Comparatively, cost savings were demonstrated by using information obtained from fracture liaison service (FLS) in the United Kingdom (National Health Service and The National Health and Care and Excellence) and the National Institute for Health (NIH) in the United States (AHRQ, 2002; Compston, 2010; Mitchell, 2013). In the United Kingdom, The National Health and Care and Excellence (NICE) has demonstrated that through the example of the fracture pyramid, FLS type programs could use the cost savings gained to pay for future program costs associated with the successful evolution and sustainment of the program (Mitchell, 2013). A pyramid gives a visual depiction of how it is possible to use cost savings from the program to pay for other interventions and further lower cost (see Figure 1); costs could be distributed to address the top of the pyramid and work down to use money saved in highest risk groups to address other patients at risk for fragility fracture (Mitchell, 2013). Hip fractures are the most costly of all fractures. The pyramid was one example of the foundation upon which this capstone project was based. The reason for the development of the telephone outreach program is to lower the rate of PNA; a dedicated NP coordinator was able to implement early identification of patients at risk for a hip fracture and then initiated and monitored the treatment of patients with a bisphosphonate therapy. This action is the most effective method in lowering the hip fracture rate. Reynolds et al. (2013) identified the rate of PNA in this bisphosphonate population; however, no protocols were developed to address

how this rate could be lowered. Improving overall adherence has been noted by several researchers (Cook, 2008; Cook, Emiliozzi, & McCabe, 2007; Giangregorio et al., 2008); all suggested that the incorporation of a telephone outreach protocol was effective in improving patient adherence to medications.

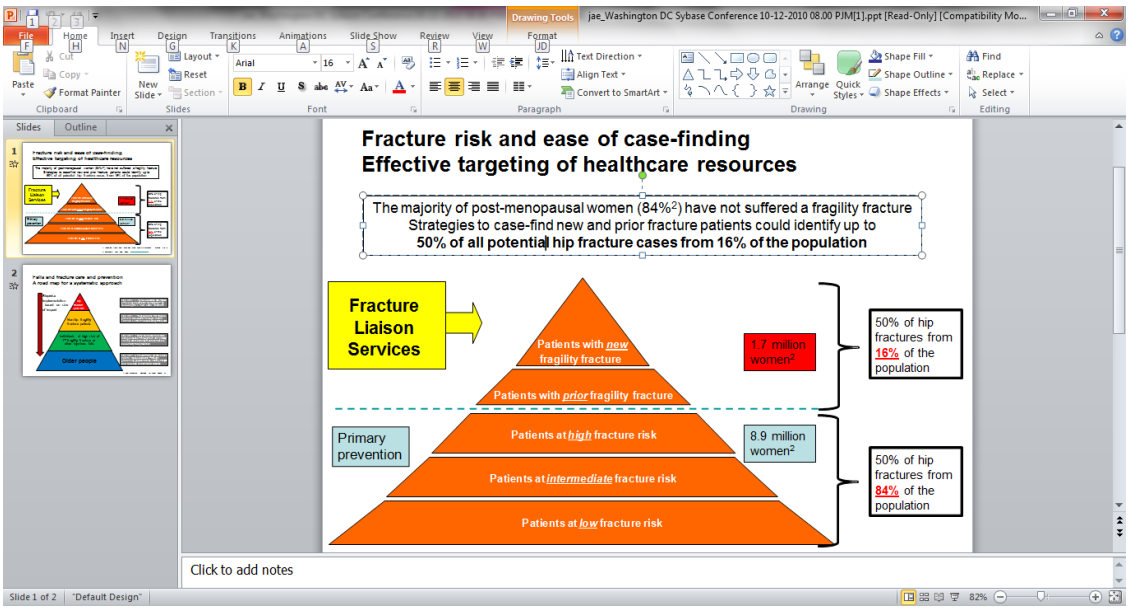

Figure 1. The fracture pyramid (Marsh et al., 2011).

Kanis, Johnell, Oden, Johansson, and McCloskey (2008) and the World Health Organization developed a risk calculator called FRAX, which assists the provider in various countries around the world in making cost-effective treatment decisions based on a series of questions that reveal the patient's probability of fracture and whether or not treatment is advised (Kanis et al., 2008). Both the online calculator (FRAX) and the fracture reduction pyramid model diagram are examples of tools to help guide cost-effective treatment methods that can be used to guide practice (Kanis et al., 2008; Mitchell, 2013). However, the patient must first pick the medication up from the

pharmacy in order for any cost-effective models to work as intended (Reynolds et al., 2013).

Nayak, Roberts, and Greenspan (2011) also made comparisons in their study to the improvements in the cost of treating patients with a bisphosphonate compared to not preventing and treating a costly hip fracture. They found that oral bisphosphonate treatment was estimated to have an adherence rate of 50% and a patient transient habit of five year on and off treatment patterns with no official program in place. Nayak et al. (2011) and Sale et al. (2011) found that of the strategies for postmenopausal osteoporosis, screening and compliance to treatment were most cost-effective when initiated by age 55 because the risk of fracture increases with the age of the patient. Adherence to the medication prescribed in this age group is improved especially if the provider discusses the diagnosis and importance of the treatment with the patient (Giangregorio et al., 2008).

Another comprehensive review (Dell & Greene, 2010) of osteoporosis fragility fracture prevention focused on cost-effective strategies to decrease fracture risk. This study focused on how to cost-effectively identify, risk stratify, treat, and then track patients at risk for osteoporosis and fragility fractures in the KP Healthy Bones Program (Greene & Dell, 2010). The Southern California Kaiser Permanente Healthy Bones Program (KPHBP) showed that with the use of a fracture liaison service (FLS) program and treatment with a bisphosphonate, four fragility fractures were prevented in every 100 patients who were treated (Dell et al., 2008). This information is useful in predicting cost savings for a program when it is applied to a large population of patients. Bogoch et al. (2006) found similar cost savings results in their fracture treatment program by using

similar techniques of FLS intervention. Early identification and treatment resulted in reduction in the fracture rate--out of every 100 patients treated, six fractures were prevented in their large patient population.

Dell (2011) confirmed cost savings data gained from using an FLS systematic approach to fracture prevention and early bisphosphonate treatment initiation. Based on four to six hip fractures for every 100 patients treated with bisphosphonates, the cost of treatment decreased due to the lower cost of generic forms of bisphosphonate medications. Solomon and colleagues (2014) further synthesized this cost savings information and determined that the cost of bisphosphonate medication was currently $250 per year compared to $507 per year 10 years ago.

Original examples of cost savings were seen with the Geissinger Health System study (Newman et al., 2003) of their osteoporosis disease management program. Based on results of their study, recommendations were made to increase diagnosis and treatment of osteoporosis in a more systematic and organized approach than was being done typically in other health centers. The Geissinger Health System was one of the first chronic disease management programs that used clinical practice guidelines in such an effective manner to address osteoporosis disease management and to prevent fractures. From 1996 (inception of their program) until 2003, the Geissinger Health System performed more than 75,000 DXAs and increased their utilization of bisphosphonates. Cost savings results were evidenced by a five-year analysis that showed a decrease in the hip fracture rate of approximately 40% (Newman et al., 2003). Although further projections of cost savings by Solomon et al. (2014) included the cost of office visits, treating side effects, and the cost of buying the medication, the Geissinger Health Study

was purely an estimation of the cost of buying the medication. Professional societies such as the American Society for Bone and Mineral Research have supported initiatives to employ best practice standards of care such as using a fracture liaison service (FLS) coordinator and implementing early treatment with a bisphosphonate (Dell et al., 2008; Eisman et al., 2012; Greene & Dell, 2010).

Other components in providing cost effective care to specifically close the PNA care gap include the addition of an EMR and information technology (IT) tools (Che et al., 2005; Cheetham et al., 2013). The IT and EMR tools have been shown to optimize both care provided and outcomes achieved (Che et al., 2005; Cheetham et al., 2013). The EMR is an effective tool in lowering hip fracture rates cost effectively through improved record keeping and the facilitation of communication techniques such as telephone outreach (Che et al., 2005; Cheetham et al., 2013). The KBT computer enhances communication by providing medical record information in real time for providers to access. The provider has the information readily available to use during phone calls and communications with the patient and with other providers as necessary. The computer uses alerts and reminders that can communicate to providers the tasks to be done. The computer is able to automate communications with the patient such as letters that remind patients to make follow up appointments. Without the computer, the provider would have to rely on the patient to provide up-to-date historical information or to wait for paper charts to arrive, which might not contain current information. This lack of readily available information makes the provider appear unfamiliar with the patient's case or his/her needs (Che et al., 2005; Cheetham et al., 2013). Computer information contributes to the overall body of knowledge by showing that fracture reduction goals can

be more easily met by enhancing awareness about chart information, improving communication, and tracking of results that cannot be done in a paper-based system (Che et al., 2005; Cheetham et al., 2013). It is important for the provider to be directly familiar with the patient's case, lab results, and diagnosis in order to build rapport and trust with the patient. Lack of current knowledge by the provider during communication with the patient might affect the patient–trust relationship (Che et al., 2005).

Causes of Primary Non-Adherence at the Patient Level

Factors at the patient level need to be addressed in determining the cause of PNA in the literature. It is important to look at the baseline reasons in the literature of why patients have self-reported they did not pick up their medications. Greenwald et al. (2002) used a patient self-reported survey (n = 144) to investigate the reasons patients had not picked up their bisphosphonate medications in 30 days. Similar to Reynolds et al. (2013), Greenwald and colleagues found that after 30 days, 37.5% of the patients in this study were shown to have PNA. Although their study did not exactly match 60 days, the reasons patients did not pick their medications after 30 or 60 days did not differ (Reynolds et al., 2013). Reynolds et al. looked at increments of time at two weeks, 30 days, 45 days, and 60 days. The main reasons for non-adherence in the Greenwald et al. (2002) study given by patients were a deficiency in the communication about the medication, the lack of understanding regarding the need for the medication, and many simply forgot to pick it up from the pharmacy. Another study by Waalen, Bruning, Peters, and Blau (2009) showed that 28.5% of women over 60 years of age (n = 102) did not pick up their bisphosphonate medication after a new diagnosis of osteoporosis in one year.

McHorney et al. (2008) and Sale, Beaton, Sujic, and Bogoch (2010) both reported common reasons patients gave for not picking up their medications: osteoporosis health concerns, drug costs, dosing frequency convenience, and potential for experiencing side effects. Multivariate analyses conducted by Sale et al. on 1,092 (33%) women showed that patients commonly were more adherent if they believed the drug would help them or if it would relieve uncomfortable symptoms. Based on these studies, non-adherence was directly connected to patient beliefs; they must believe they need the medication in order to relieve symptoms, to improve their outcomes, and if the risk of side effects are minimal. Moreover, Sale et al. stated that reasons for non-adherence were not consistent and might even evolve or change with time. Transient patient beliefs make it especially difficult to understand, measure, or to monitor compliance. Better systems using information technology could provide the methods by which behaviors could be monitored (Sale et al., 2011).

Sale et al. (2011) studied the specific reasons for non-adherence through self-reports of patients. They concluded that self- reported questionnaires might not be reliable or objective sources of data. When patients reported that they forgot to pick up their medication, they did not want to reveal their real reasons for fear of appearing uncooperative (Sale et al., 2011). Sale et al. further concluded that patients might be more truthful with their reporting if there was more open communication between prescribers, which would make patients feel more comfortable in disclosing all truthful reasons even if against the advice of the medical prescriber. Through more open dialogue, patients might feel less inhibited or judged by healthcare providers and might feel more comfortable in being frank with their responses, which might be based on fear

of a medication side effect or lack of education. Both the patients and healthcare team must work harder to improve health literacy problems. More accurate patient responses occur if patients are in a more relaxed, non-judgmental environment.

Reynolds et al. (2013) and Cheetham et al. (2013) showed that undesirable side effects of medications experienced by the patients were found to be more closely connected with secondary and not primary non-adherence because those patients with secondary non-adherence (SNA) had already previously picked up and started the medication and then suffered an undesirable side effect. Secondary non-adherence occurs when patients self-stop the medication and do not refill it again (Cheetham et al., 2013; Reynolds et al., 2013).

McHorney and Spain (2011) conducted a study in which patients self-reported reasons why they did not fill their new prescription medications. The results showed a direct association between reported reasons for non-fulfillment (PNA) and non-persistence (SNA) as compared to their particular chronic disease, which might be different and even change at times. McHorney and Spain further indicated that patients were motivated by fear of having a serious health consequence for not taking a needed medication. The patient must believe it is important for them to take their medication (McHorney & Spain, 2011).

According to Gadkari and McHorney (2010), one in three patients never picks up their medications from the pharmacy. They found the way patients perceived their disease condition or their perceived need for the medication, fear of side effects, and whether or not the medication would relieve an uncomfortable symptom played a large role in whether or not they took the medication. In their meta-analysis, 79 studies

reported pure nonfulfillment rates--59 at the patient level, 20 at the prescription level, and six in combination with non-persistence. The non-adherence rates ranged from 0.5% to 57.1%. Three primary reasons for non-adherence were identified: (a) perceived concerns about medications, (b) lack of perceived need for medications, and (c) medication affordability issues. In this meta-analysis review, patient reasons for not filling their medications were consistently the same.

In a meta-analysis of 127 articles, Silverman et al. (2011) investigated patient reasons for non-adherence to medications used to treat osteoporosis, cardiovascular disease, and other chronic disease medications. They found that suboptimal health literacy and lack of patient involvement in his/her treatment decisions by providers were reasons patients did not take their medication as prescribed. Other findings included communication barriers about the medications and disbelief by the patients that they needed the medication. Ineffective communication of information about adverse effects and too many different physicians caring for multiple patient conditions were also causes for non- adherence (Silverman et al., 2011). Since the prescriptions in this study were written largely for bisphosphonates, the findings were generalizable to osteoporosis as well as other chronic diseases (Silverman et al., 2011

Poor patient health literacy and lack of patient involvement in decisions related to treatment were found to be amongst the main contributing factors to PNA in a study by Elliott and Marriott (2009). This study investigated why patients did not initially pick up their medications from the pharmacy. In addition to health literacy problems, older people are commonly prescribed complex multi-drug regimens while also experiencing declines in cognitive and physical abilities required for medication management. This

could lead to increased risk of medication errors and need for assistance. This study reviewed published instruments designed to assess patients' capacity to self-administer medications and to gain useful information. This information might justify the need for a tool to assist the provider in identifying patients who are not picking up or taking their medications and intervene through communicating with the patient to prompt them to take their medications as prescribed (Elliott & Marriott, 2009).

In summary, the patient has a responsibility to make sure he/she has his/her questions answered by the provider. The patient must make sure he/she is communicating with the provider and letting the provider know if he/she does not understand the instructions given. The patient's responsibility is to take a more active role and become an active participant in his/her own care. Patients need to be empowered to include themselves in a shared decision-making process.

Causes of Primary Non-Adherence at the Provider level

Providers must understand the importance of patient involvement in his/her own care. Patient goals must include the patient—he/she must be included as part of the team in a shared decision-making process that will help him/her understand the importance of participating in his/her own care (McCormack & Loewen, 2007). In a study by Giangregorio et al. (2008), patient belief in the perceived importance of the medication and the connection to his/her fracture risk was found to be a very important predictor of PNA. One hundred twenty-seven women in their 60s were interviewed about their beliefs and the connection between their medication and their own fracture risk reduction. The findings showed 82% of the women interviewed had a new prescription for a bisphosphonate but no diagnosis of osteoporosis, had no conversation with the provider

about the importance of taking the medication, and did not believe there was a link between osteoporosis and their own individual fracture risks. The women in this study placed no increased importance on taking prescribed medications for osteoporosis if they did not know they had osteoporosis and had no uncomfortable symptoms they wanted to treat. The study concluded that the women did not believe they needed to take medication because their doctor did not discuss this problem with them and they had no symptoms. However, when an actual diagnosis of osteoporosis was made in a different group of 56 women and compared to those patients without a diagnosis, the patients who had an actual diagnosis of osteoporosis believed there was a link between osteoporosis and their fracture risk. Overall, 17% of the women thought their fracture was related to osteoporosis. Less than 50% of the women believed they personally had any risk of a fracture ($p < 0.001$). This study concluded there is a need for better communication between providers and patients and better ways to determine risk of PNA. If the physician does not communicate the importance of the medication or does not note in the medical record that this medication is indicated, then the mediation will usually not be taken by the patient (Giangregorio et al., 2008).

Patient compliance is a key factor to the success of any disease management program (Solomon et al., 2003). It is the provider's responsibility to make sure patients are included as a team member and practice shared decision-making to empower patients to feel that their thoughts and feelings are important (McCormack & Loewen, 2007). However, compliance and predictions of patient compliance are difficult to measure. According to Sale et al. (2011), labelling patients or grouping them into categories such as being adherent or non-adherent is not productive because it sets stereotypes and

negative messages; the reasons for non-adherence often change with time and are not consistent. Sale et al. (2011) showed that in a university teaching hospital fracture clinic program, individuals aged 65 and older who had sustained a fragility fracture within five years were at high risk or future fracture; once identified, they were enrolled in the study and prescribed a bisphosphonate medication. More than half of the patients revealed that the decision to take their osteoporosis medication was a difficult and usually not a permanent one; this substantiated Sale et al.'s findings that a patient's decision to take a bisphosphonate is transient and changes over time. It is the provider's responsibility to understand this and to maintain consistent interventions designed to enhance communication aimed at changing and maintaining patient beliefs and behaviors. One of the reasons cited by half of the patients in the study was patients were unconvinced by their health care provider that they needed to take the medication. Thus, providers need to take a more active role in assuring their communications are actually effective; they should not just assume without verifying that patients actually understand what is communicated or taught to them. In addition, patients showed concern about side effects of the medication. In the final analysis, many of the patients said their osteoporosis medication-taking status might change at a later date and that they are not permanently convinced they wanted to take the medication (Sale et al., 2011).

Brown and Bussell (2011) found the provider has a responsibility to assure that the patient is included as a team member and is allowed to be in the shared decision-making process related to their care. Findings from this study showed that provider level related causes of non-adherence including patient-provider communication barriers, lack

of knowledge about potential side effects, and lack of health information technology systems in place also contributed to PNA (Brown & Bussell, 2011).

To date, a traditional style of health education has centered on the disease process and pathophysiology of disease. This type of education alone and not in coordination with a FLS disease management type program has been shown to be ineffective in changing patient behavior such as PNA (Solomon et al., 2003). Traditionally, the physician model focuses on diseases and how they are treated. Solomon et al. (2014) confirmed that if the patient knows more about their disease and is educated with the same model of teaching the physician was taught, then the patient will become more adherent to prescribed medical treatments. The education a patient receives must be meaningful to the patient; the patient must see the perceived value to him/her before any change in health related behavior can occur stemming from provider teachings (Solomon et al., 2003). Solomon and colleagues (2003) explained that although education is important and the provider must talk to patients and teach them, without the coordinated efforts of a program such as an FLS program and a nurse practitioner (NP) coordinator to act as the glue that holds patients and treatments together, education alone will fail to impact patient outcomes. Additionally, Dell (2011) agreed that information technology tools and the assistance of an NP-led patient education program without coordinated efforts of NP clinic visits will not effectively impact hip fracture reduction (Greene & Dell, 2010).

