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Determining the Effects of Vitamin D Levels On Osteoporosis and Osteopenia

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Loretto Heights School of Nursing
Doctor of Nursing Practice Capstone Project

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Determining the Effects of Vitamin D Levels on Osteoporosis and Osteopenia

Summer Yvonne Tilgner

Submitted as partial fulfillment for the Doctor of Nursing Practice Degree

Regis University

August 28, 2014

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The Effects of Vitamin D levels on Osteoporosis and Osteopenia

Executive Summary

Problem

Vitamin D deficiency is a concern, not only in the United States, but worldwide. Identifying a correlation for osteoporosis and osteopenia in vitamin D deficient patients may reduce the risk of osteoporosis-related fractures. The PICO question for this capstone project was: In osteoporotic or osteopenic patients, what is the relationship between reduced serum levels of vitamin D OH 25 compared to normal serum levels of vitamin D OH 25, in the incidence of osteoporosis or osteopenia? Osteoporosis contributes to fracture risk in patients, which subsequently has been shown to result from an insufficient level of vitamin D.

Purpose

The purpose of the project was to evaluate the relationship between osteoporosis and osteopenia and Vitamin D OH 25 levels.

Goals and Objectives

The goal of this study was to determine if a relationship existed between vitamin D deficiency and osteoporosis or osteopenia and note its clinical significance. Identifying a correlation between these factors may help to raise awareness of the need for testing of vitamin D levels in the investigator's practice and the community she serves.

Plan

The potential correlation between vitamin D and osteoporosis and osteopenia was identified and outlined. The project was implemented using PICO analysis at the doctorate level. This quality improvement (QI) project utilized a quantitative retrospective study design involving 91 patients. Outcome data was compared utilizing patients who had previously undergone a bone density test using a DEXA scan and also had Vitamin D OH 25 laboratory testing over the previous three-year period. The main outcome that was measured was the number of patients diagnosed with osteoporosis or osteopenia and the laboratory blood level value of vitamin D OH 25. Other variables included DEXA scan results, vitamin D OH 25 lab results, gender, age, steroid use history, and exercise history. Using one-way ANOVA testing, the study identified four groups; once this was completed, multiple regression was used to analyze the variables involved.

Outcomes and Measures

The study consisted of 12 men and 79 women. 39% of patients had both osteoporosis or osteopenia and vitamin D deficiency, 36% of patients had osteoporosis or osteopenia and did not have vitamin D deficiency, 5% of patients had normal bone and were vitamin D deficient and 20% of patients had normal bone and normal vitamin D results. Results of the one-way ANOVA test showed a significance of $p=0.026$ for vitamin D when compared to the control group diagnosis. The results of this analysis show that vitamin D deficiency is a statistically significant factor in osteoporosis and osteopenia. The factor of vitamin D deficiency had a higher statistical significance than exercise history, steroid use, gender, and age.

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Problem Recognition and Definition

Statement of Purpose

The purpose of this capstone project was to identify a statistical significance between osteoporosis and osteopenia in the context of vitamin D deficiency and provide evidence that vitamin D deficiency contributes to osteoporosis and osteopenia. The knowledge gained from this project will hopefully raise provider awareness of the importance of detecting vitamin D deficiency and the relationship with osteoporosis and osteopenia in their patients. Raising awareness and incorporating treatment into practice may subsequently reduce the risk of osteoporosis-related fractures and hospitalizations. Patients who had undergone bone density testing using a dual energy x-ray absorptiometry (DEXA) scan and had a vitamin D OH 25 blood test drawn over the previous three-year period were identified in this capstone project. Patients were also required to have documented levels of exercise and steroid history to be included in the study. Steroid history use included patients taking prednisone or other steroid medications equivalent to 30 milligrams per day or greater over the previous six-month period or longer. The levels of vitamin D and DEXA scan results were recorded to determine the relationship between vitamin D OH 25 levels and osteoporosis or osteopenia. A quantitative retrospective study design was used to include all patients meeting the above mentioned criteria over the previous three-year period. Establishing a correlation between vitamin D and osteoporosis or osteopenia may contribute to the improved treatment of patients and would be considered primary preventative medicine.

Problem Statement

Vitamin D deficiency is a concern, not only in the United States, but worldwide. At the investigator's primary practice in the southwestern United States (US), the providers had

noticed an increase in the incidence of osteoporosis that went undiagnosed. The incidence of vitamin D deficiency in patients had also been acknowledged as a problem by the providers in this practice over the past few years. The primary investigator had been cognizant of the incidence of vitamin D deficiency and a possible correlation to osteoporosis and osteopenia. Osteoporosis and osteopenia may result in weakened bone and fractures affecting the wrist, hip, and vertebrae (Lowe & Friedlaender, 2013).