It is essential that NP coordinators close care gaps if there are to be successful results in the effective coordination of meeting care goals (Greene & Dell, 2010; Solomon et al., 2003, 2014). Solomon and colleagues (2003) showed that continued

under-treatment of osteoporosis in patients persists; using education techniques alone have been completely ineffective. Despite many attempts to improve patient knowledge with patient education classes, the problem remains unchanged. Patients are motivated by different factors; thus, any intervention to improve health literacy must be focused on the individual and associated causes (Solomon et al., 2003). Providers have a responsibility to implement techniques that focus on patient needs rather than using care delivery that is convenient for the provider.

The literature clearly showed that the human interaction associated with follow up by the NP and phone calls as part of a telephone outreach effort played a key role in giving more customized care and enhanced communication as opposed to other studies that used only patient questionnaire feedback in which patients claimed they simply forgot to pick up their medication. It is the provider's responsibility to make sure the patient understands the information given during the visit and allows the patient to ask questions. This communication component assists patients in deciding whether or not to not take their medications. In summary, patient reasons for not picking up their medications are individualized and transient. Often, patients who do not pick up their mediations did not forget to pick it up but made conscious decisions not to pick up or take their prescribed medication.

In their meta-analysis, Elliott and Marriott (2009) evaluated the development and validation of instruments designed to assess patients' capacity to self-administer medications. The authors showed that healthcare providers must persist with communicating with patients who have not initiated their bisphosphonate prescription. Their meta-analysis indicated that patients might benefit from knowing what to expect

from taking the medication and to include benefits and the time it takes to work. The study concluded it is the provider's responsibility to improve the health literacy of the patients as well as maintain their own health literacy.

In summary, providers must communicate with the patient the importance of taking the medication, what to expect, the benefits of taking it over the long-term, and any side effects. Multiple opportunities are available to use technology to boost patient compliance rates and make it easier for patients to become more involved in their own care (Elliott & Marriott, 2009). It is important that the provider include the patient in their care and considered the patient as a team member in order to improve patient outcomes (Elliott & Mariott, 2009).

Causes of Primary Non-Adherence at the System Level

Improvements in health literacy and information technology could contribute to better care and a decrease in the incidence of non-adherence (Dell, 2011). In this case, the computer provides information to the NP in real time to assist with tracking patient compliance and provides a protocol to be followed for telephone outreach. The computer as part of the system can assist the provider in making a diagnosis of osteoporosis, which has been shown to directly improve patient adherence in taking the medication as prescribed (Giangrigorio et al., 2008). Dell (2011) added that the computer can assist in this process by providing tools in the form of clinical practice guidelines, risk calculator tools, and patient chart information such as diagnostic tests in real time. These tools could assist the NP provider in making the diagnosis and determine whether or not treatment is advised. The computer could enhance better communication by providing tools and information that can decrease variation in practice and might add information to

dispel myths so a stronger connection can be made between osteoporosis and fracture risk by patients (Dell, 2011; Giangregorio et al., 2008).

Inclusion of an actual diagnosis on the chart and patient awareness of the diagnosis of osteoporosis might improve this association. The provider could use the electronic medical record (EMR) as a useful tool in improving health literacy for other healthcare providers as well as patients to reduce the incidence of PNA (Che et al., 2005). A clinical practice guideline (CPG) could guide practice and improve communication to the patient when it is embedded into the EMR. Alerts and reminders would tell a provider when a patient has not picked up their medication so they can be called and communication can be initiated (Cheetham et al., 2013). The EMR could also be programmed with a patient's past behaviors--the best predictors of future behavior. The computer system is an essential component to the tracking and documenting of patients in order to monitor their compliance.

Bardwell et al. (2002) examined medication-taking health beliefs in patients and analyzed how their beliefs affected their past history of compliance with taking prescription medications. The data were analyzed using a predictive tool comparable to one of the functions available as part of the Knowledge Builder Tool (KBT) in order to determine if past non-adherent behavior could be used to predict future non-adherent behavior. Results of this study demonstrated it was possible to predict non-adherent behavior and predictive models might be helpful tools for providers to use when any new prescription is written. This information could be helpful when revising the program to further improve the rate of PNA once current goals are met. When the problem is identified, then the prescriber can adequately intervene with additional communications

to help dispel any myths or fears and attempt to change patient beliefs so they can understand the importance of taking their medication (Bardwell et al., 2002).

Another factor that contributes to PNA at the system level is an inability of providers to retrieve patient data and medical chart information so they can provide patient care in real time (Dell, 2011; Greene & Dell, 2010; Siris et al., 2006). As noted in the literature, this barrier at the system level might be resolved by the added ability of the provider to track whether or not the patient has picked up a prescription medication once written. Lack of electronic prescriptions and an overall lack of communication and access to chart information directly affect the PNA rate (Che et al., 2005; Cheetham et al., 2013). Simply put, a treatment cannot work if the patient does not take it and the prescriber cannot track it.

Lack of integrated systems with pharmacy data and no existing FLS type program in place designed to assist the provider minimize PNA have contributed to the ongoing problem. This lack of a coordinated system has made it more difficult for healthcare providers to monitor and measure compliance. Thus, a coordinated system in place would assist in lowering the hip fracture rate and improve non adherence through the coordinated efforts of a dedicated coordinator (Dell, 2011; Siris et al., 2006, 2012). Use of FLS programs that use a nurse practitioner (NP) coordinator to take responsibility for patient care and outcomes and maintain telephone outreach and computer systems are helpful in decreasing the hip fracture rate (Cook, 2008; Siris et al., 2006). Simply put, fractures negatively impact patient outcomes due to the lack of proper systems in place and lack of medication treatment with a bisphosphonate (Akesson et al., 2013; Dell, 2011; Dell et al., 2008; Greene & Dell, 2010; Marsh et al., 2011; Siris et al., 2006). The

NP is able to identify, risk stratify, diagnose, treat, and follow up with patients to meet program goals. Bisphosphonate therapy is the best intervention to lower the risk of hip fracture and prevent subsequent fractures (Akesson et al., 2013; Dell, 2011; Dell et al., 2008; Ensrud et al., 1997; Greene & Dell, 2010; Siris et al., 2006).

Patient non adherence to medication treatment can have a kind of domino or cascade effect--one event affects the other. If medications are prescribed after a fracture occurs and the patient fails to acquire the medication and take it, then he/she does not benefit from it and his/her individual fracture risk goes up (Brown & Bussell, 2011; Dell, 2011; Eisman et al., 2012; Marsh et al., 2011; Silverman & Gold., 2008; Silverman et al., 2011; Siris et al., 2006). A coordinated program that considers patient, provider, and system factors is necessary to reduce PNA and improve patient outcomes related to fractures in patients with osteoporosis.

A coordinated program such as the Kaiser Permanente (KP) system could identify patients with osteoporosis or who are at risk for hip fracture, systematically intervene, and then monitor and follow up with each patient accordingly. With the system in place, the NP could receive a list of patients who have not picked up their bisphosphonate prescription from the pharmacy. The NP in this project would be the key component to this coordinated effort. However, when there is no NP coordinator and no coordinated system is in place, the computer alone cannot improve patient outcomes without the organized effort of all program components (Solomon et al., 2003). Without the computer system in place, the provider might not be aware the patient is not taking the medication and thus not benefitting from the treatment (Brown & Bussell, 2011; Cheetham et al., 2013; Marsh et al., 2011; Sale et al., 2011; Silverman & Gold., 2008;

Silverman et al., 2011; Siris et al., 2006). The fracture liaison service (FLS) program and theoretical framework would provide the structure and protocols.

Description of the Knowledge Builder Tool and Improvements in Quality

The days of the paper chart are changing into a new era of the electronic medical record (EMR). The EMR must be designed and organized to facilitate a process that is useful and can be used as a tool to close care gaps and to improve patient outcomes while maintaining quality at an affordable cost (Dell, 2011). The KBT takes the data from the EMR and converts it into actionable knowledge that can be used by care managers to close care gaps. Data are updated daily and the care manager can receive current information about DXA, laboratory results, medication treatments, and demographic information. The KBT updates the current state of the patient's health condition and then populates the information in the form of patient lists, creating a complexly interactive disease registry. The KBT was developed to reduce the barriers associated with implementing knowledge into practice with the intention of improving quality care (Dell, 2011). The Kaiser Permanente Knowledge Builder Tool (KBT) was developed by the internal infrastructure of the Kaiser Permanente Information Technology Department in coordination with the Healthy Bones Program; it is being implemented as a component of their osteoporosis disease management program to assist the NP care manager in managing problems in large populations and closing care gaps such as PNA. The KBT was tested internally by over 50 Kaiser Permanente providers and was shown to be a reliable and valid tool (Personal communications, Dr. Dell, physician champion of the KPHBP, and Xuan Chen, senior data consultant, on December 12, 2013). During the

year end KPHBP core meeting, the validity of this tool was demonstrated and confirmed through an internal validation process (Dell, 2011).

The literature provided examples of how the EMR is a useful tool and enhances the safety of prescribing and monitoring medication side effects (Cheetham et al., 20l3; Halvorson, 2009; Institute of Medicine [IOM], 2006). It is important to the success of a program to incorporate computer technology tools to close care gaps such as PNA. The IOM (2006) publication *To Err is Human* calls for the use of integrated IT systems to reduce the incidence and inefficiencies of the current medical system. These systems could effectively manage chronic health care problems safely and effectively at the level of the patient as well as the population. Halvorson (2009) described the Healthy Bones Program (HBP) as an ideal example of how a chronic disease management program should work. The HBP has made great contributions to healthcare delivery through early identification of problems. This program helps overcome barriers to meeting quality improvement goals. It is an example of a coordinated system that uses IT and NP care coordination to reduce hip fractures. The HBP uses the EMR and tools such as the KBT to provide the means through which adherence of patients with chronic health issues such as osteoporosis can be monitored, managed, and tracked (Dell, 2011; Halvorson, 2009). These systems facilitate management of side effects, improve safety and efficiency of practice, and close care gaps. The KBT was developed internally as a part of the EMR that is used to collect data and provide NPs with specific patient lists to address persisting care gaps--in this case, PNA (Dell, 2011; Halvorson, 2009).

Katzen and colleagues (2011) also supported the future development and use of the EMR and tools that could store and use clinical and administrative data. With an

EMR, the data are typically stored in a central warehouse and can be accessed directly and in real time (Katzen et al, 2011). Clinical decision support tools found in EMRs aimed at improving compliance have made great contributions to the improvement of primary non-adherence to medication (Kastner & Straus, 2009). Clinical decision support tools such as the KBT within an FLS program could be used to close care gaps and use the evidence to directly translate knowledge into practice. This practice translation is evidenced by improvement in patient outcomes.

Kastner and Straus (2009) advocated clinical decision support and the application of knowledge into practice by using a decision support tool and a knowledge to application model of care to transform information to knowledge to practice. In *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine (IOM; 2010) described PNA as an example of a care gap. The IOM discussed the benefit of using knowledge to close care gaps.

Limitations of the Literature

Over the past decade, much energy has been focused on FLS program model development as a cost-effective team approach to reduce fracture risk through coordinated program efforts. The American Society of Bone and Mineral Research (ASBMR), National Osteoporosis Foundation (NOF), International Osteoporosis Foundation (IOF), and others have recommended the implementation of coordinated FLS type programs to prevent fracture and lower the hip fracture rate (Eisman et al., 2012; Marsh et al., 2011). To date, a paucity of research is available related to addressing the PNA problem (Eisman et al., 2012). Eisman et al. (2012) reported on recommendations made by the ASBMR Task Force for the implementation of an FLS type service geared

toward early identification and initiation of a bisphosphonate and the monitoring of patients on medication treatment to lower the incidence of preventable fracture (Dell, 2011; Eisman et al., 2012; Marsh et al., 2011).

Although researchers gave recommendations for fracture prevention based on current available knowledge and from their own work and programs, hip fracture remains an ongoing problem. The ASBMR Task Force synthesized the literature and published a position paper providing recommendations that have been described in this paper designed to improve care delivered from the systems level (Eiseman et al., 2012). The literature verified that not initiating treatment post fracture would result in a poor outcome (Eisman et al., 2012; Marsh et al., 2011). The FLS model of care focuses on early identification and treatment initiation post fracture. In a prospective observational study, Kates and colleagues (2012) examined 562 hip fracture patients and found that 32% of patients with hip fracture who were not treated with a bisphosphonate were readmitted to the hospital within the first year. Subsequently, Kates and colleague also showed that the initiation of a fracture management program, including early initiation and monitoring of treatment post fracture, reduced readmission rates due to re-fracture to 10.3%. Thus, a coordinated program that used a coordinator and a coordinated IT system could reduce the rate of re-fracture by preventing fracture. Kates and colleagues attributed their success in improving patient outcomes to early treatment initiation with a bisphosphonate and patient monitoring of the treatment. However, no studies identified how to overcome barriers such as PNA.

In 2003, Boockvar et al. found similar results in an observational study in which they confirmed that patients who were not adequately treated post fracture were often re-

hospitalized and had bad outcomes. Both Boockvar et al. (2003) and Kates et al. (2012) found success in implementing similar FLS techniques of early treatment initiation and monitoring of treatment adherence compared to those organizations without a program in place. Information technology makes it possible to monitor large and growing populations of patients that cannot be done by hand in a paper-based system; thus, a computer is a necessary component (Che et al., 2005; Cheetham et al., 2013; Dell, 2011). Use of an FLS coordinator-based program has been shown to have some of the solutions but there are limitations. One of the limitations is FLS programs have not been able to connect all of the necessary components to close all care gaps such as PNA. It is important that solutions be found to this problem and those solutions must be translated into practice.

Primary non-adherence (PNA) has been discussed as being caused by failures at the patient, provider, or system levels. Literature supported programs that incorporate the FLS model of care, telephonic outreach, EMR, and integrated pharmacy systems as necessary components of a successful disease management program. To date, attempts have been made but no one has been able to integrate all needed components (Kastner & Straus, 2012).

In spite of studies (Gadkari & McHorney, 2010; Giangregorio et al., 2008; Greenwald & Farnham, 2000; McHorney & Spain, 2011; Sale et al., 2011) on primary non-adherence to bisphosphonate medications, major inconsistencies in evidence and definitions regarding compliance have made it difficult to compare them. Additionally, lack of consistency in study results and lack of systematic reviews have further compounded addressing the issue of PNA. Commonly, studies use small population

sizes, making generalizability difficult. After an extensive literature search, it was found that for such an important issue, very limited information was available on PNA in general. Methodological limitations included use of self-report questionnaires in some studies compared to predictive models that used past behavior data to predict future behavior. Many of the studies identified problems but did not give solutions. Reynolds et al. (2013) identified the problem of a 29.5% PNA rate in the program they studied but offered no solutions of how to improve on it. Given this limitation, it is important for studies to focus on solutions and make recommendations for possible future studies.

The literature consistently showed that patient education techniques alone do not work and have failed miserably in affecting outcomes (Eisman et al., 2012; Solomon et al., 2003). The only benefit seen was patients learned that osteoporosis is a serious health condition and it might have serious health consequences, but it did not improve patients' ability to connect osteoporosis and hip fracture reduction to their medical treatments (Solomon et al., 2003). Additionally, Cook et al. (2007) found that patients' reasons for not picking up medication usually had a psychological aspect such as fear of side effects and needing to overcome denial of having a chronic condition, feeling the medication was not important, that they did not need the medication, and that they did not want to spend the money on it because they believed a good diet was sufficient to prevent osteoporosis. Many patients, even after extensive medication education, still did not adhere to taking it and stated that although they understood osteoporosis is a serious condition, they did not make the connection between osteoporosis and the fracture and how the medication would prevent fracture. The main limitation of the literature was the studies did not give solutions to how the problem of PNA could be resolved. Although

informational, the articles especially did not provide recommendations that could be translatable into practice.

Another study (Siris et al., 2006) confirmed that when patients do not have symptoms, they do not feel motivated enough by education about the disease to take a medication. Since osteoporosis does not have a symptom until the fracture event, patients do not always understand the importance of taking their medication. The literature had direct application to this capstone project because patients who are screened for osteoporosis might not understand the importance of taking their bisphosphonate medication because they do not have symptoms until the fracture event and sometimes after the fracture has occurred. Although health education is an important topic, it should be left to health educators. Teaching classes is not the best time spent by the NP health provider when patient identification, risk stratification, treatment, and follow up have been shown to be more effective. Bisphosphonate treatment is the most effective way to reduce a person's risk for fracture. However, if they do not take the medication, they do not get the benefit of fracture risk reduction.

Summary

Primary non-adherence (PNA) has been discussed as being caused by failures at the patient, provider, or system levels. Literature supported programs that incorporated the FLS model of care, telephonic outreach, EMR, and integrated pharmacy systems as necessary components of a successful disease management program. To date, attempts have been made but no one has been able to integrate all needed components (Kastner & Straus, 2012).

The literature has shown that patients with a first time prescription for a bisphosphonate were not all picking up their medications. This problem has sparked an interest to develop a system and protocol that could be applied to improve PNA. Evidence-based guidelines are ineffective unless they are implemented and the evidence must be translatable into practice. The implementation of an osteoporosis disease management program, especially if an electronic health record is used, is an effective tool in lowering the hip fracture rate. Through the use of clinical practice guidelines and guidance practice of the staff trained with TBP, acceptance and implementation of such systems would facilitate changing current provider behaviors. The literature did not clarify all factors concerning the reasons for PNA. There is still much confusion and no standardization of terms and definitions, which makes describing the problems and solutions difficult to compare between studies. This capstone project implemented a protocol for which outcomes were measured to determine its effectiveness in addressing the problem of medication adherence in patients with osteoporosis. Once standardization is established, other researchers can build upon it instead of recreating and applying new terms to what has already been established.

CHAPTER II

STUDY DESCRIPTION AND OBJECTIVES

Study Description

Primary non-adherence (PNA) to bisphosphonate medication is a growing problem that needs to be addressed by an osteoporosis/fracture prevention/disease management program. Hip fracture reduction goals can best be achieved by having all the care gaps easily identified with the help of information technology tools. These tools incorporate all the clinical practice guidelines of the organization's osteoporosis/fracture prevention program and automate the steps to identify all patients who have a care gap related medication non-adherence. Not taking a prescribed bisphosphonate increases the risk to the patient for future fractures. By developing a procedure reflecting the most recent research evidence, the Doctor of Nursing Practice (DNP) student wrote a protocol for telephone outreach in collaboration with organization leaders to improve the incidence of primary non-adherence to a bisphosphonate.

Objectives of the Study

Two objectives were identified in this study. The first was to develop and implement a protocol to target patients diagnosed with or at risk for osteoporosis and hip fracture who had not picked up their bisphosphonate medication from the pharmacy within 60 days. The second objective was to decrease the current rate of PNA by 20%

from its identified rate of 29.5% in order to be clinically significant during the study period, which spanned four months.

Study Design

This prospective observational study was designed to determine the effect of using an information technology tool at the facility to systematically identify all patients at potential risk of becoming non-adherent to their anti-osteoporotic medications over a period of 60 days. The data collection lasted approximately two months (n = 216); the study followed each patient for 60 days or until he/she picked up the medication. The care manager at the medical facility was a nurse practitioner (NP) and was part of the program. She provided the patient care and coordination. This study used the Reynolds et al. (2013) article as a benchmark in setting a goal of using approximately 216 patients in an attempt to lower the rate by at least 20%.

The program uses a systems-based approach to disease management to monitor and change a course of action. Applying the theory of planned behavior (TPB) to guide patients' decisions to develop an intention to pick up and then take their medication, the nurse practitioner (NP) used a telephone outreach protocol to enhance communication, build rapport, and assist patients in getting the information necessary to resolve issues leading to non-adherence. Adoption of this method allowed for improvements in efficiency and effectiveness and maximized the time to accomplish it as expediently as possible. This method enables researchers to apply the same protocol to each patient equally and minimize disparity (Navarro, Greene, Burchette, Funahashi, & Dell, 2011). The NP used the protocol to guide the practice in the right direction. Productivity was monitored and measured to maintain a course of action and adopt the new protocol.

Setting and Study Population

The study included all patients aged 55 and older who had a new prescription for a bisphosphonate medication and no history of ever having a bisphosphonate prescribed to them. The patients were entered into the disease management registry and had a dual energy X-ray absorptiometry (DXA) scan or a diagnosis of osteoporosis that was not exclusionary.

Patients were excluded for the following reasons:

1. Patients who were not Health Maintenance Organization (HMO) members or who had died or been terminated from their insurance.
2. Those patients who had a history of taking a prescription or had taken a bisphosphonate in the past.
3. Patients with chronic kidney disease (CKD) 4 or 5 or if they were on dialysis.
4. Patients with diagnosed hypocalcemia.
5. Patients with allergies or other contraindications to taking a bisphosphonate.

Patients who were excluded at any time were not carried through in the data base tool population for the purposes of this study only.

The study setting was an NP-led disease management program. The following patient demographics were currently in the system and were extracted from the department for use by the program: (a) age, (b) race/ethnicity, (c) gender, (d) diagnosis of osteoporosis (if there was one), (e) score from DXA scan, and (f) diagnosis of a fragility fracture (hip, distal radius/ulna, spine, humerus, pelvis, and other femur). All were confirmed to have a prescription for a bisphosphonate.

Background of the Fracture Liaison Service

The program began in 1998. It has a 16 year history of using teams and technology in reducing fracture rates and saving money. This study's focus was the role information technology tools played in translating evidence into practice in order to improve patient outcomes. Current practice protocols reside in the osteoporosis/fracture prevention clinical practice guideline (CPG). The organization's 3.7 million members' records are automatically updated every day with the use of the Knowledge Builder Tool (KBT). The KBT automates the steps in patient enrollment, applies the rules of the CPG protocol, and determines actions needed. Patient data are displayed as well as actions needed in a secure, password protected, and user-friendly interface. The system receives feedback from the program nurse practitioner (NP) care managers when they work within guidelines developed to close care gaps.

The average care manager spends several hours a day searching for patient data or screening patients to determine each patient's appropriateness for the program (Dell, 2011). It is very time consuming for the NP to search data in order to generate appointments for patient encounters or to conduct program outreach operations. The KBT cuts down tremendously the amount of time it takes for someone to manually search for information. Thousands of records can be sifted by the computer and an updated list can be generated on a daily basis, thus allowing the NP to work the list, organize time, and set priorities more efficiently. The time it takes for the KBT to run a report on 3.7 million records is the approximate time it takes for a NP care manager to review one complete patient chart. The power and speed of this tool is unmatched by anything that can be done manually (Dell, 2011).

This medical center has run previous pilot projects and was the first site to roll out implementations to address care gaps in osteoporosis and fracture prevention. This site volunteered to be the beta testing site of the new tool to address PNA and was the site to implement this study. The patient intervention group had data collected on bisphosphonate prescriptions and tracking of dispensed bisphosphonate medications. There was no control group. The number of days from the time the medication was prescribed to the day of pickup was tracked and measured within a 60 day period using percentages and a questionnaire. A Likert scale for the interview questionnaire measured NP beliefs before and after the intervention and patient beliefs were measured by a yes/no questionnaire in the form of a telephone outreach tool.

Description of the Knowledge Builder Tool

The Knowledge Builder Tool uses an SAS-based 9.2 program with Enterprise 4.3. There are many advantages of using the SAS version of the Knowledge Builder Tool. It is a far superior development platform for disease management registries used by all the health plan organization's sites. The KBT is built from a toolkit of over 1,000 modules and is able to capture data from laboratory results, diagnostic tests, clinic visit notes, hospitalizations, surgical history, and other data housed in the clarity data warehouse (CDW). Data are updated on a daily basis. The chosen data components are downloaded daily into the disease management program and patients are placed onto a list worked by the NP care manager. The various parts of the registries can be used by NP care managers to manage a patient's care gaps (Dell, Loo, & Loomis, 2012). For example, the FLS team recently started implementing the new osteoporosis/fracture prevention clinical practice guideline (CPG) as well as several new guidelines addressing such things as drug

holidays for bisphosphonates and re-DXA schedules based on the last DXA result. New recommendations to address primary medication non-adherence are currently being updated and added (Kanter, Lindsay, Bellows, & Chase, 2013).

The KBT began as a disease management registry in 2011 and since has expanded to incorporate clinical practice guidelines in an interactive and dynamic data registry tool that can address all care gaps and patient needs programmed into it (Dell et al., 2012). The registry is updated on a daily basis from the CDW described earlier. For example, a patient with a need for screening will be targeted as "needs DXA" so the NP will receive a list with all needed information so this care cap can be addressed. For the PNA tool, the same thing applies. All care gaps are decided upon by the program and become strategic goals. On a yearly basis, the data are matched with existing guidelines to ensure the guidelines are being followed.

By using the KBT, it is possible to convert the rules inherent in the new osteoporosis/fracture prevention and CPG into modules that capture certain rules and apply them. The FLS nurse practitioner care manager is able to see the daily updated list of patients who have one or more of the care gaps and address each. For the purpose of this project, they addressed the care gap of primary non-adherence (PNA).

The KBT is built with knowledge builder modules that have global variables to allow SAS developers to very quickly change the variables to see the medications and monitor them, as in the case of bisphosphonates. This program tracks all patients with a certain diagnosis, such as osteoporosis, or a prescription for a certain drug; it searches the CDW to find which patients are prescribed this medication or have this diagnosis and then downloads the information to the NP care manager. According to Che et al. (2005),

closing care gaps and using measures, such as healthcare effectiveness data and information sets (HEDIS) to determine how to stay compliant with meeting quality measures, are important components in identifying and closing care gaps, especially in the prevention of fragility fractures such as hip fractures--one of the most debilitating of all fractures. The tool was originally developed as a part of the organization's safety net project where it was extensively tested and validated. The KBT program applied lessons learned from previous studies and developed useful guidelines, such as osteoporosis with this intervention study.

The Complete Care program, also sometimes referred to as Safety Net Project, provided a care framework that changed systems within the organization in many ways across multiple levels and provided an avenue for validating the KBT. An article by Kanter et al. (2013) showed examples of the care teams who used clinical decision support of the KBT and how it was integrated across different sites. This article described how the tool was accepted and validated. Work on this project was undertaken to break down care silos and act as a way to provide aggressive outreach/care management services for individual patients as needed to achieve care goals and close care gaps (Kanter et al, 2013). The KBT was validated through many studies.

The KBT was developed so it could be interfaced with the electronic medical record (EMR) to target and close specific care gaps in various disease management programs within the system. An information technology tool based on Drools Guvnor (Dell et al., 2012.) software was selected to be the foundation and the principle rule upon which the Knowledge Builder Tool (KBT) was built and validated. The KBT is basically a relational database management system that can be transformed into a database system

according to an individual user's needs. Access to the KBT is controlled and password protected; it is possible to lock down and restrict access so only approved individuals can view and make edits. The tool is automated and includes internal components of decision making. This enables providers to focus on treatment and follow-up by having information readily available

Ethical Considerations

Institutional Review Board

Since this was not an experimental study, exempt review was sought and obtained from the Institutional Review Board (see Appendix A). Each participant signed a consent form agreeing to participate in this research study (see Appendix B). There was no experimental or control group. The DNP student researcher did not have any direct contact nor made telephone calls to patients. This was the responsibility of the organization's nurse practitioner care manager. The NP coordinated all care related to the management of the patients. The student researcher directly communicated with the care management team and staff members for the duration of the study. All ethical and legal considerations were observed with respect to privacy of patient electronic medical records. The DNP student researcher obtained Institutional Review Board (IRB) approval from the HMO where the study was conducted (see Appendix C). The DNP student reviewed chart records to gain information and track patient performance. Patients were given anonymity through the use of a unique identifying number and to prevent duplication. All patient information was encrypted and password protected and all information in the records was protected to the highest level of security as possible.

All patients were notified that they were being enrolled in the FLS program--a regular component and service provided by their health plan. They were not coerced or forced to participate in any way. All patients were given an opportunity to refuse to participate. Patients who chose not to participate were marked as PNA and removed from the study. If at any time the patient had a change of interest, he/she was easily added to receive the full services the FLS program had to offer them. Patients who dropped out of the program were encouraged to follow up with their primary care provider (PCP) in order to have access to an ongoing continuity of care. All patient privacy was upheld by the laws of the organization and all state and federal laws such as Health Information Privacy and Accountability Act (HIPAA) were observed. Patient information was not shared outside of the study's environment.

Memorandum of Understanding

The Memorandum of Understanding (MOU; see Appendix D) was an agreement between the DNP student researcher and the organization. The role of the DNP student and involvement with the study were outlined as follows:

1. The DNP student would actively work with staff members in the FLS program, the physician champion, the information technology department, and leaders and front line care managers from the Osteoporosis/Fracture Prevention Disease Management Program.
2. The new protocol as written provided a framework for NP practice. The DNP student trained the NP regarding the protocol steps and the theory behind it. Training was for the purpose of increasing the NP's knowledge base and improving her ability to integrate and disseminate the new protocol

successfully. This was done during a face to face meeting with senior leadership in December of 2013.

3. The DNP student would work with the existing staff of the program. There was no direct patient contact by the student.
4. The organization would like to be referred to as a large HMO in Southern California.
5. The DNP student researcher would interface with staff members and physician champion and have access to patient records only. There was no direct contact of the student researcher with patients. The student attended meetings by phone and face-to-face and was onsite for specific meetings. Most interaction was by telephone or email. All patient information was kept confidential and this study had already received organization approval (see Appendix C).

Goal of the Study

The study goal was to align and advance current nursing practice with the best available evidence and current clinical guidelines for osteoporosis chronic disease management and fracture prevention with the goal of improving the existing PNA rate by 20%. This study measured changes in PNA rate through the implementation of a telephone outreach protocol. Other healthcare delivery systems might see the benefit in implementing an FLS program and use similar systems to meet various goals and close all existing care gaps. Additionally, the basic design of this tool was compatible with the software being used and could be generalized to many different settings.

Desired Outcomes of the Study

Attitudes and Behavior

The theory of planned behavior (TPB) specifies the nature of relationships between beliefs and attitudes. A person's evaluations of or attitudes toward behavior are determined by their actions and behavior. A belief is defined as the subjective probability that the behavior will produce a certain outcome. The theory of planned behavior's positive evaluation of self-performance of the particular behavior is similar to the concept to perceived benefits, which refers to beliefs regarding the effectiveness of the proposed preventive behavior in reducing the vulnerability to the negative outcomes, whereas their negative evaluation of self-performance is similar to perceived barriers.

In this study, the NP acted as the change agent--the entity who causes the change to occur (Rogers, 2003). By implementing the protocol, the NP began an action that was predicted to bring about positive change in the patient's behavior. The goal was to get patients who had not picked up their medication after 14 days to change their intention, then change their behavior, and pick up the medication. It was believed the telephone call would be instrumental in changing the patient's behavior. Patients were asked questions during the call, which in turn measured their responses and beliefs. The NP was a critical component in the process of changing the patient's behavior from not picking up the medication to picking up the medication from the pharmacy. It was important for the NP to have positive feelings, attitudes, and beliefs about her individual influence and control to effect change in each individual patient she encountered. Behavior and behavioral intention are defined as follows:

Behavior. An individual's observable response in a given situation with respect to a given target. Ajzen (1991) said a behavior is a function of compatible intentions and perceptions of behavioral control; perceived behavioral control is expected to moderate the effect of intention on behavior, such that a favorable intention produces the behavior only when the perceived behavioral control is strong.

Behavioral intention. An indication of an individual's readiness to perform a given behavior. It is assumed to be an immediate antecedent of behavior (Ajzen, 1991). It is based on attitude toward the behavior, subjective norm, and perceived behavioral control with each predictor weighted for its importance in relation to the behavior and population of interest.

Self-Evaluation Questionnaire of the Nurse Practitioner

Below is an example of the way NP beliefs data were collected to determine her state of beliefs and attitudes before and after the staff education regarding the theory of planned behavior (TPB) and its application to the study (see Figure 2). The telephone outreach tool was presented to the NP and her opinions and beliefs were measured. The NP was asked to rank the responses of her beliefs before and after the study (see Appendix E for the NP questionnaire).

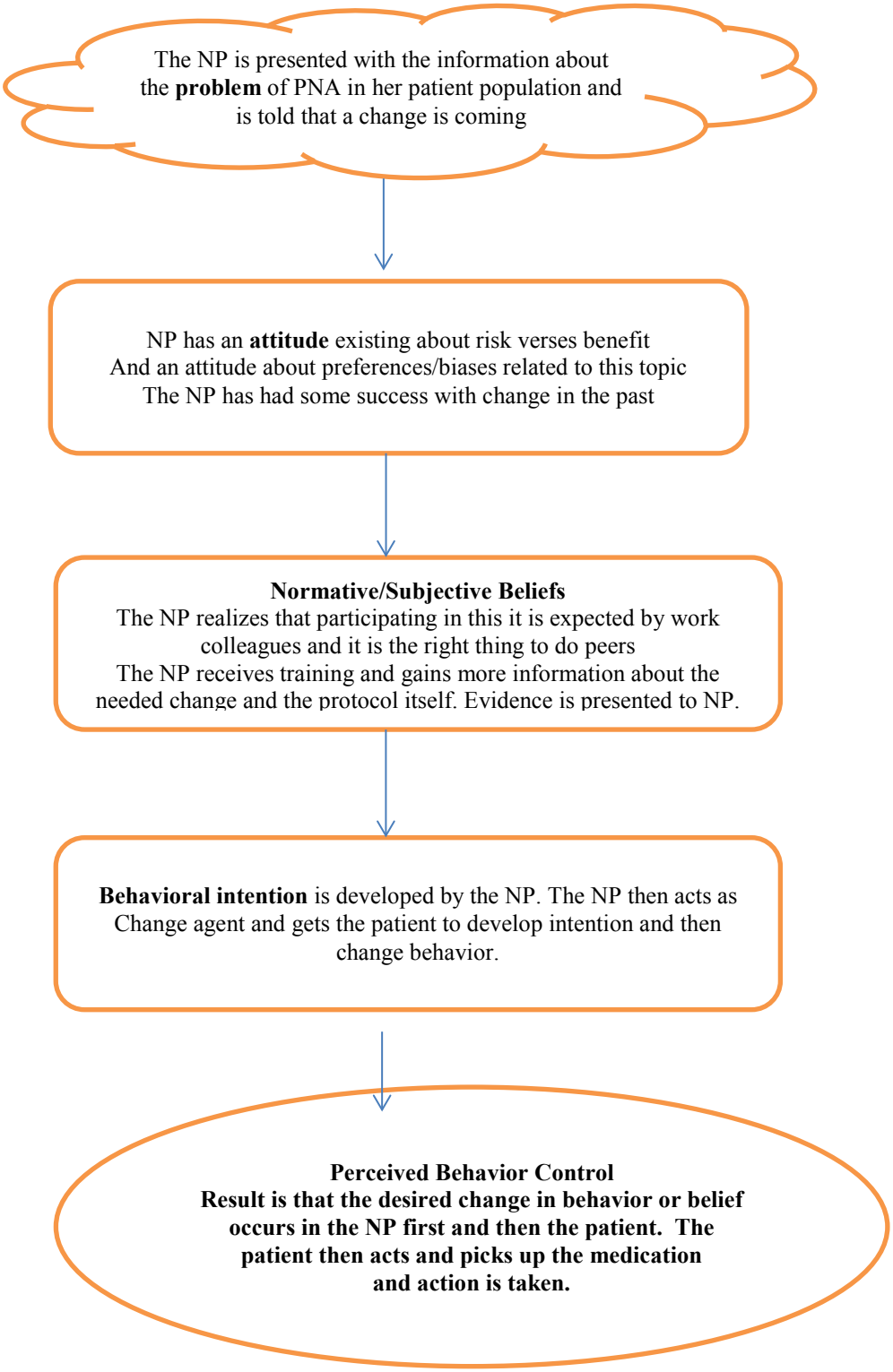

Figure 2. Flow diagram of how the theory of planned behavior effects change in attitudes and behavior of patient and nurse practitioner.

Evidence

Both patient and NP responses were yes/no on the tool and then further broken down on Likert scales to show specific effect and strength on behavior change. The evidence being collected for this project was the patient and NP beliefs before and after the intervention. This was analyzed and based on TPB principles. The principles of TPB that influence intention development and behavior change were normative, subjective, and perceived control and are described as follows:

1. Subjective norm: The belief that the person is doing the right thing.
2. Social norm: The belief that the behavior is what is expected of them to do by others such as peers or superiors.
3. Perceived behavior control: The belief that the person has control over the ability to make the change happen.

The patient evidence was collected from the feedback from the telephone calls, patient responses, and the outcome showing the patient picked up their medication or not. The NP behavior was important but only as it facilitated patient behavior change.

Evidence-Based Study Intervention

This study used a theory-based protocol developed by the DNP student and given to the staff of FLS program, specifically the NP. This protocol was intended to improve the staff's knowledge, self-efficacy, and skills concerning PNA. Using the protocol, the NP acted in the role of change agent. This action of calling the patients would effect change in patient behavior and as a result, a change in intention and behavior would occur, thus improving outcomes in PNA. The study plan was to investigate the impact of implementing an FLS program telephone outreach protocol on the rate of PNA. The goal

ws to lower the rate of primary non-adherence by 20% within a two month period. Studies have shown this to be a feasible and cost effective goal (Che et al., 2005; Dell & Greene, 2010; Eisman et al., 2012; Kates et al., 2010; Reynolds et al., 2013; Solomon et al., 2014). The theory of planned behavior was used as a theoretical framework to guide practice and the beliefs of the providers and the patients.