Several studies have demonstrated the significance of vitamin D deficiencies related to fractures and osteoporosis (Geriatrics Society Guidelines, 2014 and Johnson, Smith, Smith, & Sanzone, 2008). A growing concern in the US is the incidence of hip fractures and periprosthetic fractures in the elderly and the vitamin D deficient (Leyland, 2013).

Periprosthetic fractures occur during or after joint replacements or fracture repairs. As a result, periprosthetic fractures may result in prolonged healing times. Hip fracture patients are almost universally deficient in vitamin D (Hairon, 2005). Hip fractures and periprosthetic fractures may result in increased morbidity, longer recovery periods, increased health care costs, and post-operative complications (Leyland, 2009). Analysis of population data shows that patients with a diagnosis of osteoporosis and osteopenia are at a higher risk for fractures.

Previous studies were used for comparison with similar data conducted on patients with osteoporosis and osteopenia and vitamin supplementation. Meek, Norwood, Smith, Brenkel & Howie (2011) identified patients studied over a ten-year period and evaluated approximately 1000 patients yearly; on average, 10-15% of patients (mostly female) were positive for fractures. Another study showed fractures averaged between 0.3%-4.2% in patients with osteoporosis and osteopenia (Boulton & Rodriguez, 2009).

Vitamin D is important to bone health due to its ability to help regulate parathyroid hormone, which then helps to regulate bone loss. Vitamin D also contributes to stimulating intestinal and renal calcium absorption (Lowe & Friedlaender, 2013). Therefore, preventative medicine plays an integral part in reducing health care costs (Terry, 2011) by lowering the risk of complications and hospital stays resulting from osteoporosis.

PICO Question

This capstone project was an evidence-based practice (EBP) project in which a quality improvement plan, program evaluation, educational, or standard of care intervention was completed. In most cases, a pre-test and post-test evaluation will assess the effect of the intervention. The project was internal to an agency and informed the agency of issues regarding health care quality, cost, and patient satisfaction. The results of this project were not meant to generate new knowledge or be generalizable across settings, but rather seek to address a specific population, at a specific time, in a specific agency. These projects translate and apply the science of nursing to the greater health care field.

Projects utilize the acronym “PICO”, rather than stating a formal research hypothesis. The acronym stands for: Population or Disease (P), Intervention or Issue of Interest (I), Comparison Group or Current Practice (C), and Outcome (O), and is usually framed as a question (Melnik & Fineout-Overholt, 2011).

The PICO question for this capstone project was: In osteoporotic or osteopenic patients, what is the relationship between reduced serum levels of vitamin D OH 25 compared to normal serum levels of vitamin D OH 25, in the incidence of osteoporosis or osteopenia? (Melnik & Fineout-Overholt, 2011). The original goal was to analyze data for up to 200 patients throughout the six-month study period. The population sample for this capstone

project consisted of 91 patients. Since this was a retrospective study, patients were not asked to undergo testing for the purpose of this study. Data extracted for the use of this study was existing data in patients previously screened with a DEXA scan and vitamin D OH 25 blood testing. If these two tests had not been completed previously, the patient was excluded from the study. Other variables were also included in this project and patients were required to have the following inclusion criteria documented in their charts: age, gender, exercise history, and steroid use history.

Project Significance, Scope, and Rationale

According to Steven (2012), the incidence of periprosthetic fractures occurring intra-operatively and post-operatively is 1.5-4% in the US. Another study by McGraw, Spence, Baird, Eckhardt & Ayana (2013) documented the incidence of periprosthetic fracture after hip arthroplasty to be 4%. Patients commonly have documented low vitamin D OH 25 levels associated with a diagnosis of osteoporosis or osteopenia. Two orthopedic surgeons at the primary investigator's practice have documented the incidence of osteoporosis in hip fracture patients, and often recommend a different treatment plan for those patients, such as non-weight bearing on the affected limb and delays in physical therapy with immobilization. This altered treatment plan affects the patient's recovery time and could all be prevented with a recent diagnosis of vitamin D deficiency or osteoporosis and proper supplementation.

Osteoporosis contributes to an increased fracture risk in patients, which may be the result of an insufficiency in vitamin D. Bogunovic, Kim, Beamer, Nguyen & Lane (2010) documented that all patients with fractures should be assessed for vitamin D 25 (OH), pointing out the importance of better management of hypovitaminosis to prevent fractures. Multiple studies have been performed showing fracture risk in osteoporosis (Geriatrics

Society Guidelines, 2014; Johnson, 2008; Lawrence, 2008); however, limited studies show evidence of research on vitamin D insufficiency and deficiency in these same patients.