Information technology and NP care managers systematically identify and target patients who are at risk for PNA. The outcome would be to prevent them from progressing to PNA. This plan began from a need for an intervention to assist patients to pick up their bisphosphonate medication. Previously, no action or intervention has worked with patients who did not pick up or take their bisphosphonate medication. A protocol was developed and tested that identified patients who had not picked up their medication within 14 and 60 days. The nurse practitioner (NP) received a list of patients from the computer and then worked the list by calling each patient on the list at different increments of time such as at 14, 30, and 45 days. During each telephone outreach call, the NP used a protocol that consisted of a series of questions to identify why the patient did not pick up the medication. The NP used an evidence-based solution to change the patients' intentions to get them to pick up and take the medication, which they would not have previously done without the intervention. The protocol demonstrated how the theory of planned behavior (TPB) concepts was used as a basis for change in patients' behavior related to primary non-adherence (PNA). The effects of the protocol, developed using evidence-based guidelines and TPB on the patient's intention and behavior change to pick up and take their medication, were measured. The NP applied concepts of TPB to address patient beliefs and guide behaviors regarding taking their medications. The NP

addressed each factor and evaluated what could be done to get the patient to pick up the medication. For patients in the study, the reasons why they did not pick up the medication and action by the NP were noted.

The following NP actions were taken during the implementation of the protocol and evidence was collected during the telephone outreach protocol (see Appendix F):

1. The NP answered patient questions and engaged in education as needed. Effective communication was evidenced by patient answering a questionnaire during the call.
2. The NP made an appointment for patient to come for a face-to-face care management visit.
3. The NP changed the medication if the patient did not want this one. For example, the patient might need to have the medication changed from a weekly to a monthly dosage.
4. The NP removed patient from the list if patient refused to take the medication or just did not want to be called. Patient was referred back to PCP. If the time went past 60 days and patient did not pick up the medication, then he/she was PNA.
5. If patient concern warranted a switch of medication because of a medical contraindication, medication was stopped until specialty approval was given.
6. The NP referred the patient back to the PCP or specialist for any concern or any reasons deemed necessary by NP.

The plan for educating the staff was described including content, strategies for delivery, and using TPB as rationale for specific strategies to change staff behavior.

A face-to-face meeting was held in December 2013 for the purpose of staff education and orientation. At the meeting, the Reynolds et al. (2013) study and its results were discussed in detail. The staff understood that this study was being used as a base of comparison or benchmark. At this meeting, goals for PNA were set at a reduction of 20%. It was decided that a pilot site would begin developing a protocol. A second meeting was held on May 20, 2014 where the staff was given information about the protocol questions, more on the TPB and self-efficacy, and the importance these theories would have to the study. This site volunteered to be the pilot and testing site. However, although all staff received information about the study, only one NP implemented the protocol. The student researcher developed the protocol along with the NP and the physician advisor. Prior to this, no protocol was in place. The telephone outreach protocol was discussed completely at this meeting. The study design was discussed and the NP agreed to do this.

Plan for Staff Education and Training

The plan for educating the staff included content and strategies for delivery that used TPB as a rationale for specific interventions, which led to a change in staff beliefs and behavior. The staff consisted of one nurse practitioner from this site. Other staff members working with the FLS program at other locations had access to the information and training but did not participate in the actual study. All FLS program staff were educated to the changes and implementation of the PNA study. This training was only in

anticipation of expanding this program to other health organization sites. Staff were given a copy of the protocol and information related to TPB.

The development of translatable knowledge involved steps that first identified patients with a care gap related to not picking up a new prescription medication from the pharmacy. It was important to risk stratify this population into groups that need specific care gaps, in this case--primary non adherence (PNA) to prevent a bad outcome. This systematic approach was the best way to manage the care gap of PNA as well as track patients over time. The NP care coordinator took responsibility to take appropriate action to get patients to change their behavior through a coordinated program that would result in better adherence to treatment recommendations. The protocol and care plan included information technology tools that would help in the care being delivered. The care team needed to be all on the same page including the patient who must be considered as a member of the team.

Budget and Financial Disclosures

The resources used were the existing staff of the FLS program. The existing staff implemented a telephone outreach protocol to call patients who had not picked up their prescription medications at different incremental time periods. The staff used existing departmental space and computer equipment they used every day in their regular job function. No new budget was created. As appropriate to the individual study and determined by the advisor and mentor, the DNP student included a market analysis, strategic analysis, product/services, or financial plan that justified the need, feasibility, and sustainability of the study (see the financial impact section in Chapter I).

There was no set budget for this research study. The DNP student researcher was a non-paid volunteer and not an employee of the organization. This was not a grant funded project. There was nothing financial to disclose and there was no conflict of interest. This program was designed to be self-sustainable. The whole disease management team was involved in the education and planning of this project including all managers, physician champions, and NPs at all other organization sites. These staff members were educated to the PNA protocol because it was planned to be expanded to their sites after it was first implemented at the facility. Other staff members were aware and updated but were not involved. It was predicted that the final results of this project would prove to be a cost savings to the organization. Studies have shown that non-adherence to mediations is costly to the organization and to the healthcare system in general. Patients do not benefit from medications not taken. This problem could result in serious consequences and bad patient outcomes.

Primary Non-Adherence Workflow Process for Telephone Outreach

The process of using the information technology tool to identify patients who had not picked up their medications within 60 days involved the NP receiving a list of patients each week who had a prescription and had not picked up their medications. The NP called the patients at 14 days. After 14 days, the NP documented whether or not she had been able to reach the patient and the response. At 30 days, the patient was called again and an internal message sent to the primary care physician (PCP) that the patient had not picked up the bisphosphonate prescription from the pharmacy. Then after 45 days, the patient was called again and a letter sent to the patient encouraging them to make an appointment to follow up with their PCP. For the purpose of the FLS program,

the patient stayed on the list until the NP took them off and they remained on the list for further follow up. However, for the purpose of this study, the patient was no longer followed after 60 days and was considered PNA (see Figure 3 for diagram and letter sent to patient and provider in Appendix G).

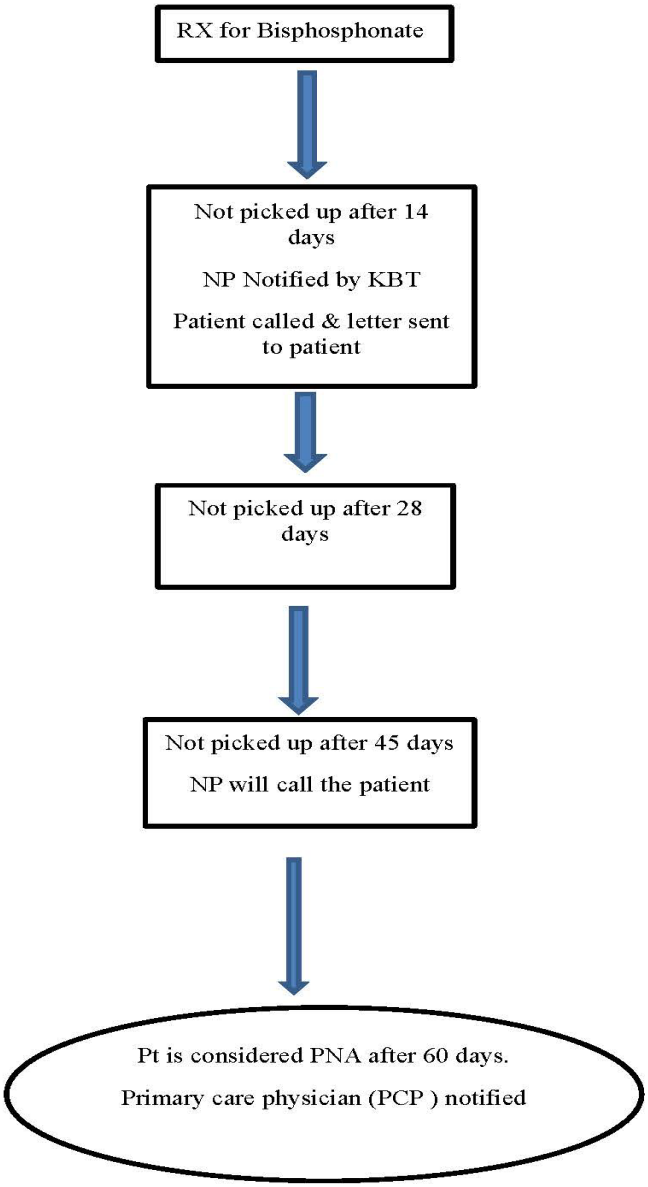

Figure 3. Timeline for protocol.

The Study and Agency Strategic Plan

The organization desired to have a strategic plan in place to lower patients' risk of hip fracture through early identification, risk stratification, treatment initiation, intervention, and follow up of patients. Many of the patients (29.5%) targeted with a bisphosphonate treatment were not picking up their medication from the pharmacy. This identification sparked an interest in developing a protocol to improve the rate of primary non-adherence (PNA) to a new prescription for a bisphosphonate with the overall goal being improved patient outcomes through less hip fractures.

The plan in this study reflected how the concepts in TPB were used as a basis for strategies in the protocol that was developed. This included an example of the strategies that impacted patient beliefs regarding taking their medications. This was evaluated by a Likert scale developed by Morisky, Ang, Krousel-Wood, and Ward (2009) who were able to show that adherence to medications could be evaluated through six domain topics: (a) knowledge, (b) attitude, (c) , (d) social support, (e) stress, (e) coping, and (f) medication complexity. The new protocol fit within the existing framework of the organization's policies for the FLS program. Primary non-adherence was considered a new care gap that must be closed. The Knowledge Builder Tool (KBT) is a computer system that has each care gap listed inside. The NP clicked on the list of patients who needed an intervention and then proceeded to work the list according to the clinical practice guideline embedded under each specific topic. In this case, it was the development of a new protocol to improve PNA in patients with a new prescription for a bisphosphonate.

The telephone outreach tool questionnaire has been piloted. Nor has this specific situation ever been studied. However, the questions were developed from a validated tool to measure medication adherence in an outpatient setting (Morisky et al., 2008). The outreach tool was based on the domains derived from the Morisky tool. Each question was developed to relate to one of the following domains:

1. Knowledge
2. Attitude
3. Social support
4. Medication complexity
5. Stress
6. Coping.

Timeline of Study Phases

The timeline was four to five months in duration--two months consisting of patient enrollment, approximately two additional months to conduct the study, and one additional month to analyze and prepare the results. Each patient in the study was followed for 60 days or until he/she picked up the prescription from the pharmacy. The study began when the initial proposal was accepted by the researcher's doctoral committee and the proposal was been approved by the University of Northern Colorado's Institutional Review Board (see Appendix A). Then the following phases were implemented: (a) recruitment phase was two months, (b) protocol implementation phase was 60 days for each patient enrolled in the study, (c) data collection phase lasted 60 days for each patient recruited, (d) data analysis began two weeks after the data were all collected, and (e) evaluation phase was congruent with the two weeks of the data

analysis. Evaluations were ongoing during the study while NP evaluation data collection sheets were being filled out (see Table 1).

Table 1

Timeline of Phase Implementation

Phases	Activity Conducted	Timeframe for Phase
Recruitment	216 patients will be enrolled in the study. The protocol and how data and phases will be measured have been explained to the NP.	2 months. The first 2 months. Starting at the day the medication is written the patient goes on the list.
Protocol implementation	The patients will be identified as not picking up the medication and will be called and protocol applied.	Day 14 of each patient not picking up medication. This will run 60 days for each patient. Starting at the first day of medication prescription. Action by NP starts at day 14.
Data collection	Telephone outreach tool will be applied.	This will run for 60 days for each patient starting at the first day of the prescription.
Data analysis	The outcome of the telephone encounters is applied and data were all collected.	Two weeks after data collection phase ended
Evaluation	The results will be reposted and all actions are evaluated	This will take two weeks to begin at the end of the data collection phase.

Note. The shortest possible time would be three months and longest time would be five months depending on the rate the patients picked up their medication.

All patients with a new prescription for a bisphosphonate were eligible to be enrolled. Both men and women over the age of 55 years with a new prescription for a bisphosphonate were included. This age of 55 and older was chosen because it was directly comparable to the Reynolds et al. (2013) article that discovered the problem of

PNA at the facility. The only difference was men were also included in this study since the Reynolds et al. study included only women.

Bisphosphonates used in the study were Alendronate, Residronate, and Ibandronate. The NP could see in the computer system the prescription and the medication prescribed. However, they were marked only as bisphosphonate for the sake of this study. All prescription orders were placed electronically so all prescribed mediation data were captured in the system electronically. The data were stored in the organization's pharmacy information system (PIMS) and also housed in the clarity data warehouse (CDW). The medication prescription information was updated once daily and downloaded into the system. Patient information data were also downloaded to the disease management registry for all patients in the facility's pharmacy. These systems interfaced with the disease management registries through the existing electronic medical record (EMR). These interfaces allowed access to secure patient data of all new prescriptions for a bisphosphonate and whether a prescription order was picked up. Additionally, if orders were discontinued, cancelled, or changed by the prescriber, or the patient was terminated as a member, this was also noted in the system. No prescriptions for bisphosphonates were written on paper. The name of medication might have been populated but for this study, it was yes or no if the patient had a prescription for a bisphosphonate. There was nothing to collect other than the NP acknowledged looking at this information and the call was placed to the patient during the appropriate period of time such as 14 days, 30, and 45 days. The NP communicated with the researcher on a weekly basis.

Descriptive Statistics

The mean was calculated to determine the average age and average time interval the prescription was either picked up or not from the pharmacy. The statistical analysis determined the interpretation of results and showed whether or not the goal was met. Statistical significance of and differences were determined.

Absolute risk reduction (ARR) is also called risk difference (RD). Absolute risk is a very accurate way of presenting research results and help with decision-making. In this example, the ARR of 6% equated to a relative risk reduction of 20%. This meant that if 100 patients were treated, six would be having PNA to see a 20% reduction in the group. Relative risk reduction (RRR) tells how much the treatment reduced the risk of bad outcomes of one person relative to the control group who did not have the treatment. The relative risk included everyone in the intervention group as compared to the control group.

Power analysis was necessary to determine whether the sample size selected was adequate. In this case, a power analysis determined it would be necessary to have 216 patients to represent a sample size that could be generalizable to the population. The sample size and findings were designed to be statistically and clinically significant in order to be representative and show an improvement in the PNA rate, which was the goal of the program. It was decided to run the study for two to three months to have enough patients because men were included in the study.

The Reynolds et al. (2013) study was used as a benchmark because it showed the incidence of occurrence in this study population to be 29.3%. The data were useful because they were selected and used from the same population. It was decided by the

research team that data collection for the span of two months would be adequate in generating the sample size needed to show statistical significance (n = 216).

Data Collection Method

The data collection method with the use of this tool was through an interactive website that interfaced with the clarity warehouse wherein patient data were updated on a daily basis. Most of the data were already stored within the EMR. The NP collected data from the telephone encounters.

Measures/Instruments

The measurements were taken and recorded by the NP into the Knowledge Builder Tool (KBT) embedded into the disease management registry. All patients with a new prescription for a bisphosphonate were included in the study (n = 216) and the rate of PNA was measured after 60 days of patients not picking up their prescription.

Variables Measured

A dependent variable depends on the independent variables. In this case, the dependent variables were medication adherence and primary mediation non adherence. An independent variable is a variable that has an effect on the outcome. Its value determines the value of other variables. For example, it stands alone and is not changed by the other variables being measured. An independent variable causes some kind of change in the other variables, such as dependent variables. Six independent variables were identified in this study. The following variables were not collected by the NP since they are already in the in the KBT to assist the NP with information if needed and to help the NP determine that the patient was eligible for the program. They were analyzed at the end of the study to report on the characteristics of the patient who was PNA versus

adherent to bisphosphonate therapy. The data added value to the analysis of the results. It was important to understand the characteristics of the patient who is adherent versus primary non-adherent.

Age. The age of the target population was set at 55 and older. Age was measured in years and months. The reason to use age and 55 or older in this study was to make the data more comparable; the number 55 was selected mainly in an effort to improve the rate of PNA. The Reynolds et al. (2013) article found that age as a characteristic affected adherence risk and was used as a predictive variable. The more closely their characteristic could be matched with our study population, the more significant the findings.

Gender. This study population included men and women. Men and women were selected because not much is known in the literature about men; this population has been historically underserved with osteoporosis diagnosis and treatment. The population size was large enough so women could be directly compared to women in the comparative study with Reynolds and colleagues (2013). Then our own women data could be compared internally with our male data to gain more knowledge and insight into men being characteristically more, less, or the same as women when compared in this setting.

Characteristic of prescriber: Nurse practitioner or primary care provider. Characteristics of the prescriber were assessed and compared to similar characteristics in the Reynolds et al. (2013) study. It was thought that PNA could be predicted when certain characteristics of the prescriber were known. In this study, only the characteristic of whether it was the NP care manager or the PCP who generated the prescription was collected and compared since these data were comparable. For example, if the

prescription was written by the NP care manager, then the patient would have received program interventions such as education and face-to face-counselling with the NP that might not have occurred if the prescription was not written by the NP. This factor was not as well controlled when the prescription was not ordered by the care manager. Medication teaching might vary from provider to provider if not implemented from within the program protocols, guidelines, and policies. The NP did not collect these data as discussed earlier. It was important to see if there were similarities related to the characteristics of the prescriber and patients who had PNA or were adherent.

Summary

In summary, this capstone project implemented a protocol for which outcomes were measured to determine its effectiveness in addressing the problem of medication adherence in patients with osteoporosis. This project was a population based study (n = 216) that implemented an information based tool to reduce the rate of PNA by 20% from the current rate seen in this population. The study was a prospective, observational analysis and includes all out-patient men and women in the program age 55 and older with a first time prescription for bisphosphonates.

The evidence-based telephone outreach protocol was fed by the KBT to provide the NP with a list of patients who needed a call. The protocol was implemented by the NP as part of an existing osteoporosis disease management program (ODM). Statistical analyses calculated and measured the variables, compared them to each other, and then determined whether or not the use of the tool was the reason for meeting the goal of a 20% reduction in the PNA rate.

CHAPTER III

STUDY EVALUATION PLAN

This was a prospective, observational study conducted in a health maintenance organization (HMO) in southern California that measured the effectiveness of the use of a telephone protocol on the primary non-adherence (PNA) rate for bisphosphonates. This study hypothesized that the intervention of a disease management program NP care manager who used a telephone outreach information technology (IT)-based tool on a population of patients with a first time prescription for a bisphosphonate would have an effect on improving the primary non adherence (PNA) rate. A total of 216 male and female patients enrolled in the study who were 55 years or older.