According to Bahlous, Farjallah, Bouzid, Klouz, Mohsni, Sahli, Lakhal, Sallami & Abdelmoula (2009), 45.2% of women tested in their study were found to be vitamin D deficient or insufficient.

In a study conducted by Gallacher as reported by Hairon (2005), study leader Dr. Stephen Gallacher found that vitamin D inadequacy was a significantly correctable risk factor for fragility fractures.

Meek, Norwood, Smith, Brenkel & Howie (2011) reported that the incidence of periprosthetic fracture after knee arthroplasty is 0.6-2.5% and 4% after revision arthroplasty. The incidence of periprosthetic fracture after hip arthroplasty was higher, at 1.1% and 4% after revision arthroplasty (Meek et al, 2011). The article also documented that periprosthetic fracture after total hip and knee arthroplasty may be the second leading cause of revision after aseptic loosening. It can be assumed that an overall reduction of hospitalizations from periprosthetic fractures and total revision arthroplasty will reduce the risk of secondary complications, such as pneumonia, stroke, cardiac events, and deep vein thrombosis. Reducing the risk of hospitalization will reduce overall healthcare costs.

Theoretical Foundations

The Community Nursing Practice Model and Betty Neuman's System Model were analyzed for their appropriateness and were deemed applicable to this capstone project. The Community Nursing Practice Model is based upon the following concepts: respect for the person, people are caring, people are whole, and always connected to each other, their families and their community (Barry, Gordon & Lange, 2007). The basis of the Community

Nursing Practice Model is formed by values and provides grounding for primary care patients. The patient is identified as an entirety, not simply a diagnosis or a problem. The Community Nursing Practice Model identifies factors such as respect, caring, and wholeness of the patient (Barry et al, 2007). Patients are encouraged to interact and participate in their diagnosis and care plan. The Community Nursing Practice Model identifies values affecting primary care, such as access, empowerment, and community participation. Health care is easily accessible and allows interaction and community education, as well as individual patient education.

Empowerment through education and support gives patients a sense of responsibility for their own health and well-being, assuming patients are responsible for their medical treatment and empowering themselves through education. If patients understand why they are being treated, the disease course of action, prevention, and community support, then they are better able to function independently and contribute to their own treatment and well-being. Patients will likely be proactive in primary preventative medicine by reducing their fracture risk through the use of vitamin D therapy in conjunction with bone density testing. When compared to the consequences of a hip or wrist fracture, this concept is simple. If the Community Practice model is applied, a reduction in comorbidities could be expected, as well as a potential for a decrease in hospital stays. A decreased number of hip fractures and periprosthetic fractures could also be predicted.

Betty Neuman's model focuses on patient care and treating the whole person, not simply treating the diagnosis. Providers can sometimes be guilty of treating a diagnosis instead of the patient. Neuman's theory allows treatment in its entirety, as well as the health and welfare of the patient. This model focuses on external environmental factors playing a large part in the treatment and response of the patient (Ross & Bourbannais,

1985). Neuman's model is considered multidisciplinary and universal. The model can be applied to a multitude of different situations affecting health care, and can be applied to research, education, and nursing practice (Ross & Bourbannais, 1985).

Neuman's model allows for change in the future and emerging health care trends, such as the Affordable Care Act and state-run medical care. Individuals are assessed and the nursing theory is used to identify stress, relationships, and their application to patients (Ross & Bourbannais, 1985). The core of Neuman's model consists of energy resources such as body temperature, genetics, weakness, ego, and response. Patients are assessed using lines of resistance that represent stressors. The purpose is to maintain patient stability through prevention. Patients are asked to apply prevention by using a strategy of defense mechanisms, increase their resistance, and a return to wellness through the use of education.

Patients should be educated on how to identify factors influencing osteoporosis or osteopenia and take an active role in their medical care. External factors affecting the diagnosis of osteoporosis and osteopenia can include family history, smoking history, exercise history, steroid use, diet, supplement use, and menopausal age. These factors are seldom similar, and if they are, the ensuing impact on the patient will not be similar. Thus, there is a justification for treating each individual as unique. Using Neuman's model, each patient should be educated on factors that they can control, such as smoking, caffeine use, weight bearing exercise, steroid use, and vitamin supplementation. Patients should be participants in the review of their bone density results and understand how to read the study themselves. Patients could also potentially participate in a one-hour physical therapy session for weight bearing exercise training and prevention of further disease and fracture. Patients should

ultimately be given the tools to prevent osteoporosis and osteopenia by assessing lifestyle and factors that may affect their diagnosis and reducing their exposure to these variables.