This intervention was completed by using a computer program known to the organization as the Knowledge Builder Tool (KBT). The KBT was used to capture patient data including new prescriptions and tracked those prescriptions for patients who did not pick up their new prescription bisphosphonate medication during a period of 60 days. In this study, at 14 days, an intervention in the form of a telephone outreach encounter was performed by the NP care manager of the fracture liaison program. The following paragraphs describe details of how this study was evaluated, what evidence-based measures were applied to the plan, what instruments or measures were used for each objective, and what method of analysis was used to measure each objective. The variable of patients who picked up their medications prior to 14 days and then from 14

days to 60 days was tracked and compared to determine if a statistical significance occurred as a result of the program action and not purely by chance..

Searching for patient data is very time consuming for the NP and not a cost-efficient way for a provider to spend time (Akesson et al., 2013). Without an appropriately integrated system in place, the NP could spend valuable program time searching for data to generate appointments and to communicate with the patients. The KBT assisted with this by generating patient information to the NP on a daily basis. This time saving feature allowed the NP to receive the list of patients with whom she could intervene related to their PNA actions in a timely and accurate manner.

The NP started this study on December 8, 2014 following Institutional Review Board (IRB) approval from the University of Northern Colorado. The study implemented a protocol in the form of a telephone outreach tool and evaluated the effectiveness of the protocol on primary non-adherence (PNA) of patients with osteoporosis over a two month period.

Exclusion Criteria

Patients were excluded from the study if they

- were younger than 55 years of age
- had chronic kidney disease (CKD) 4, 5, or were on dialysis
- had a history of a previous prescription for a bisphosphonate that was picked up
- did not have a current organization membership or current pharmacy benefit
- had filled their prescription in an outside pharmacy
- had the medication discontinued or placed on hold

- had allergies to bisphosphonate medication
- had any medical contraindication to taking a bisphosphonate
- died or lost eligibility for the organization membership at any time.

Measureable Objectives

Two objectives were identified in this study:

1. To develop and test a protocol to identify patients with osteoporosis or at risk for hip fracture with a new prescription for a bisphosphonate who had not picked up their medication from the pharmacy.
2. To lower the primary non–adherence rate to bisphosphonate medication by 20%.

To meet the first objective, the Doctor of Nursing Practice (DNP) student wrote a protocol for telephone outreach in collaboration with the organization leaders to improve the incidence of primary non-adherence to a bisphosphonate that was shown to be a prior problem in this population (see Appendix F for protocol). As the protocol stated, non-adherent patients were called at increments of 14, 28, and 45 days. They were considered to be PNA at 60 days.

The telephone outreach protocol was used by the NP to apply and to meet the objectives. The computer sifted through patient data and sent the NP a list of patients for whom she could apply the telephone outreach tool. The DNP student researcher closely monitored the NP's activities and analyzed the performance of the NP in addressing primary non–adherence (PNA) by using the protocol. The NP met with the DNP student researcher and the physician advisor on a weekly basis for approximately 20 minutes for a total of 26 meetings. The purpose of all 26 meetings was to verify that all patients were being called on time, which patients were to be continued in to the next week, and that all steps of the

protocol were being followed properly. At the end of each week, the physician advisor and DNP researcher had a telephone meeting to verify patients on the list and who were to be continued into the next week.

There was no deviation to the study or the protocol at any time. If steps were not being followed at any time, adjustments in the form, clarification of which patients were still on the list, and verification that the intake forms were being filled out on time for each call made were discussed. If a message was left, the intake form was filled out indicating that the patient was not spoken to but received a reminder message on the answering machine.

The second objective was to lower the primary non–adherence (PNA) rate to bisphosphonate medication by at least 20%. The rate of PNA was depicted as a percentage and was compared to the baseline PNA rate of 29.5%. Microsoft Excel Statistical Tools® was used to determine the rates and percentages that were compared in this study.

Evidence-based Measures Applied to the Evaluation Plan

The theory of planned behavior (TPB) was used as a theoretical basis to change both the NP's practice behavior and the patients' behavior to create a new intention to perform the functions in order to improve PNA. Clinical significance using Chi square analysis (*p* value) was determined. Each independent variable was evaluated and compared for adherence and non-adherence (PNA) properties and their clinical significance was determined. The connection to the protocol being responsible for making the change was evidenced by patients' responses to questions during the telephone interview and pharmacy data indicating whether or not the patient picked up the medication after the phone calls were made.

Effective program evaluation is a systematic way to improve actions and monitor what has been accomplished. In analyzing and using data to examine the effectiveness and efficiency of any program, it is important to include a process for continuous quality improvement to monitor progress and outcomes. The following is a framework designed to guide health professionals in the process of program evaluation; specifically, this framework was used in this project to evaluate the telephone outreach protocol. This evaluation tool was developed by the Centers for Disease Control (2010) and is comprised of six steps that were used to evaluate the program's effectiveness (see Figure 4).

1. Engage stakeholders. The stakeholders were all involved in the protocol development. They attended frequent face to face meetings and had an opportunity to give their input. The identified stakeholders in this project were (a) the DNP student researcher, (b) the MD champion, (c) the HMO administration, (d) HMO pharmacists, (e) HMO Information Technology data analysts, (f) Disease Management Program staff, and (g) the patients.
2. Describe the program. The program is part of a fracture liaison program (FLS) and was designed to improve the rate of primary non-adherence to a bisphosphonate medication. The NP coordinated a telephone outreach service to record patient responses as to the reason they had not picked up their medication within the allotted 60 days. The NP called each patient on the list sent to her by a computer system that identified patients who had not picked up their medication. The NP followed a telephone outreach protocol and contacted the patients. The goal of the study was to have the patients

develop an intention to pick up the medication. Using principles of theory of planned behavior, the NP acted as a change agent to have patients pick up their medication to patients who prior to the intervention did not pick up their medication.

3. Focus on the evaluation design. The focus of this design was to identify the factors that led to the patient not picking up the medication. The goal of the NP was to make the patient more aware of the fact that he/she had not picked up his/her medication to achieve self-efficacy
4. Gather credible evidence. The literature review discussed the credible and evidence-based measures used in the paper. Evidence generated by this study was in the form of data collected during the phone call that was collected, analyzed, and compared.
5. Justify conclusions. Proactive program design coordinated by NP using IT tools was used as an effective method to reduce PNA.
6. Ensure use and share lessons learned. There were desirable actions that would lead to an improvement in PNA. Lessons learned from this study could be generalized to other FLS programs.

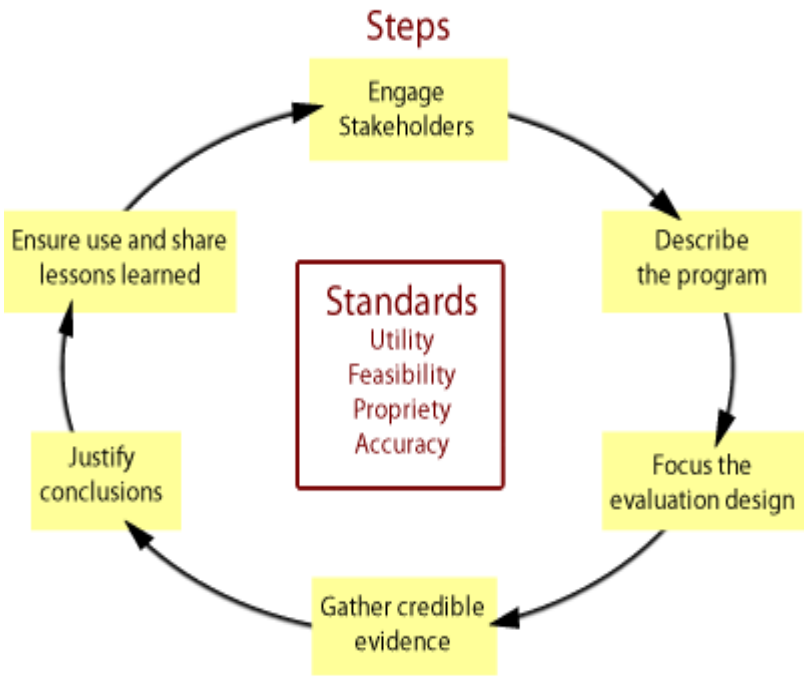

Figure 4. Framework for program evaluation. Source: CDC (1999).

Evaluation of Plan for Dissemination of Findings

The findings were disseminated within the organization prior to the roll out at all remaining 12 medical centers in southern California. The plan was to publish the highlights and the results of this program with the University of Northern Colorado as well as in a selected medical journal so the results and knowledge gained from this study could be accessed accurately by the medical community.

Evaluation of Nurse Practitioner Beliefs About the Theory of Planned Behavior

The theory of planned behavior (TPB) is based on Bandura's (1977) theory of self-efficacy. The NP was given information and trained related to self-efficacy and the importance of TPB to this study. The concepts of TPB such as normative, subjective, and control beliefs were presented to the NP. The Healthy Bones NP's beliefs and training

were evaluated by a questionnaire (see Appendix E). She was asked a series of questions regarding attitudes and beliefs related to the application of the TPB on the population of patients in the study in order obtain baseline information of her beliefs before and after she was exposed to the study information.

Measurement and Evaluation of Patient and Provider Behavioral Intention and Behavior Change

The NP enhanced communication with the patient and built trust and rapport through the telephone conversations (Rogers, 2003). In this study, the NP assessed, identified, and determined that change was needed in the patient's behavior. This was evidenced by whether or not the patient picked up his/her bisphosphonate medication from the pharmacy on time. The NP utilized her skills in conducting an informational exchange of information with the patient in the form of a guided telephone call that helped guide patient decisions (Rogers, 2003). After this step, intention in the patients was developed that translated into a new behavior. This transition to independence and change in beliefs and behaviors was due to the intervention and was measured by asking the patient a series of questions during the telephone interview (Morisky et al., 2008). To be an effective change agent, it was helpful that the NP believed strongly in what she was doing and that her actions led to an improvement in the patients' outcomes. For this purpose, the NP's beliefs were measured on a Likert scale in the form of a questionnaire to determine improvements in her beliefs before and after the in-service of the study was completed.

Evaluation of Ongoing Study Participation

On a weekly basis, the NP, DNP researcher, and physician advisor evaluated whether or not the data collection forms were being completed and helped to resolve problems; none were identified (see Appendix I for NP Intake Form). The results of these meetings were summarized and recorded to insure that the protocol was being implemented appropriately with each patient enrolled in the study.

Measurement of Patient Behavior Intention, Behavior Change, and Measurement and Evaluation of Outcomes

This study was based on the premise that the patient would develop a change in intention after receiving the telephone call and then change behavior as the result. This change was measured as evidenced by the outcomes seen in the responses of the patients who were called. The data collected were compared to show whether or not they picked up the medication after they received a reminder call. If the patient was unable to be contacted, this was noted in the results of how many patients were not actually spoken to (see Appendix I) but were left messages by the NP. Data collection sheets were used by the NP to collect data during each telephone call (see Appendix I).

Additional Necessary Resources

The statistical tools used in this study consisted of an initial power analysis to determine the number of patients needed to determine statistical significance. In this case, the number of patients enrolled in the population was 216. A Chi square analysis was used to determine statistical significance of each variable. The descriptive statistics used were the percentage of patients who were adherent versus the number of patients

who were primary non adherent (PNA). The percentage of adherent patients was compared to the percentage of PNA patients. These two groups were comparable because they all received the same intervention and all met the requirements for study inclusion. The formula used was as follows:

# of prescriptions picked up/total patients in the study

PNA = 1- adherence.

For example, in the Reynolds et al (2013) study, PNA equaled 1-0.71, which was 29.5% and 70.5% adherence rates. The same descriptive statistics formulas were used in this study. In this study, PNA + adherence =1 or 100%. Data analysts from the HMO's division of research validated that all results were calculated accurately.

Summary

This protocol was evidence-based and used an existing theoretical framework based on the belief of changing behavior by creating intention. The protocol used the NP and the computer to make sure there were no disparities in the way patients were treated. All patients in the study who did not pick up their medications at 14 days received telephone calls that asked each patient why he/she had not picked up his/her medication. Lastly, the data collected and analyzed showed results as a percentage and were compared to the previous rate of 29.5%, which reflected what existed in the program when no active steps were in place to reduce PNA, i.e., a protocol. It was hoped this protocol could be replicated at all of the medical centers within the health plan in which this study was done and patient outcomes would improve when patients adhered to their bisphosphonate medication.

CHAPTER IV

RESULTS AND OUTCOMES

This capstone project evaluated the implementation of a newly developed protocol designed to improve the primary non-adherence (PNA) rate in men and women 55 years of age and older with a first time prescription for a bisphosphonate. The goal was to improve patient outcomes related to medication adherence by changing his/her behavior to pick up his/her medication from the pharmacy and to answer the following research question:

Q1 Will a telephone outreach protocol based on the theory of planned behavior (TPB) be effective in lowering the primary non-adherence rate (PNA) to bisphosphonate medication by 20% in a large Health Maintenance Organization (HMO)?

Objectives of the Study

There were two objectives in this study:

1. Develop and implement a protocol to target patients diagnosed with or at risk for osteoporosis and hip fracture who had not picked up their bisphosphonate medication from the pharmacy within 60 days--primary non-adherence (PNA).

This objective was met as evidenced by the protocol implemented in this study. The protocol identified the patients at risk, established the timeline, and was based on

questions in a theoretical framework (see Appendix F for an example of the telephone outreach protocol tool).

2. Decrease the current rate of PNA by at least 20% from the identified rate of 29.5%. The current rate of 29.5% of PNA to bisphosphonate was decreased by 26.3% to 3.2%. At 14 days during the study, the adherence rate was 87.5% prior to patients receiving a phone call. The PNA rate had been reduced to 12.5%. This result is further discussed in Chapter V. The results showed an overall 26.4% absolute reduction and an 89.2% relative reduction. The goal of a 20% reduction was exceeded.

Study Population

Initially, 224 patients were identified as having a new prescription for a bisphosphonate and then screened for inclusion into the study. Of the 224 patients, eight people were excluded, leaving 216 patients who were enrolled and completed the study (see Table 2 for exclusions). Of the 216 patients, 168 were women (78%) and 48 were men (22%). The age range of participants was 55-95 years old with an average age of 70.8 years; the standard deviation was 8.9 years. Race was not included in this analysis because we did not have accurate race data.

The timeframe for recruitment and enrollment of the 216 patients took one month. Inclusion criteria requirements were all patients 55 years of age and older--both men and women with a new prescription for a bisphosphonate medication in a large healthcare system.

Participant Exclusion

There were several reasons for participant exclusion. Table 2 presents each reason, the number of patients in each group, and the percentage of each group.

Table 2

Reasons for Participant Exclusion

Reason	Number	%
Allergy to medication	1	12.5
Chronic kidney disease 4/5 or dialysis*	1	12.5
Outside pharmacy**	2	25.0
Skilled nursing facility or hospice***	2	25.0
Medication discontinued	1	12.5
Low Vitamin D or calcium on hold	1	12.5
Total	8	100

*A bisphosphonate is contraindicated in patients in chronic kidney disease.
**Patient used an outside of the facility pharmacy so could not be tracked.
***Patient is confined to home or another facility and would be given their medication by a nurse

Implementation of the Telephone Protocol by the Nurse Practitioner

The study began after IRB approval was obtained (see Appendix A). The NP was oriented to the telephone protocol and she agreed to implement this project on a voluntary basis. She was administered a questionnaire that investigated her beliefs regarding the theory of planned behavior (TPB) at the beginning of the study and then two weeks into the implementation of the study. The questionnaire used a 5-point Likert scale to respond

to the eight questions: 1—*Strongly disagree*, 2—*Disagree*, 3—*Neither agree nor disagree*, 4—*Agree*, and 5—*Strongly agree*. The results of the questionnaire showed she scored all 5's equaling 40. The pre- and posttests revealed no change (see Appendix E). The NP answered the same on the pre- and posttests with a score of 5 on each question, showing she was in strong agreement with the study. The purpose of this pre- and posttest was to serve as a proxy to determine she understood the TPB, agreed with the concept, and agreed to work with the researcher in conducting the study in addition to the consents.

The team consisting of the NP, DNP student researcher, and the medical advisor met on a weekly basis to discuss what had occurred that week and to see if there were any patients who still needed to be called. The NP was given an opportunity to ask questions and make clarifications. These meetings occurred during the enrollment period and throughout the calling period for three months when the study was officially closed--a total of 14 meetings. The results of the meetings showed they were helpful in keeping the study on track. The data collection ended earlier than planned because the last patients refused the medication. In addition, the DNP student and the medical advisor met each week to discuss enrollment and review the data collected at the end of each week to see if there were any questions.

The following were highlights of the study plan and flow:

1. The DNP student researcher, the medical advisor, and the NP care manager developed a protocol for this telephone outreach tool prior to the proposal acceptance of this study.

2. Telephone outreach was already included in the tasks of the NP care manager.
3. Questions in the telephone protocol were developed based on self-efficacy and the theory of planned behavior (see Appendix F).
4. After IRB approval was obtained (see Appendix A), patient enrollment began at the end of 2014.
5. Weekly meetings occurred during the course of the enrollment and study period for 14 weeks at which point the study was officially closed.
6. During the course of the meetings, the study flow was verified and all telephone calls were tracked.
7. No problems occurred and any concerns were worked out in weekly meetings.
8. Each week, the NP received a list of patients who had received a prescription for bisphosphonate medication 14 days prior and had not yet picked up their medication. The NP implemented the protocol with these patients to impact PNA.
9. The following unforeseen events occurred as a result of the study and are described in greater detail in Chapter V:
    a. Two patients picked up medication after 14 days but before the NP could call them.
    b. Six patients used pharmacies outside of their assigned pharmacy.

c. The pharmacy sometimes told patients to come back another day if they did not have stock or due to other pharmacy workflow concerns. This number was not known.

The study officially ended 14 weeks after recruitment began when the protocol had been implemented on all patients enrolled in the study and/or all patients were 60 days out from receiving their bisphosphonate prescription.

In this study, NP beliefs about TPB were collected by a questionnaire both before and after the information about TPB was taught to her. There were no changes from the first time it was completed to the second; she scored the same, all 5s, and her score was 40 on both questionnaires. She knew this study was being planned because of meetings during the planning phases with the organization. She was very proactive in preparing for this study as she wanted to end up with good results and report success of the program. The NP's beliefs were not being monitored other than to see that she understood the TPB and was in agreement with the belief of her ability to act as change agent in the study. The questionnaire served as a proxy to determine she was on board with the study and she agreed with the concepts being presented.

Telephone Outreach Protocol Tool

The telephone outreach protocol was a tool implemented on 27 patients who were not adherent in the first 14 days of receiving their bisphosphonate prescription. At 14 days after a patient in the study had not picked up his/her new prescription for a bisphosphonate, the NP implemented the protocol by placing a phone call to the patient. Twenty (74%) of 27 patients picked up their medication after receiving one or two phone calls from the NP who had applied the telephone outreach protocol. Twenty-six calls

were made to 20 patients in this group for an average of 1.3 calls for each patient. Two (10%) of these patients in the telephone outreach group picked up the medication after no calls.