Review of Evidence

Background of the Problem

A comprehensive literature review was completed and revealed a correlation for patients with low levels of vitamin D and patients with hip, wrist, and vertebral fractures. Multiple studies related to vitamin D deficiency in fracture patients were available for review.

In a retrospective study by Streit, Merle, Clarius & Aldinger (2011), a total of 354 patients were analyzed, whereby 14 of these patients had periprosthetic fractures in relation to osteoporosis. In another study reported by Meek, Norwood, Smith, Brenkel & Howie (2011), an evaluation of osteoporotic patients was completed over a ten-year period. This particular study reviewed approximately 1000 patients yearly over a period of three years. On average, 10-15% of patients (mostly female) were positive for periprosthetic fractures.

The scope of evidence supports an ongoing concern for identifying patients at risk for osteoporosis and osteopenia, which may result in a preventable fracture. The incidence of osteoporosis and osteopenia contributes to fracture rates and may be preventable with the correction of vitamin D deficiency. Bahlous et al (2009), noted that all fractures should be assessed for vitamin D 25 (OH), pointing out the importance of better management of hypovitaminosis to prevent fractures.

According to Lowe & Friedlaender (2013), there is evidence associating vitamin D intake with fracture reduction. In a meta-analyses study performed, oral vitamin D supplementation at any dose led to a 7% to 10% decrease in fracture risk. In subjects who took the highest vitamin D doses, the reduction risk was greater (Lowe & Friedlaender, 2013).

Literature Review

Systematic Review of the Evidence

During a systematic literature review performed by the primary investigator, 35 articles were used to perform this capstone project. The literature review consisted of articles containing information on vitamin D deficiency, calcium use, osteoporosis, osteopenia, and fractures related to weak bone. The focus of the investigator during the literature review was to gather information on previous studies, which related to this capstone project. Using information from studies in the literature review, the researcher was able to assess factors that had been identified as significant in previous studies. The strongest factors relating to osteoporosis were identified as steroid use, exercise history, age, and gender. For this reason, these factors were applied to this capstone project in conjunction with vitamin D deficiency.

The articles for the literature review were gathered over a six-month period utilizing multiple resources, including search engines, peer reviewed articles, and key words that were pertinent to the project. Key words used for the search included vitamin D deficiency, vitamin D, periprosthetic fracture, bone density testing, DEXA, osteoporosis, osteopenia, and hypo-vitaminosis. In total, the search engine results located 26,000 articles. After narrowing down from this vast search, 35 articles were then selected as the most appropriate articles by the primary investigator at her discretion as applicable to this project. The search engines that were utilized included PubMed, Medline Plus and the Cumulative Index for Nursing and Allied Health (CINAHL). All of these studies were used for data comparison and benchmark targets. In total, 28 quantitative studies and seven qualitative studies were deemed to be the most applicable to this capstone project. Of the 35 research articles, the breakdown using Houser and Oman's levels of evidence revealed 12 Level II studies, ten Level III, nine Level

IV, and four Level V studies and were referenced in the systematic review of literature during the second year of the doctorate of nursing practice program (Houser & Oman, 2011).

In a study by Brady (2010), the author addressed the need for taking calcium and vitamin D, prevention of deficiency, and ultimately treatment of the deficiency. The authors' goal was to educate the public about vitamin D deficiency. Vitamin D supplementation was recommended at doses of 800-4000 international units (IU) daily or 50,000 IU weekly (Brady, 2010). This study however, recommended a large range of vitamin D dosage instead of specific ranges based on laboratory values. Another study recognized that one-year supplementation of vitamin D significantly decreased bone turnover. This study noted a decrease in the incidence of osteoporosis and fractures (Herrmann, Kirsch, Kruse, Eckert, Graber & Obeid, 2010). No specific dosing instructions were given, however, the study had 93 participants and was performed over one year (Herrmann et al, 2010).

Vitamin D3 and vitamin D2 were compared in an attempt to prove which supplement increased bone strength over 105 days (Macarena, Gonzales, Marote, Pellegrini, Pighin, Landeta, Lifshitzjj, Friedman, Mandalunis & Zeni 2009). This study was inconclusive and used rats instead of humans. The bone turnover rate over the research period of 105 days was not found to be significant enough to determine validity (Macarena et al, 2009). According to Cashman (2012), severity of vitamin D deficiency has been more profound in the past several years. In a study published in Food and Nutrition Research Journal, it was unclear whether vitamin D3 was more effective than vitamin D2, but a lack of overall vitamin D supplementation was recognized (Cashman, 2012).

In a retrospective study that aimed to prove the importance of vitamin D beyond bone health (Marz, 2011), more data review was recommended based on the findings. It was

determined that daily food intake was not sufficient enough to increase low vitamin D levels (Marz, 2011). Vitamin D at doses of 4000-5000 IU daily was recommended as a safe and simple way to reduce vitamin D deficiency and improve bone health, as well as many other medical issues.

In an expansive literature review study written by Fulvio, Marcello, Giorgio, Dallagio & Pablo Cada, (2010), it was reported that vitamin D was a significant contributor to osteoporosis and multiple body systems. Singh et al (2012) conducted a literature review of 40 patients to determine how many were diagnosed with osteoporosis and how many were vitamin D deficient. The study noted about 80.6% of cases as vitamin D deficient and 42.5% of cases had documented osteoporosis of the spine (Singh et al, 2012). A positive correlation was determined between vitamin D deficiency and low bone mineral density scores (Kritanjali et al, 2012). This study was specific to thalassemia patients and the two variables were not cross referenced for further comparison.

Another case control double blind trial studied two groups of patients all deficient in vitamin D. Patients were treated with vitamin D supplementation with or without B vitamins added to the regimen. This study found significant increases in vitamin D levels and a decrease in bone turnover in all patients regardless of the presence of B vitamins (Herrmann et al, 2010). Dosing regimens also have an effect on vitamin D levels with serum levels increasing as dosage increases (Ivorra, Valls, Fernandez-Llanio, Comella, Chalmeta, Oliver & Roman-Ivorra, 2006). Recommended vitamin D dosages between 600 IU and 3200 IU per day were considered optimal and contributed to adequate laboratory values (Ivorra et al, 2006).

Periprosthetic fractures are a significant complication caused by osteoporosis and may be preventable in patients undergoing elective and non-elective surgery. Periprosthetic fractures are a significant contributor to increased health care costs (Higgins et al, 2009). Mortality risk is increased with revision after fracture and is a preventable surgical exposure (Young et al, 2008). In two retrospective studies using literature review, it was determined that preventative medicine is far more cost effective to the health care system as well as reducing risk to patients (Higgins, Davis, Revell & Porter, 2009; Young, Walker & Pitto, 2008). In a study done by Dunbar, Howard, Bogoch, Parvizi & Kreder, 2009, they predicted less hip fractures by the year 2020 with a reduced incidence of osteoporosis. More orthopedic surgeons are treating osteoporosis prior to joint replacement with vitamin D level screening as part of the correction process (Dunbar et al, 2009).

A group of orthopedic surgeons conducted an observational study using retrospective review to identify 723 patients undergoing surgery over a 14-month period (Bogunovic et al, 2010). Strong recommendations were made in regards to vitamin D dosing prior to surgery after finding that almost half of the patients had low levels of vitamin D. In a case control study, a non-specific correlation was determined between decreased bone density and vitamin D deficiency in patients with advanced osteoarthritis (Glowacki, Hurwitz, Thornhill, Kelly & Leboff, 2003). The study did recognize a positive correlation between osteoarthritis, vitamin D, and osteoporosis (Glowacki et al, 2003).

No studies were found in this literature review that used vitamin D as a factor contributing to osteoporosis and osteopenia when compared to other factors or directly comparing the two variables. The studies utilized for the literature review recognized vitamin D and calcium supplementation as contributory factors for the prevention of osteoporosis and

osteopenia. Previous studies recommended vitamin D supplementation of 400-600 IU per day for the prevention of osteoporosis and osteopenia (Lowe & Friedlaender, 2013). The National Osteoporosis Foundation (NOF) has recently raised their recommended upper limit of vitamin D supplementation to 4000 IU daily due to the increased recognition of vitamin D deficiency.

Project Plan and Evaluation

Strengths

The primary investigator was able to obtain data by performing a retrospective data analyses on 91 patients to include multiple variables that may have contributed to the diagnosis of osteoporosis and osteopenia. Comparing the variables to vitamin D deficiency and the diagnosis of osteoporosis, osteopenia and normal bone differentiated the strong and weak variables. Variables assessed included age, gender, exercise history, and steroid use. Assessing multiple variables gives the study reliability and confidence to the reader.

The primary investigator had access to the data and focuses her expertise on rheumatologic and orthopedic patients in a private practice. The primary investigator has access to osteoporotic patients and sees referrals in a large medical building consisting of neurology, orthopedics, neurosurgery, physical therapy, primary care, women's health, and chiropractic care. A bone density machine is located onsite for patient convenience. The primary investigator had experience with vitamin D deficiency and osteoporosis and had been exposed to orthopedic patients undergoing both osteoporosis-related fractures and periprosthetic fractures occurring intra-operatively and post-operatively. Frontline exposure to these orthopedic patients allowed the primary investigator basic knowledge and resources to conduct the study.