Adherent Group

Overall, the adherence rate in the study was 96.8% (189 + 20 = 209 divided by 216). This represented the adherence rate of the telephone outreach group and non-telephone outreach groups combined (see Tables 3, 4, and 6). The groups were stratified by age showing results for adherence and PNA after one and two calls. No one in the adherence group had three calls placed. Two people who did not receive a call picked up the medication at 17 and 18 days. Although they were included in the telephone call group, their reasons for not picking up the medications prior to 14 days were not captured. The following is a breakdown of the calls in the telephone outreach adherent group: 10 (37%) patients received one call before becoming adherent, 8 (19%) received two calls before becoming adherent, and 2 (7%) received no call before becoming adherent.

Table 3

Adherence Rates Before and After Telephone Outreach Call

Age Group	Picked up Prior to Day 14		Telephone Call Adherent after 1 call		Telephone Call Adherent after 2 calls		Non-Adherent		Total
	N	%	*N*	%	*N*	%	*N*	%	
55-59	18	94.7	1	5.3	0	0	0	0	19
60-64	17	85.0	1	5.0	0	0	2	10.0	20
65-69	60	80.0	10	13.3	4	5.3	1	1.3	75
70-74	33	97.1	0	0.0	0	0	1	2.9	34
75-79	23	92.0	1	4.0	1	4	0	0.0	25
80-84	22	88.0	1	4.0	0	0	2	8.0	25
85+	16	88.9	1	5.6	0	0	1	5.6	18
Total	189	87.5	15	7.9	5	2.3	7	3.2	216

Table 4

Descriptive Statistics of Telephone Outreach Protocol

	Average Age	Age Range	SD	N	%
Picked Up Not in Telephone Outreach Prior to Day 14	70.94	55-93	8.9	189	87.5
Picked Up in Telephone Outreach after Day 14	69.25	55-95	8.3	20	9.3
Picked Up Total	70.80	55-95	8.9	209	96.8
Primary Non-Adherent	72.90	61-88	10.4	7	3.2
Overall	70.85	55-95	8.9	216	100

Table 5

Adherence of Patients

Patient Characteristics	*N*	%	Average Age	Age Range	Median Age	*SD*
Adherent With No Telephone Calls Prior to 14 Days after Receiving Prescription	189	87.5%	70.94	55-93	74	8.9
Adherent After Receiving 1 or 2 Telephone Calls After Day 14	20	9.3%	69.25	55-95	75	8.3
Adherent After Receiving 1 Telephone Call After Day 14	10	4.6%	69.25	55-95	75	8.9
Adherent After Receiving 2 Telephone Calls After Day 14	8	3.7%	69.25	55-95	75	8.9
Adherent after 0 calls after Day 14	20	.9%	67	65-69	66	1.5
Total Number of Patients who were Adherent following implementation of protocol	209	96.8%	70.85	55-95	75	8.9
Total of Primary Non-Adherent	7	3.2 %	74.5	61-88	74	10.4
All Patients In Study	216	100%	70.85	55-95	74	8.9

Table 6 shows a summarized version of days needed to pick up the call after one or two calls, if a message was left, or if the patient actually spoke with the patient. A slight difference was noted; the average age in the group needing one call was 66.3 years old as opposed to two calls for 72-years-old. The overall age of adherent patients was 69.2-years-old.

Table 6

Adherent Patients Needing a Telephone Call

Number of calls needed for adherent telephone outreach patients	Total patients	Average age	sex	Age range & Median age	SD	2 messages left by NP Pt did not speak to NP	Spoke with NP 1st call	Spoke with NP on 2nd call	messages On 1st call	Message left on the 2nd call	Total calls to 20 patients	Total calls resulting in conversation	Total calls resulting in messages left
0	2	73	F	69& 77 Median= 73	5.6yrs	0	0	0	0	0	0	0	0
1	10	66.3	2 (20%) men 8 women (80%)	55-81= Median= 66	6.4yrs	0	7(27%)	0	3	0	10(10x1)	7(27%)	3(12%)
2	8	68.3	2men (25%) 6 women (75%)	65-79 Median=	5.2 years	6	0	2	0	6	16 (8x2)	2 (8%)	14(53%)
3	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	20(9.3%	0	4 (20%) men 16 women (80%)	0	0	6(23%)	7(27%)	2(8%)	3(12%)	6(23%)	26 (1.3 calls per person)	9(45%)	17(65%)

Note. Percentages were rounded to nearest number

Table 7 shows descriptive statistics of one call versus two calls to pick up the medication in the telephone outreach adherent group.

Table 7

One Call Versus Two Calls to Pick Up Medication in the Telephone Outreach Adherent Group

Days	*N*	Average No. of Days In Which Medication obtained	*SD*	Men		Women		Average age
				N	%	N	%	
After First Call	10	2.7	2.1	2	20	8	80	66.3
After Second Call	8	6.6	6.0	2	25	6	75	72
No Calls Needed	2					2	10	73

Primary Non-Adherent Group

The remaining 7 of the 27 patients (26%) did not up the medication after being called. Four of the seven patients (57%) stated they did not know her and wanted to wait until they spoke with their prescribing doctor. Two patients (29%) told the NP on the first call they forgot; on the second call, they stated they had changed their minds and did not want the medication due to fear of side effects. One person (14%) who needed a phone call was not able to be reached by phone and then went on to be PNA after three messages were left by the NP. Nine calls (35%) resulted in a conversation with the patient and 17 calls (65%) resulted in messages left. Table 8 provides the origin of the prescription, reasons for not picking up the medication, whether or not the NP spoke to the patient, how many calls were made, and how many messages were left.

Table 8

Reasons for Not Picking Up Medication

Patient	Origin of Prescription	Number of Calls Made	Reason Given for Non-Adherence	Talked to Patient	Messages Left
1	NPCM	3	Unknown	0	3
2	NPCM	2	Initially said forgot on first call; now refuses medication--worried about side effects	1	1
3	Other	2	Initially said forgot--now refused on second call. Worried about medication side effects and wants to talk to prescribing doctor	1—Spoke on second call	1
4	Other	1	Refuses treatment--wants medication discontinued, has concerns about drug complications, and does not think meds are needed	1	0
5	Other	1	Refused--has concerns about side effects Refuses treatment – Discontinued--concerned about drug complications	1	0
6	Other	1	Refused--has concerns about side effects. Wants to talk to primary doctor	1	0
7	Other	1	Refused--has concerns about side effects	1	0
Talked to patient vs message				6	5
Total number of Calls					11

Note. NPCM = Nurse Practitioner Case Manager

Characteristics of the Prescriber

Of the 216 patients in the study, 121 (56%) prescriptions were written by the NP care manager in the program. Of these 121 patients, 14 needed one or two calls by the NP and 2 (1.7%) went on to be PNA; 105 (87%) picked up their meds in the NP prescription group prior to 14 days and were included in the overall study adherence group. Being part of the HMO system, the patients see other physicians who might generate a prescription for a bisphosphonate and those patients might have been included in this study. Although the Chi-square analysis was exactly at .054864 and not less than .05 for the NP writing the prescription and not the primary care provider (MD) or another outside prescriber, this result was not statistically significant although highly suggestive. It would be helpful to have the NP write the prescription and call and follow up with patients.

Ninety-five prescriptions were written by another provider other than the NP. Of these 95 patients with prescriptions written by someone other than the program NP, five were in the PNA group and 84 (88.4%) picked up the medication within 14 days and did not require a phone call. After 14 days, six (6.3%) patients required a phone call and of these patients, five went on to develop PNA (5.2%). When they were called by the NP, several gave reasons such as they were afraid of side effects or wanted to talk to their doctor again. Four patients stated they did not know the NP since she had not written the prescription; they wanted to speak to their prescribing doctor before they would take the medication so they refused to pick up the medication. Table 9 provides the prescriber characteristics for non-adherent patients. Figure 5 shows prescriptions by the nurse

practitioner versus other clinician for study telephone protocol primary non-adherent versus adherent groups.

Table 9

Prescriber Characteristics for Non-Adherent Patients

Prescriber	Reason for PNA	Number	Average Age of Patients	Media Age of Patient
NP Case Manager	Unknown	1	66	67
	Fear of side effects	1		
	Want to speak to doctor	N/A		
Other	Fear of side effects	5	72.8	74.5
	Want to speak to doctor	5		
Total		7		

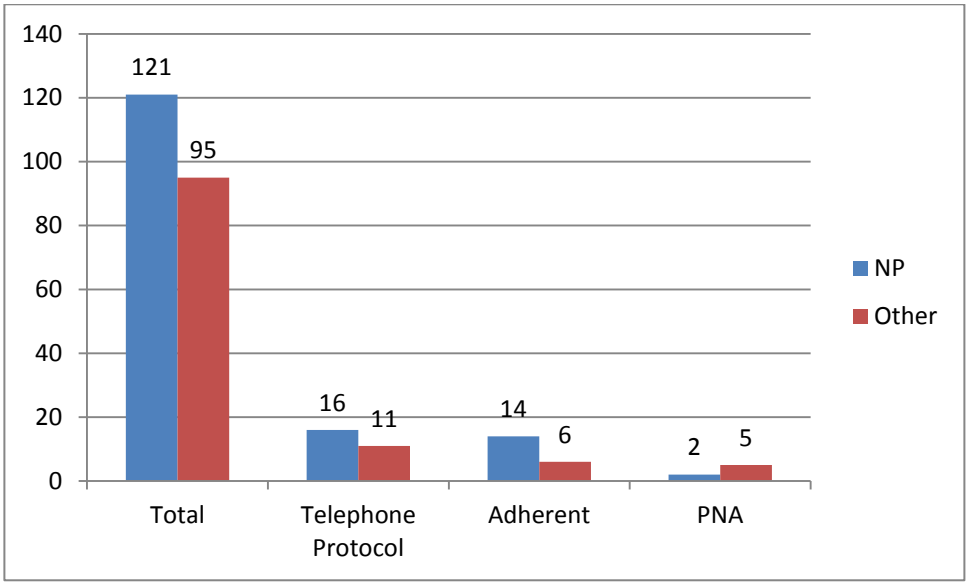

Figure 5. Prescriptions by nurse practitioner versus other clinician for study telephone protocol primary non-adherent versus adherent.

The first two columns in the chart represent all patients in the study. In the telephone outreach group, the program NP wrote 121 and 95 prescriptions were written by another clinician. Results showed that in the NP group, patients were more adherent and had fewer incidence of PNA than other clinicians. Patients in the NP group appeared to respond better to the telephone outreach protocol than the prescriptions written for other clinicians although this was not found to be statistically significant possibly due to the small sample size.

Table 10 provides the number of prescriptions written by the nurse practitioner, the number of calls made, the reasons for not picking up the prescription, and messages left if no contact was made. In the telephone outreach group, the program NP wrote 121 prescriptions. Five (35.7%) of 14 patients in the NP prescriber group answered more frequently that they forgot and the call served as a reminder. Table 11 shows that 95 prescriptions were written by another clinician; also show, is the number of calls made, the reason for not picking up the prescription, and messages left if no contact was made. Five (45%) patients stated they wanted to speak to the prescriber first.

Table 10

Prescriptions Written by Nurse Practitioner

	Total patients	Percent	Reason for not picking up prior to 14 days	Could not reach patient after 3 messages left
PNA	2	1.7	1 patient stated on 2nd call 1 message left &second call reached the patient .She stated initially forgot but now has decided not to take the medication - fear of side effects	1
Picked up after 1 or 2 calls	18	11.5	Forgot stated will pick up within the week Calls or messages left served as a reminder for this group.	0
Picked up after no calls in telephone outreach group	2	1.65	Patent was on call list but NP did not get a chance to call yet. Pt picked up at 17 and 18 days	0
Picked up prior to 14 days so did not need a call by NP	105	87	N/A	0
Total	121	100		1

Table 11

Prescriptions Written by Another Prescriber

	Total Patients	Percent	Reason for not picking up prior to 14 days	Could not reach patient after 3 messages left
PNA	5	5.2	4 patients wanted to speak to prescribing doctor first 1 patient had fear of side effects	0
Picked up after 1 or 2 calls	6	6.3	2 patients forgot 1 patient was out of the country 3 patients were not contacted	3
Picked up prior to 14 days—did not need a call by NP	84	88.4	N/A	0
Total	95	100		

Summary

Of the men and women in the study, 161 women (95.8%) picked up their medication within 60 days and all 48 men (100%) picked up their medication. The data analysis showed the Chi square statistic of 2.067 did not reach significance in men versus women who picked up their medication. The *p* value was .150519; thus, it was not significant at $p < .05$.

A total of 26 calls were made to 20 patients in the study; nine resulted in conversations with the NP and 17 resulted in a message left. Men were more adherent than were women in picking up after one message was left: 16 (80%) women vs 4 (20%) men in the adherent group. The PNA group consisted totally of women.

The current rate of 29.5% of PNA to bisphosphonate was decreased by 26.3% and the rate of PNA was reduced from 29.5% to 3.2%. This was a 26.4% absolute reduction and an 89.2% relative reduction. The goal of a 20% reduction was exceeded; thus, the two objectives of the study were met.

Figure 6 presents the results from the statistical analyses conducted on the above three categories.

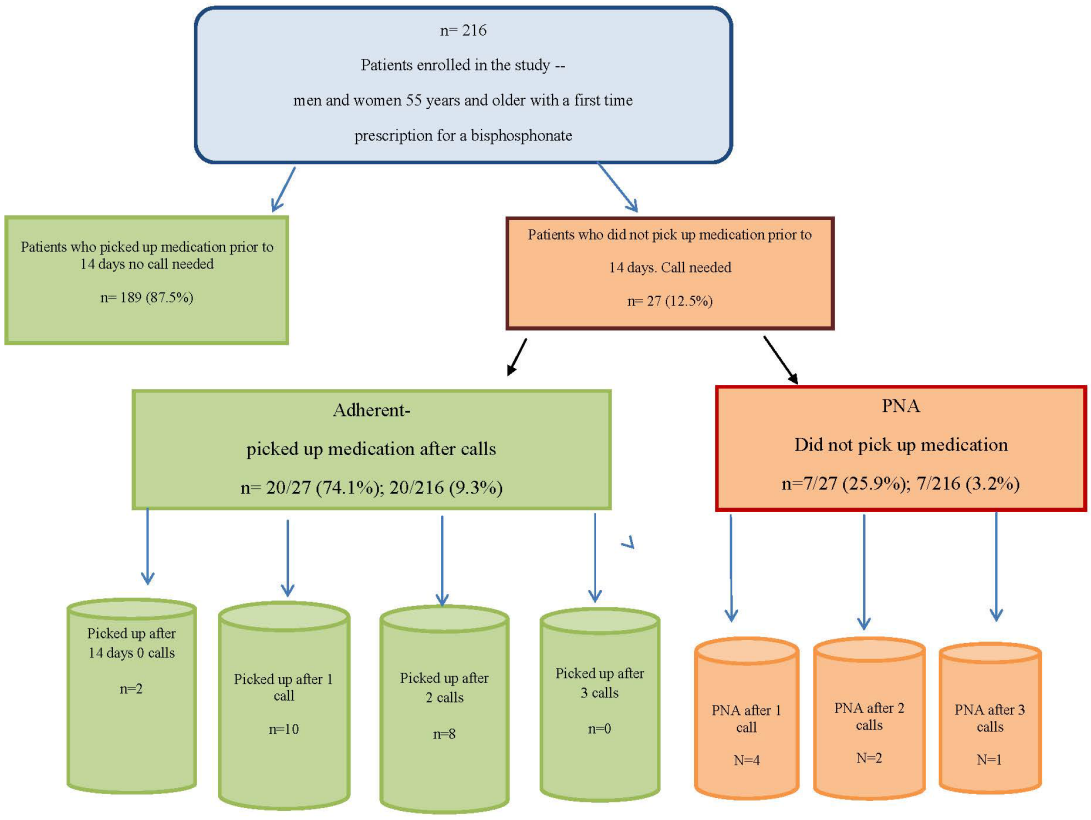

Figure 6. Results of telephone outreach protocol.

CHAPTER V

DISCUSSION

The goal of any disease management program is to prevent disease from worsening. The NP-led clinic in this study allowed for patients who had not picked up their bisphosphonate medication to be identified and tracked more easily than not having a dedicated person responsible for doing this. The results of this paper showed the objectives in this study were met. The objectives fit into three levels or categories of non-adherence: the systems level, the patient level, and the provider level. In addition, the following research question is discussed:

Q1 Will a telephone outreach protocol based on the theory of planned behavior (TPB) be effective in lowering the primary non-adherence rate (PNA) to bisphosphonate medication by 20% in a large Health Maintenance Organization (HMO)?

The ultimate goal of the program was to lower the PNA rate by targeting those patients who had not picked up their medication and by changing their behavior to develop an intention to pick up their medication. The evidence gathered showed the benefit gained by using the telephone outreach protocol to assist patients in being adherent in taking their medication. The study results in this paper showed success in decreasing the PNA rate from 29.5% to 3.2% when the NP used the protocol to facilitate patient adherence.

Systems Level

At the systems level in this study, a disease management program setting had the advantage over other settings because it used a dedicated NP and patients were identified by using the Knowledge Builder Tool (KBT). The KBT systematically identified non-adherent patients and sent the NP a list of patients who needed a phone call after 14 days of not picking up the bisphosphonate medication. The telephone outreach tool was used to implement the prevention intervention strategy to improve patient outcomes. A major component of the success of this program was it gave the NP the ability to monitor the treatment of patients using the computer system to follow up and track patient responses. Using the disease management program telephone outreach protocol allowed the NP to use a systematic approach when identifying and closing the care gap of PNA. The systematic approach utilized by the NP insured the intervention was performed uniformly with each patient receiving the same intervention.

However, it is unclear whether the success of the study was due to the protocol itself or the message having an effect on patient change in behavior. The integration of information in this system allowed the NP to focus on calling the patients since the computer conducted the case finding for her. She applied the protocol to patients who had not yet picked up their medication at 14, 28, and 45 days. Patients were considered to be PNA after day 60. If patients in the telephone outreach group did not answer when the NP called, she left a message to remind the patient to pick up their medication or to call the department if they had questions. Of the 27 patients in the telephone outreach group, 20 picked up their medication (74%) following a total of 26 reminder calls. The other seven patients went on to PNA (26%), yielding a PNA rate of 3.2% for all patients

in the study. Of the 26 reminder calls made, 17 resulted in messages left and nine calls ended in a conversation with the patient in which the protocol was applied. In the adherent group, 23% of the patients never spoke to the NP and had only messages left prior to picking up the medication. The messages left might have been be just as effective in achieving the desired change in behavior as the telephone call or the protocol. Limited data in this area preclude drawing conclusions and further study in this area is indicated. In the PNA group (7/27= 25.9%), 11 calls were made to seven patients resulting in six (55%) conversations with patients and five (45%) messages left. One person in the PNA group was not reached and three messages were left. For these patients, a message was not effective in changing behavior. In the PNA group, five of the seven (71%) received their prescription from a prescriber other than the NPCM and only two (29%) received their prescriptions from the NPCM. The differences between those who received the prescription from the NPCM and those who received it from another prescriber were not statistically significant. Comments made by the patients who answered that they refused to pick up the medication before making an appointment to speak with their prescribing doctor suggested clinical differences as they did not pick up the medication prior to 60 days of the prescription after speaking to the NP.