Weaknesses

There was a margin of error and patients were excluded if they had not had a bone density test and a vitamin D OH 25 level drawn in the previous three-year period (Meek et al, 2011). Some patients were not included in the study if all variables were not available. Variables included exercise history, steroid use history, gender, age, diagnosis, and level of vitamin D OH 25 lab value. Multiple patients were excluded from the study if they did not meet the criteria. A larger number of patients may have given this study greater significance. Documentation was retrieved from their charts on file and accuracy is assumed based on patient reliability.

Patients with smoking history were not assessed for this study. Smoking history may be defined in a number of methods. Smoking history can be categorized as direct exposure to smoke and indirect exposure to smoke. Patient may have smoked while in their thirties suppressing bone turnover when it was at its peak, and subsequently quit smoking a few years later. Due to difficulty assessing this variable, it was excluded from this study and may have contributed to the results.

Opportunities

The study allows for recognition and correction of osteoporosis and osteopenia by acknowledging a treatable problem early on instead of treating patients with prescription strength medication at later stages. Given the opportunity to recognize vitamin D deficiency at an earlier age and therefore prevent a future diagnosis of osteoporosis or osteopenia, it may allow the patient to reduce future long term prescription medication intake with potentially detrimental side effects and decrease the incidence of comorbidities. Some patients have

difficulties tolerating these medications and are often trying to correct this diagnosis after they have been assessed as having osteoporosis or osteopenia or have fractured a bone.

This capstone project aimed to raise awareness to both providers and patients exposed to osteoporosis and osteopenia. By recognizing and correcting the problem, primary preventative medicine will play an important role in the prevention of osteopenia and osteoporosis. Using teaching methods, patients may benefit from a new protocol preventing further fracture, consistency in DEXA scanning, and reduced fracture risk. Using primary preventative medicine before the diagnosis of osteoporosis or osteopenia or a fracture occurs, will help to reduce the incidence of osteoporosis-related fractures.

Threats

There were minimal threats to the study. A larger database of patients may have resulted in stronger study results. A larger database may have been achieved by documenting patient findings for the past five years instead of three years. Incorporating another provider's practice into the study may also have expanded the database. However, strong correlation between vitamin D and osteoporosis and osteopenia was achieved nonetheless. The primary researcher originally desired 200 applicable study patients and managed to achieve a population of 91. Institutional Board Review (IRB) approval was received later than expected and changes were made to the original IRB. The original study was changed from an experimental type study to a retrospective data analysis.

Other considerations included the possibility that patients had already undergone a correction in vitamin D level, which may have been completed over the previous three month period. They still may have been given diagnosis of osteoporosis or osteopenia, which would have taken much longer to correct. Most low vitamin D levels can be corrected within six

months, but osteoporosis and osteopenia can often take much longer to correct. The possibility of this correction of vitamin D may have affected results of the study.

Potential threats to validity and reliability to the project were few; volume of data was essential for high quality results. A power of 0.80 was documented giving the study reliability and a confidence level of 95% in regards to the relationship between vitamin D and osteoporosis and osteopenia. These results were accomplished using one-way ANOVA testing and comparing the variables independently, while also comparing variables to each other. Zaccagnini and White. (2011), identified that project implementation is the exercise of leadership and control of the project. The study gathered as much data as possible, but the ability to maintain the integrity of the project within a parameter that was controlled by a single investigator was crucial. Missing or incomplete data was excluded from the study. Zaccagnini and White, (2011), recommended that the investigator think about foreseeable and unforeseeable events. Unforeseeable events may have included too few charts to review or time constraints relating to collecting information. Other unforeseeable events were charts that lacked enough variables to meet all criteria and were then excluded. A population of $n=91$ was achieved which was sufficient for study results and reliability. A population of $n=78$ was desired for the strongest results.

Driving and Restraining Forces

Budget and resources were minimal to the primary researcher. A retrospective data analysis was used, and therefore, data was readily available at no cost to the primary investigator. An employee of the primary researcher contributed 20 hours of time for data collection and was able to complete the second review of information to verify data already collected by the primary investigator. The verification of data by both the employee and

investigator ensured consistency and reliability. The primary investigator devoted about 260 hours to this capstone project for data collection and analyses. The statistician cost for a project this size was quoted at \$400-\$500. The statistician was not needed for this project as the primary researcher was able to use the Statistical Package for the Social Sciences (SPSS) version 22 statistics program with the help of an academic instructor and prior knowledge from a statistics course.

Needs, Resources and Sustainability

There were several resources that became readily available to the researcher. The data was collected using a data collection tool (see Appendix A). Charts were then reviewed from the past three years utilizing existing data. Patients were not asked to undergo testing for the purpose of this study. Patients were asked to fill out a questionnaire prior to DEXA scan documenting the variables used for this study. If all the variables were documented in the chart, the data was used. If pertinent variables were not documented, the data was excluded and the patient was not used for this study.

The primary investigator was able to use an employee knowledgeable with the practice charts. SPSS v. 22 statistics were used for the analyses. SPSS v. 22 was accessible at a cost of \$50 and was already purchased for a statistics course. Other resources included an Excel spreadsheet, which was also accessible to the primary investigator at no cost. The resource of time was a large component. The researcher spent over 260 hours and a medical assistant spent about 20 hours documenting data. The charts were reviewed over a six-month time period.

Feasibility, Risks and Unintended Consequences

This capstone project identified multiple benefits in recognizing factors contributing to osteoporosis and osteopenia. Several factors contribute to the diagnosis of osteoporosis and osteopenia. Four factors were utilized for the purpose of this project, and were identified as age, gender, exercise history, and steroid use history. Other patient factors could have included smoking history, family history of osteoporosis, age of menopause and fracture history but were not included for the purpose of this capstone project. Calcium levels were also not used as a variable in this study and may have contributed to data findings. Preventing osteoporosis may result in a decrease in fragility fractures and reduce comorbidity. Risks to the study participants were minimal since this was a retrospective study. There were no new interventions introduced and no new treatment was introduced before study completion.

As a result of the study, the researcher recognized that many of the bone density tests were outdated. Patients were not being scheduled for bone density tests every one to two years depending on their diagnosis as is recommended. It was acknowledged that continuity of care is a deficit and this could be addressed in the future. Patients should have a bone density test for screening of osteoporosis or osteopenia every two years, starting at the age of 65 years. If patients are diagnosed with osteoporosis or osteopenia or have a new fracture, they should be offered a bone density test every year.

Stakeholders and Project Team

The project team for this capstone project was minimal and included the primary investigator, a capstone mentor who practices as an orthopedic surgeon, and one employee from the primary investigator's practice that was used briefly for data collection. The primary investigator was responsible for overseeing data collection and documentation. The primary

investigator was also responsible for maintaining integrity of the project and patient confidentiality. A medical assistant was used to help with data collection. Data was retrieved from the charts and information was available within the practice. The medical assistant was experienced in chart review.

The stakeholders affected by retrospective data analyses and possible implementation of a new policy may include patients, families, providers, and insurance companies. Patients have a vested interest in primary preventative medicine as well as their health and wellbeing. Preventing a fracture of the wrist, hip and vertebrae may result in less comorbidity, higher quality of life, and reduced co-pays to insurance companies (Johnson, 2008).

A Hologic™ bone density machine is located at the office of the primary investigator. Providers at the primary investigator's practice locations have the potential to make a profit on a new policy development with bone density reimbursement if rates increase from their current low reimbursement fee schedule. DEXA scanner representatives such as Hologic™ have reported significantly less sales and renewals of leases on bone density equipment since the cuts in reimbursement (Johnson, 2008). Patients undergoing regular bone density testing will be covered by most insurance plans, which consequently becomes a minimal reimbursement to the providers (King & Florentino, 2011). Insurance companies may also benefit by preventing fractures that may result in hospitalizations, thereby saving Medicare and other insurance companies significant costs for hospitalization, surgery, and rehabilitation.

Cost and Benefit Analysis

According to Houser and Oman (2011), cost and benefit analyses are difficult to project in the early analyses phase of evidence-based practice. The costs to the patients were

minimal due to the use of a retrospective chart analysis. Charts were available to the primary researcher and this incurred no costs for the patients. In the future, most insurance plans will cover the cost of bone density testing yearly or every two years depending on the patient's history, diagnosis and symptoms. The average cost of a bone density test billed to the insurance is \$150, and reimbursement rates are approximately between \$40 and \$75. Cash pay rates at the primary investigators practice is \$60 per bone density scan. Some of the patient identifiers in the investigator's practice include smoking history, alcohol use, family history, fracture history, long-term use of high dose, and rheumatologic diagnosis. At the primary researcher's practice and most practices, the patient's insurance would require authorization before the procedure could take place.

Vitamin D supplementation usually costs between \$5 and \$20 per month. Patients are typically advised to take supplementation based on their lab results after follow-up. The Hologic™ bone density machine was purchased by the primary investigator at a cost of \$50,000 and was available for lease over a five-year time period. Using the diagnosis code of 268.9, which is unspecified vitamin D deficiency in the International Classification of Diseases 9 (ICD-9) manual, most insurances cover the cost of the vitamin D OH 25 laboratory test. The cash price for a vitamin D OH 25 laboratory test is typically between \$150 and \$250.