The findings suggested that had the NP been the prescribing clinician on the phone with the patient, these patients might have had their questions answered and might have been persuaded to pick up the medication. Having the prescribing NP call the patient might be effective as evidenced by four PNA patients' comments with prescriptions written by other than the NP coordinator. These patients stated they needed

to speak with the prescriber again to have questions answered and clarification of side effects before they decided to pick up the medication.

Provider Level

Overall, this study was successful--the rate of primary non-adherence (PNA) was lowered, indicating improvement in outcomes for patients. The provider NPCM played a large role in the success of this study. The rate of PNA went from 29.5% to 12.5% in the first two weeks of the study. After the first two weeks, a 14 day non-adherence that began at 87.5% improved to 96.8% by using the telephone outreach tool and leaving telephone messages reminding patients to pick up their bisphosphonate medication. The NP's behavior and communication with patients might have been impacted by the fact she knew she was being watched/studied (Hawthorne effect; McCambridge, Wilton, & Elbourne, 2014). This could have been a potential threat to the validity of the study.

Other departments were also aware the study was taking place in the program and prescribing patterns and PNA were being studied at that facility. The effect of the expectation of others on changing the NP's behavior as outlined in TPB could also have been impacted by the Hawthorne effect (McCambridge et al., 2014) and thus a threat to validity. Whether or not the patient's behavior was impacted by the Hawthorne effect should be considered as well. However, there were inefficient data to say this happened and should be investigated further to prove this theory. The patients were blinded to the study so the Hawthorne effect was not a factor in their decisions to change. Since the bisphosphonate was a normal part of their healthcare, they did not have to sign consents and were not told their behavior with regard to compliance was being tracked. However, the TPB may have had an effect on them--the telephone calls and messages made the

patients aware of an expectation of the organization was they would pick up their medication. Knowledge of this expectation could have affected them to develop an intention and carry out the behavior being asked of them.

The TPB states that someone's behavior might be changed when he/she knows a behavior is expected of them by others. The TPB was applied here with the protocol but might also apply in the cases where the NP did not ask the questions, i.e., the telephone messages left. In 50% of the patient responses in the PNA group, they indicated they had more questions. The telephone call served as a way for the NP to answer those questions. The NP's ability to alleviate patients' fear of side effects or answer questions about concerns could increase patients' feelings of confidence about taking the medication (social/normative). Additionally, the TPB states that people change their behavior based on having the belief they are doing the best thing for themselves. Believing one is doing the best thing for oneself, doing what is expected by others, and the perception of control to perform the action are three principles of TPB that must be present for behavior change to occur. The telephone call might serve as an impetus to having those three concepts present and assist with the behavior change in this way.

Table 5 showed that 8 (40%) of 20 patients who needed a telephone call had one or two messages left and then picked up the medication without speaking to the NP. This showed promise that a telephone message might be just as effective as a conversation in getting patients to pick up the medication. The message might serve as a reminder and the patient has no questions or reluctance to pick up the medication. However, in the cases of messages left, there was no patient feedback to be confident of the purpose the messages served. In other words, not enough data were available to determine how

effective a message was compared with a conversation using the protocol. Either way, the time to pick up the medication by patients was reduced after the phone calls were placed.

The results showed some kind of action was triggered after the call or message when previous to the call, there was no patient action. The average time to pick up the medication after the first phone call was 2.7 days; prior to the NP action, the patient had not picked up the medication after 14 days of the prescription being written. Just the call itself might have called upon the TPB--the patient, whether speaking to the NP or upon hearing the message, would realize the organization was expecting an action from him/her to pick up the medication. Since no data were collected on 17 (65%) of the calls resulting in messages left and 30% of those patients never actually spoke to the NP, there is no way to determine the degree of value the messages served when compared to actual phone conversations.

Patient Level

At the patient level, patients have a responsibility to take their medication and to work with their healthcare provider to meet their healthcare needs—in this case, lowering their PNA rate. Patient responses on telephone calls were recorded to know the reasons why the patients had not picked up their bisphosphonate medication. All of the patients who were PNA were women. This was shown to be statistically insignificant. Perhaps, it could be inferred that men might be at less risk for non-adherence when previously they were thought to be more non-adherent than women.

In this study, the patients participated by responding to the phone calls and answered questions why they had not picked up their medication prior to 14 days. In four

out of seven PNA patient responses to the NP on the phone, the patients stated they felt more comfortable talking to the person who prescribed the medication and they needed to talk to their doctor before deciding to pick up their medication because they had more questions. Since the patients stated they did not know the NP caller, they did not feel comfortable making a decision on the phone with her that day. Having the prescriber of the medication talk to the patients as follow up when they do not pick up their medication might be effective. If the caller and the prescriber were one and the same, this barrier to the patient picking up the medication could have been resolved with the phone call. This substantiated the argument that the program NP should write the prescriptions for a bisphosphonate as part of the program and then call patients who did not pick it up. If contact was not made, it was speculated that a telephone message might be just as effective as actually speaking with the patient. By responding to the calls, the patients assisted the study in meeting the goal of lowering the PNA rate.

A majority of the responses by patients were "I forgot" (50%); the telephone outreach calls might have served as a reminder that taking the medication was important to the care provider, which fits into the concept in the TPB. The telephone outreach call could prevent the need for an additional appointment, which could be translated into cost savings for the patient and the HMO organization. In the private sector, the fee-for-service period of the past is slowly being replaced global billing or one fee for a diagnosis for a set period of time. It would make sense to conserve face-to-face visits for patients who really need a visit that cannot be achieved by a phone call or virtual visit. Although billing and payment were outside of the scope of this study, the HMO does not collect any additional revenue for face-to-face visits that could easily be handled remotely.

Timetable to Completion

Enrollment began as soon as the University of Northern Colorado's Institutional Review Board (IRB) approval was obtained. Inclusion and exclusion criteria of enrolled patients was discussed and verified by the medical advisor that each person met criteria for inclusion/exclusion. The medical advisor and the team met with the Information Technology Department (IT) to have all patients assigned a unique identifying number so data presented to the student researcher were blinded from any identifying factors. The NP started to call patients who met the two week prescription date from November 24, 2014 and applied the protocol to patients meeting the incremental dates of not picking up their medication from the pharmacy at 14 days and beyond. Weekly meetings were conducted to troubleshoot and to monitor the course of the study.

Overall, the study flowed well according to the planned timeline. The enrollment and actual timeline of enrollment took one month; it was predicted to take two months. When the study began, the providers were prepared to write necessary prescription and knew that they were being studied. This might have had some effect on the faster rate of enrollment.

Work Flow Process/Project Activities

The workflow of the study involved the NP working within the disease management program. She was given a list of patients to call with a new prescription for a bisphosphonate and then she used the telephone outreach protocol to call the patients at varied increments of time. The NP was the key player in the success of this study. She had a physician supervisor and the ability to order a referral to endocrinology services or to her physician champion for patients needing a specialty consult. She was also the

primary person who collected the data for the study, which consisted of patient answers to questions from the telephone outreach protocol. The call, conversation with the patient, and messages left did not vary in the information provided by the NP and would have had the same effect on the outcome.

The NP believed she was familiar with the self-efficacy theory (SET) and the TPB and decided to study these theories on her own as she wanted this program to be a success. She volunteered to implement this protocol at her program site and had experience implementing other programs in the past. She was very confident that change was possible and believed this study would succeed as was stated by her at one of the meetings while the study was being planned.

The NP called the patient at various intervals of time pre-determined in the protocol. Using questions designed from the theory of planned behavior (TPB) and the domains of self-efficacy, the reasons for patient primary non adherence (PNA) and whether or not the patient changed his/her behavior and picked up his/her medication were recorded. The protocol targeted patients with primary non-adherence to their bisphosphonate medication; the goal was to use the protocol to change the patients' behavior to become adherent to the prescribed bisphosphonate. Although this was a new tool and was not validated or tested prior to this study, previously published validated data were used in developing the questions (Ajzen, 1991; Morisky et al., 2009). However, 17 of the calls in the adherent group ended up with a message being left 23% of the time; the patients did not actually speak to the NP and picked up the medication after having two messages left by the NP. This might have prompted the patients to pick up their medication because the call acted as a reminder, letting the patient know an

action was expected of them by their healthcare provider. An assumption could be if the doctor or other healthcare provider thought it was important enough to call several times, then it must be important and must be taken seriously by the patient. The concepts of TPB might be applied here even without the administration of the questions that state the person will change his/her behavior if the action (a) is believed to be beneficial, (b) behavior change is expected by others, and (c) the behavior is in the perceived control of the patient. All three of these concepts might have occurred purely by the patient receiving a call or a message. The expectation of a response by the patient was requested by the NP either during the telephone call or the telephone message that asked the patient to please pick up their medication prescription for a bisphosphonate from the pharmacy. The patients became aware this action was being monitored and was an expected and desired action by their doctor who was following up on this action.

According to Eisman et al. (2012), using a NP coordinator to make phone calls is a cost effective way to manage care gaps. As a normal part of her daily activities, the NP collected the data and communicated with the patients to get feedback that could be used to improve the goals. Since telephone outreach was already an existing work function for her, the study did not add more work for her. This study, as indicated by the program, sparked an interest in future research to evaluate whether or not a phone call might replace a clinic face-to-face visit to address PNA. Although no time and cost studies were done in this study, the NP was able to call patients on the phone and save the time and staff it would take to conduct an office visit. This might be both a time and cost effective way to close PNA care gaps and should be further investigated.

Implementation of the telephone outreach program based on TPB was discussed as a plan to be added to the organization's strategic goals and implemented organization wide given the favorable results of this study. However, in cases where the NP did not speak to the patient directly, no feedback was obtained about the patient's intention, leading to insufficient data to determine if the call or message were received by the patient in the manner intended or if the telephone outreach prompted a response by the patient. It was assumed some change occurred because 23% of the patients picked up the medication within 2.7 days after the call; whereas prior to the call, no action had been taken to pick up the medication greater than 14 days.

Recommendations and Implications for Practice

Primary non-adherence (PNA) has been discussed as being caused by failures at the patient, provider, or system levels. Literature (Kastner & Straus, 2012) has shown that successful disease management programs all incorporate the fracture liaison service (FLS) model of care, telephonic outreach, electronic medical record (EMR), and integrated pharmacy systems. To date, attempts have been made but no one has been able to integrate all needed components of this kind of program. This statement gave rise to the need for further work and research.

The literature has shown that patients with a first time prescription for a bisphosphonate were not picking up their medications. This problem sparked an interest to develop a system and protocol that could be applied to improve PNA. Evidence-based guidelines were ineffective unless they were implemented and then translated into practice. The implementation of an osteoporosis disease management program, especially if an electronic health record is used, could be an effective tool in lowering the

hip fracture rate. Through the use of clinical practice guidelines and a staff trained with TBP, acceptance and implementation of such systems could facilitate changing current provider behaviors. The literature did not clarify all factors concerning the reasons for PNA. Confusion and no standardization of terms and definitions made describing the problems and solutions difficult to compare between studies. This capstone project implemented this protocol for which outcomes were measured to determine its effectiveness in addressing the problem of medication adherence in patients with osteoporosis. Once this program standardization is established, other researchers can build upon it instead of recreating and applying new terms to what has already been established.

The study by Reynolds et al. (2013) was used as a motivator and gave credibility for the need to implement this program. As a result of this project and success of the program, the plan is to expand this program to all 13 medical centers in this organization and employ a NP-led clinic that could easily implement this protocol for patients who had not picked up their bisphosphonate medication. The computer system is connected to all sites, centralizing patient chart information; pharmacy data are also connected and easily tracked. An NP would follow the protocol with those patients who had not picked up their medication.

It is recommended that this protocol be adopted into practice and integrated into the organization's strategic plan. The philosophy of the organization is based on identifying and then preventing problems known as care gaps using a systems-based approach to close each care gap. The FLS program has various strategic goals to meet concerning medication adherence; finding a solution to the problem of PNA could

become an internal strategic goal of the organization. The NP at the facility would take a role in training NPs at the other 13 facilities where this protocol would be implemented.

Another recommendation would be to include having the disease management program NP work more closely with the pharmacy regarding patients who had not picked up their medications. Mail orders might be adopted in the future to send prescription medications to patients who are unable to drive to the pharmacy to assure that patients receive the medication. Additional action by pharmacists would help overcome at least one barrier to patients receiving their medication as they could encourage the patient to pick up all of their prescribed medications and send a note back to the prescriber letting them know when a patient has elected not to pick up all medications and when a medication has been unfilled for any prolonged period of time. This information could serve as a future recommendation to include the telephone outreach tool and the pharmacy to close the care gap of PNA.

Although this program was implemented in a closed system, where the patients were all members of the health plan and all used the organization's pharmacies, this type of program could be implemented in open systems as well. Within any organization, the computer system would be able to interface with all of the departments and the patient medical record could be received in real time. The HMO system exemplified in this organization might offer an advantage to private paying systems. However, it is possible to implement this in any system where a dedicated person such as an NP could identify, risk stratify, coordinate the care of the osteoporosis patient, and implement the telephone outreach program to track patient compliance. It is important that each program maintain

outcomes information about patients who pick up the medication versus patients who do not and then use quality measures to continue to improve upon the results.

The literature has shown it is necessary to use a systematic approach and a dedicated coordinator to close care gaps. It is very time consuming for an NP to search data to generate appointments for patient encounters or to conduct program outreach operations. Thus, the KBT could cut down tremendously on the amount of time needed to track patients. Thousands of records could be sifted by the computer and an updated list generated on a daily basis, thus allowing the NP to work the list, organize time, and set priorities more efficiently.

One recommendation for the future would be to automate calls. Call automation in this organization is currently being performed for other reminders such as scheduling appointments or diagnostic tests when it is not necessary to speak directly to the patient. Automated telephone calls to remind patients they should pick their medication could be made in the voice of the prescriber. By automating the calls, the NP's schedule could be freed up to coordinate patient care and follow up needed, further improving time efficiency and saving money by not paying an employee make the calls. The NP's time could also be utilized to answer calls from patients who have questions and have the machine take a message for patients wishing a return call from their providers. Further study should be conducted to assess cost effectiveness and cost savings gained from implementing this protocol, i.e., whether an automated call could be just as effective in lowering the incidence of PNA as the NP speaking directly to the patient.

Using an NP as a care coordinator could further the opportunity to meet fracture reduction goals and improve the rate of PNA. It would be interesting to repeat this study using more patients to see if differences noted were statistically significant.

In addition, it appeared that even without any action being taken, the PNA rate could be reduced by having a dedicated person write prescriptions, monitor patient activity in the program by making phone calls when necessary, and work a list provided by the computer. In this study, only 37 calls were made, which made a significant difference in the outcome when compared to what was happening before the outreach was implemented. On average, it took two calls to have a patient pick up their medication. These 37 calls were successful in motivating 20 people to pick up their medication. This left seven patients as PNA compared to the 64 patients (29.5%) seen as PNA prior to the reduction sparked by the outreach effort. In this study design, the threshold to meet the reduction goal of this study was set at 50 (20%) people in order to reduce the PNA rate and meet goals. Having as little as 50 people with PNA in this study, outcome would have acceptably met the objective of at least a 20% reduction in objective #2. Instead, this expectation was exceeded and only seven patients were PNA.

Barriers and Unintended Consequences

A few barriers and unintended consequences were encountered during the study. During the first week of the study, it was difficult to coordinate weekly meetings with the NP due to her availability but after that, a regularly established day of the week was scheduled without fail. This weekly meeting was essential to the success of the program because it clarified communication and kept the study on track. The communication went as planned as the study progressed. Another perceived barrier quickly overcome

was the NP reported she could not reach some patients on the phone so she left voicemail messages. This was accepted into the study and documented as an outcome. Although the patients still picked up the medication 2.7 days sooner than prior to the call as compared to 10-14 days with no activity, it is not known what the outcome would have been if the patients had been reached by the NP. Once the study organization was up to date on the timeline, the study actually flowed according to plan.

Several unintended consequences were encountered during the study. The first was not all patients picked up their medications from the medical center pharmacy to which they were assigned. For example, there were several instances when the patient, after having surgery for a hip fracture, stayed with family living in the area of another medical center--the prescription was at one facility but the prescription was picked up in another area, which delayed the patient from picking up the medication by a week or more. This situation did not meet the criterion of an outside pharmacy because it was still within the organization's pharmacy system and so was able to be tracked. This issue was not addressed in this study but will be added to future department meetings. There are plans for the pharmacy to be invited to a monthly meeting so possible solutions to this problem can be discussed and solutions provided. This was outside the scope of this project but will be included in the organization's strategic plan to improve the system and deal with pharmacy issues.

Another circumstance arose when a patient picked up the medication between 14 and 21 days and might have picked it up prior to receiving the first phone call. This patient was included in the call group but was also past the first two weeks by a couple of days and had not yet been called by the NP. Upon chart review, whether or not the

patient had received a call was clarified, was listed in the results in the call group as zero calls, and adherent past 14 days. If the patient had not received a call, it was noted that the patient was adherent upon his/her own accord and was not influenced by the call to pick up the medication. Two patients met these criteria--they decided to pick up the medication at 17 and 18 days. Although they were on the call list to be called by the NP, the NP had not yet called them and they picked up the medication without needing a call. This could be solved by establishing a more uniformly and systematic method of implementing timely phones calls.

Still another unforeseen circumstance came when the patients went to the pharmacy on the day the prescription was written and were told by the pharmacy to come back another day because the medication was not in stock, back ordered, or the line was too long and the patient could not wait. Some patients stated they were not able to return the next day, thus delaying them in getting a ride back to the pharmacy on another day to pick up the medication if they did not drive. This situation was discussed with the pharmacy director and the pharmacy has now started a mail order program and is keeping a larger shelf stock of this particular medication to avoid these problems from re-occurring in the future.

Lastly, the actual rate of PNA had dropped to 12.5% instead of the 29.5% prior to any intervention beginning. This change might possibly be due the organization knowing there was a problem. After the NP and the organization were aware they were being studied, the Hawthorne effect (McCambridege et al., 2014) might have played a role here as well.

Framework of the Organization's Strategic Plan

The contribution of this PNA project was improvement in the overall rate of PNA in patients with a prescription for a bisphosphonate organization-wide. This protocol implementation improved the quality of care being delivered and might have saved money. The outcomes of this study have shown the importance of increasing the patient's involvement as a team member in this process. Obtaining their feedback was invaluable in closing the gap and improving systems to meet organizational goals. Communication between the patient and the provider can continue to be improved and the communication path should begin as early as the day the prescription was written. A verbal contract prior to the prescription being written and verbal acknowledgement that the patient accepts the prescription being written and is aware of it being sent to the pharmacy are important steps that should be added to every patient encounter. The patient must be informed early in the process so he/she can be prepared for what is expected of him/her. Secondly, a component that should be added is more DXA scan orders and more diagnoses of osteoporosis or low bone mass so patients can be risk stratified and counselled. This process of risk stratification could spark a communication between the provider and the patient and stress the importance of taking the prescribed medication. These are teaching moments, especially if the patient has already suffered a fracture and been told how a second fracture could be prevented. Enhanced communication and acceptance of the protocol or achieving "buy in" from the patient could surely improve patient adherence to his/her prescribed medications.

This telephone protocol worked well within the organization's strategic plan because it used a protocol telephone outreach that was simple and easy to implement.

This was evidenced by having only one NP manage calls within the program. Human interaction might be potentially replaced by a computer to call and leave automated messages. Since many of the patients in the study picked up the medication after receiving only a message, it might still be effective to leave an automated message. Patients who wish to speak to a person can opt to leave a message to have someone return their call.

The telephone outreach approach to closing a PNA care gap could cut down on the amount of time and staff needed to add face-to-face visits that could be replaced by a phone call. The telephone encounter was believed to lead to cost savings because it was carried out by a single NP and used minimal staff time. Although, the actual amount of time or cost savings was not measured, this needs further study. The results of this study suggested a telephone message might be just as effective as a telephone conversation as the average amount of time needed to pick up medication after a telephone call was 2.5 days. Twenty-seven out of 216 patients needed one or more calls. Many of the 20 adherent patients picked up their medication after receiving only a reminder message. Using a computer instead of a staff person for reminder calls could results in cost savings provided it was effective. A telephone call could replace clinic time to answer questions or to follow up on monitoring care or treatments. Since telephone outreach is already a function of the NP's normal duties as a care manager, this protocol could be easily worked into the daily activities of a disease management program coordinator's duties. This work as done by NP care managers or possibly a computer could easily be assimilated into any chronic disease management program to improve outcomes.

Results not having statistical significance in this study were shown to have clinical significance and vice versa. For example, two patients picked up the medication prior to receiving a call. This result had no clinical significance because although they were not influenced by the call, they went past 14 days and so they were counted in the call group. Therefore, although they appeared to be PNA, they actually had intention of picking up the medication and did so without the need for coaching by the NP.

In this study, the NP answered the same on the questionnaire before and after the implementation of the study. There might have been more opportunity to focus on how the NP could have augmented conversations with patients to use the TPB more effectively as it was intended to change patient behavior.

Contribution of the Project to the Attainment of Personal Leadership Goals

This project was a very important research study in the attainment of the researcher's personal goals. This project addressed an interest in practicing in the area of population disease management, identifying care gaps, and then working to develop clinical practice guidelines to close those care gaps. Primary non- adherence (PNA) in the field of osteoporosis disease management is a huge problem that has prevented the program from attaining its goals and improving patient outcomes. The study results showed this telephone outreach program worked in one system might also be implemented in other programs with high non adherence rates. Chronic diseases such as diabetes and hypertension have no symptoms until the diseases have progressed to dangerous levels. Patients with asymptomatic chronic diseases such as osteoporosis have a high risk of PNA. Until the fracture event occurs, many patients do not understand the

importance of prevention. Medication in this case could prevent fracture from occurring 50% of the time.

Disease management programs rely heavily on patients taking their medication in order to prevent the progression of their disease but to date no interventions have monitored whether or not patients were actually picking up their medication from the pharmacy and taking it as prescribed. It is extremely rewarding as a healthcare provider to see patients getting better and to prevent the progression of disease, morbidity, and mortality. If outcomes in disease management are to be improved, it is important to understand the patient from his/her viewpoint and include them as a member of the healthcare team. This study and protocol were intended to include the patient as a team member and to use communication and feedback to find out the reasons patients did not take their medication and then intervene appropriately. Historically, this happened 30% of the time; now it has been shown to be less than 5% and hopefully in the future, it can be reduced to zero.

How the Project Compares to the Solution

The study goals/objectives were reached as expected quite expediently once the NP had a protocol and understood the task at hand. The patients who were contacted were very cooperative. Only a small amount of patients could not be reached or continued to choose non-adherence despite the multiple attempts by the NP to talk to them. The project appeared to fit the solution needed. This was evidenced by the significant decrease in the PNA rate reported. There was an 89.2% decrease in relative reduction in PNA from the historic PNA rate and the current rate retrieved from the

study. The chi square for the significance of this occurrence was $p < .0001$, which means the reduction seen in this study could not have been by chance.

Summary

It has been two years since the Reynolds et al. (2013) article was published and the implementation of the telephone outreach solution tool. Acknowledging a problem and implementing a protocol as a different way of talking to patients or prescribing might have led to an unconscious improvement in the rate of PNA prior to the study because the staff knew what was expected of them and the NP knew her actions were being monitored. This was reflected in the NP questionnaire when she received the same score on both pre- and post-tests, showing she already had a strong belief in PNA and the implementation of the study. Her beliefs did not change or improve after the implantation of the study and remained strong and in full support throughout.

The literature has shown that having a dedicated NP coordinator could reduce the hip fracture rate and improve outcomes. Using a telephone outreach program, patient and provider communication would be enhanced and this could translate into better medication adherence. Waalen et al. (2009) indicated an FLS program using a telephone outreach protocol to improve medication adherence was slightly better than the general population. Furthermore, Eisman et al. (2012) determined that having a dedicated coordinator communicate and coordinate fracture care and treatment translated to cost savings. A telephone outreach might augment an existing the FLS program to improve adherence to bisphosphonate medication and enhance communication essential to improved adherence. This study documented a problem of PNA and used an FLS program NP and a systems-based approach to close the care gap. It is hoped this study

could be conducted on a larger scale to further investigate this aspect of the FLS program, determine the benefits of implementing a telephone outreach protocol based on the theoretical principle of self-efficacy and TPB, and see whether medication adherence would improve outcomes and save time and money. Additionally, an automated telephone outreach systems could free up the coordinator's time even further to effectively automate calls to remind patients and let them know an action to pick up their medication from the pharmacy was expected, thereby increasing opportunities to improve care through better communication and monitoring of treatment modalities.

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APPENDIX A

UNIVERSITY OF NORTHERN COLORADO
INSTITUTIONAL REVIEW BOARD
APPROVAL

UNIVERSITY of NORTHERN COLORADO

Institutional Review Board

DATE:	December 8, 2014
TO:	Denise Greene, MSN, FNP-C
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[661082-4] Addressing Adherence to Bisphosphonate Medication Using a Systems-Based Approach
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	December 8, 2014

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

Hello Denise,

Thanks for the modifications requested. You are approved and good luck with your study.
incerely,

Nancy White, PhD, IRB Co-Chair

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX B

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

UNIVERSITY of NORTHERN COLORADO

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Addressing Adherence to Bisphosphonate Medication Using a Systems – based Approach
Researchers: Denise Greene, NP, Gloria Dominguez NP, Richard Dell MD
Phone: 323-376-9418 denisgreene10@gmail.com; Richard.M.Dell@kp.org
Contact person for concerns about treatment of research subjects or selection process
Please contact Sherry May IRB Administrator Office of Sponsored Programs
Kepper Hall University of Northern Colorado
Sherry.May@unco.edu 970-351-1910

Purpose and Description of project: The primary purpose of this study is to determine the effectiveness of using a systems-based approach and a telephone outreach questionnaire to improve patient non adherence to bisphosphonate medication.

It is a population based study that will involve having a Nurse Practitioner call patients who have not picked up their bisphosphonate medication from the pharmacy within 60 days of the prescription.
Risks are minimal and may involve minor annoyance or feeling anxious to have to talk on the phone with your healthcare provider about the prescription bisphosphonate medication that has been written for you and that you have not picked up. Additional benefit to you is that you will receive information and access to have questions answered that will help to decrease your fracture risk. You will gain the benefit of the medication should you decide to pick it up from the pharmacy and the questionnaire may act as a reminder to you to do so, in case you may have forgotten to pick it up. You will have the opportunity to ask questions and have extra access to your health care provider to have any questions answered completely.

Participation in this phone call is voluntary. You have the right to refuse to participate. Your decision will be respected. No consequence will come to you should you decide to not engage in this call. All information given is kept confidential. Answering these questions will be consent for your participation in this telephone outreach call. Do you give me consent to ask you the following questions about your prescription medication?

I _____am giving consent to participate in this research study. I will be following and maintain all rules of confidentiality and protection of human rights as I understand according to HIPAA and the policy and procedure manual of my

organization. I understand that participation is voluntary and I can withdraw at any time. I agree that I will not share any information about this study outside of the organization and outside of the communication with the researchers directly involved. I can retain a copy of this consent for my own records. I have been given an opportunity to ask questions. I have the contact information of my co- researchers available to me and I know that I am free to contact them at any time.

Should you have any additional concerns about the treatment or selection of patients for this study please contact: Sherry May IRB coordinator at the University of Northern Colorado Office of Sponsored Programs- Kepner Hall, Greeley Colorado 80638 tel: (970)351-1910

Signature_____

Date_____

APPENDIX C

INSTITUTIONAL REVIEW BOARD APPROVAL FOR KAISER PERMANENTE

KAISER PERMANENTE®

Approval Notice

Institutional Review Board
Kaiser Permanente Southern California

July 18, 2014

KPSC Principal Investigator(s)
Richard M Dell, MD, KPSC - Orthopedics
9353 E. Imperial Hwy, Downey, CA 90242

KPSC Co-Investigator(s)
Annette L Adams, Denise F Greene, Ronald A Navarro, MD

Non-KPSC Co-Investigator(s)
Ajay Gurbani, Christopher Grimsrud, MD, Daniel Tran, Eric Eisemon, Joan Lo, MD, Sanjay Menon, Stephanie Eischen-Lee, Stuart L Silverman, Susan Ott

Study Title: Assessing the Effectiveness of the Kaiser Osteoporosis Disease Management Program (#4000)

On **07/18/2014**, a sub-committee of the Kaiser Permanente Southern California (KPSC) Institutional Review Board (IRB) reviewed and approved the following modification(s) submitted for this study:

- To expand on the Healthy Bones program to capture primary patient non -compliance with bisphosphonate therapy
- The title of the new modification will be : "Addressing Adherence to Bisphosphonate Medication Using a Systems-Based Approach".

Sincerely,

Signature applied by Armida Ayala on
07/18/2014 9:21:12 AM PDT

Armida Ayala, MHA, PhD
Director
Human Research Subjects Protection Office
Institutional Review Board

Cc:
Area Research Chairperson
Pharmacy Services Director

APPENDIX D

MEMORANDUM OF UNDERSTANDING

Statement of Mutual Agreement
University of Northern Colorado
Doctorate of Nursing Practice Capstone Project
Denise Greene
August 5, 2014

The purpose of the "Statement of Mutual Agreement" is the shared vision between Denise Greene and the Kaiser Permanente Healthy Bones Program to improve the care and outcomes of patients in the Healthy Bones Program. The vision is to use the program protocol and technology to improve the rate of patients to pick up their prescribed bisphosphonate medications from the pharmacy.

Proposed Project Title:
Addressing Adherence to Bisphosphonate Medication Using a Systems-Based Approach

Brief Description of Proposed Project:

Implementing a protocol and a systems-based approach to improve patient adherence to first time prescription to a bisphosphonate medication. The protocol uses the theoretical framework of the Theory of Planned Behavior (TPB) and telephone outreach by a nurse practitioner.

Goal of Capstone Project :

The goal of the project is to improve primary adherence of patients who have been prescribed a bisphosphonate medication by 20% within 60 days of the date of the prescription.

Proposed On-site Activities:

The Healthy Bones Care Manager Nurse Practitioner (NP) will work within the existing program to screen patients with a protocol and telephone outreach program to lower the current rate of primary non adherence to a bisphosphonate. The program is designed to facilitate a change in patient intention and behavior using a theoretical framework and a systems based approach. The patients will pick up their bisphosphonate medications from the pharmacy.

Confidentiality of Patient Records: (If applicable)

Confidentiality of patient records will be maintained using internal Kaiser Permanente Healthy Bones Program policies and HIPAA.

The designated Capstone Community/Agency member will agree to participate in the review and approval of the proposal and presentation of the final version of the project.

He/she will attend both on campus or remotely. The student researcher will have no contact with patients.

The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

Denise Greene_____August 3, 2014
Signature of Student Date

____λ_____8-5-14
Signature of Agency Member Date

____*Yvonne Yousey , RN, PhD.*_____8-9-2014
Signature of Capstone Chair Date

APPENDIX E

NURSE PRACTITIONER QUESTIONNAIRE

The purpose of this questionnaire is to elicit feedback from the NP regarding her understanding that there is a problem of PNA before and after her in-service and to gauge her beliefs of the possibility of arriving at a solution to PNA by using the protocol. You are being asked to rank your responses on a scale of 1-6 of your beliefs before and after the study. Please circle your response and sign the bottom.

1. How much of a problem do you believe PNA poses in your patient population?

   Please circle 1--no relationship to 6--extreme positive relationship

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

2. Do you believe you can play a role to improve the rate of PNA using the protocol?

   Please circle 1--no relationship to 6--extreme positive relationship

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

3. How important of a role does patient input play in the process of improving PNA?

   Please circle 1--no relationship to 6--extreme positive relationship

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

4. Do you believe you understand what is PNA?

   Please circle 1--no relationship to 6--extreme positive relationship

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

Normative/Subjective Belief

An individual's perception about the particular behavior is influenced somewhat by the judgment of significant others. The individual NP's perception of social normative pressures and relevant others' beliefs that he or she should or should not perform such behavior. In this case normative behavior will be affected by what the NP believes her peers will think of her and what is in her scope as an NP. Behavior that is influenced by the judgment of significant others or others with influence or others such as managers. Such as in this case, the NP is influenced by the telephone protocol steps and the desires of her manager to implement the protocol.

5. What are your beliefs about your normative/subjective belief in this study? Please rank that you are influenced by what is expected of you by others.

   Please circle 1 = no influence to 6 = extreme influence

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

Control Beliefs /Perceived Behavioral Control

An individual's perceived ease or difficulty of performing the particular behavior (Ajzen, 1991). It is assumed that perceived behavioral control is determined by the total set of accessible control beliefs. In this case, the NP needs to believe she has control of the environment and will positively influence each individual patient with whom she interacts.

6. What are your beliefs about your behavioral control beliefs in this study?

Please circle 1 = no influence to 6 = extreme influence

Before	1	2	3	4	5	6
After	1	2	3	4	5	6

Below is an evaluation checklist to be done by the DNP student for each patient enrolled in the study and contacted by the NP.

NP Evaluation Checklist

NP Evaluation form date	14 days	30 days	45 days	60 days	Comments
Provider--who wrote the prescription					
Name of patient					
Medical Record #					
Comments made by Care Manager					
Sex					
Age					
Medication					
Date Ordered					
Last DXA					
Tscore					
Hx AFF (Exclude if yes)					
Last FX					
Last FX Date					
LTC/SNF/Hospice (Exclude if yes)					
Allergy (Exclude if allergy BP)					
Last CKD (Exclude if CKD 4,5 or Dialysis)					
Last CKD Date					
Dx Exclusion					
Dx ExclusionDate					
Reclast Date (Exclude if last Reclast within 1 year)					
Home Phone					
Work Phone					
Med Center					
Meds written to pick up outside Kaiser - excluded					

Patient Evaluation of Responses During Telephone Outreach

Question	Domain of Adherence	Theory of Planned Behavior	Patient Responses
The system shows that you have not picked up your anti-osteoporosis medication from the pharmacy. Are you aware of this prescription?	Knowledge		Yes/no
Is there a reason you did not pick up the medication?	Attitude		Yes/no If yes state reason
Do you believe that you need this medication?	Attitude		Yes/no
Are you satisfied with your doctor visit experience and the instructions given to you about the medication?	Satisfaction, knowledge	Social	Yes/no
Do you have family and other support to help you with bone health issues?	Social support	Social	Yes/no
Taking medications regularly is a hassle to some people. Do you feel that taking your medication is too inconvenient or too complex?	Medication complexity	Subjective	Yes/ no
Do you have concerns such as fear of taking this specific medication? If yes state the fear.	Stress	Perceived Control	Yes/no
Do you sometimes feel like you don't want to take your medication because you don't believe that you	Coping	Subjective	Yes/ no
Do you plan to pick up the within the next week?	Developing intention	Control	Yes/no
Was this call instrumental in helping you to decide to pick up your medication?	Developing intention		Yes/no
Was this call helpful in answering all of your questions?	Developing intention		Yes/no

APPENDIX F

TELEPHONE OUTREACH PROTOCOL

Telephone Outreach Protocol

Do you give me consent to ask you questions about your prescription medication?

Questions	**Yes/No**
1).The system shows that you have not picked up your anti-osteoporosis medication from the pharmacy. Are you aware of this prescription? Level of intention to pick up	
2)Is there a reason that you did not pick up the medication? State the reason	
3) Do you believe that you need this medication?	
4).Are you satisfied with your doctor visit experience and instructions given to you about the medication	
5Do you have family or other support to help you with bone health issues?	
6) Taking medications regularly is a hassle to some people. Do you feel that taking medication is too inconvenient or complex?	
7) Do you have concerns such as fear of taking this specific medication?	
8) Do you sometimes feel like you don't want to take your medication because you don't believe you need it?	
9). Do you plan to pick up the medication within the next week?	
10). Was this call instrumental in helping you to develop a new intention to pick up the medication?	
11). Was this call helpful in answering all of your questions?	

APPENDIX G

LETTER TO PATIENT AND PROVIDER

Dear Ms. Test Patient,

This past week you were diagnosed with osteoporosis, which means you are at an increased risk for having a fracture or broken bone with a simple fall or minor accident. As I reviewed your health records, I noticed you have not filled your prescription to treat your osteoporosis with Alendronate. This medication reverses bone loss, strengthens bones, and prevents fractures and is usually taken for at least five years.

Please fill this prescription as soon as possible. When your prescription runs out, you may request a refill by calling the pharmacy. If you have any concerns regarding treatment with this medication or if you have any questions regarding your osteoporosis, please do not hesitate to call me.

Sincerely,

Healthy Bones Team NP Care Manager

APPENDIX H

PATIENT INTAKE AND PATIENT RESPONSE FORMS

NP Intake Form/Patient Feedback

Patient Identifying Number_____

MR#_____

Date of Rx_____

Date of call_____

Sequence in the process/protocol of calls :
Circle one :

14 day,
30 day,
45 day,

60+ days since patient has picked up medication

Did call go to voicemail? Y / N
Left message to call back Y / N

Patient Reason for not picking up the medication_____
_____
_____

Plan for follow up: _____

Summary of Patient Responses

Patient Population	**Adherent %**	**PNA%**	**Pvalue=**
N=216	N=	N=	
Independent variable	**Number Adherent**	**Number PNA**	**Pvalue=**
Age			
55-64			
65-74			
75-84			
85+			
Sex=Men			
Sex= Women			
Characteristics of Prescriber			
NP			
MD			
Other			