Reducing the possibility of emergency room visits and hospital visits will have a tremendous effect on the patient and the healthcare system in general. Emergency room visits and hospital stays can cost between \$100 and \$25,000, based on insurance and diagnosis. The benefits of reducing hospital stays include avoiding surgery, immobilization, complications

secondary to surgery such as periprosthetic fractures, and reducing comorbidities (see Appendix B).

Using retrospective study analyses, the researcher identified patients over the past two years who have had a bone density test and a vitamin D OH 25 lab level drawn. Bone density testing was available on site for convenience to the patient. The purpose of the study was to identify a correlation between osteoporosis and osteopenia findings on a bone density test and the incidence of vitamin D deficiency. Identifying a correlation may help to identify patients at risk for osteoporosis and osteopenia and reduce the incidence of fractures.

Mission and Vision

The mission of this capstone project was to determine if there was a relationship between vitamin D deficiency and osteoporosis or osteopenia, which may lead to a decrease in bone density. By determining a relationship between vitamin D deficiency and decreased bone density, it would allow the primary researcher to identify patients at risk and prevent further disease. The vision for this study was to decrease the overall risk of osteoporosis and osteopenia in clinic patients with proper supplementation and prevention.

Goals

The goal of this study was to determine whether the relationship between vitamin D deficiency and osteoporosis or osteopenia was statistically significant. The problem of vitamin D deficiency and the correlation with osteoporosis was identified and the project was implemented using a PICO analysis at the doctorate level. Another goal was to reduce the overall incidence of the diagnosis of vitamin D deficiency, osteoporosis, osteopenia, and fragility fractures within the primary investigator's practice with proper supplementation and

prevention. An overarching goal of this study was to include as many patients' data pertinent to the PICO question as possible.

Process and Outcomes

The purpose of the project was to evaluate the relationship between osteoporosis and osteopenia and low vitamin D OH 25 levels. This project was an evidence-based practice (EBP) project in which a quality improvement plan, program evaluation, or simple educational or standard of care intervention (with post-test evaluation) was completed. Timeframe was an important aspect of the success of this study (see Appendix C). Projected time frame included data collected over the previous three years with an anticipated completion date of July 1st, 2014. Collaborative Institutional Training Initiative (CITI) training was completed by the primary investigator in the fall of 2012 (see Appendix D). The PICO question was completed February 2013 and oral capstone proposal presentation was completed October 2013. A letter of support was obtained by the primary investigator's physician mentor in the clinic where the capstone project took place in January 2014 and IRB submission was completed in February 2014 (see Appendix E). Data analysis was completed between March 2014 and July 2014. The final oral capstone defense presentation took place in August 2014 and was accepted.

The process was implemented over a two-year study period with completion of the Doctorate of Nursing Practice degree requirements. The capstone project was completed at the primary investigator's practice with direction from a mentor and orthopedic surgeon at a secondary practice. Outcomes affected the primary researcher's personal practice and also the practice of the researcher's partners and colleagues located in the same facility. The mentor, practicing as an orthopedic surgeon has changed his practice guidelines due to study findings.

The providers that were affected by the outcomes included two orthopedic surgeons, a neurosurgeon, neurologist, primary care nurse practitioner, women's health nurse practitioner, chiropractor, and several physical therapists. The objective of this project was to determine the number of patients diagnosed with osteoporosis or osteopenia and vitamin D deficiency. Once this was accomplished, documented risk factors were evaluated to determine the correlation between the variables and the diagnosis of osteoporosis or osteopenia.

Process Model

The process model for this capstone project (see Appendix F) outlines antecedent, independent and dependable variables in a clear manner. The dependent variable was the diagnosis of osteoporosis, osteopenia or normal bone. The independent variables were vitamin D levels, exercise history, age, gender, and steroid use history. Relationships between dependent and independent variables in this study were analyzed and compared for optimal results. Using one-way ANOVA testing variables were compared to the diagnosis. Statistical significance was identified and compared to the other variables.

Antecedent variables occur prior to the occurrence of the independent and dependent variables that may influence the dependent variable. Current protocols for initiating vitamin D therapy are poorly illustrated in guidelines. Some primary care providers do not include testing in yearly screening. Bahlous et al (2009), recognized that 45.2% of women tested in their study were found to be vitamin D deficient or insufficient. Moderator variables influence the relationship between the independent and dependent variables. Moderator variables would include patient age, gender, exercise history, steroid use history, vitamin D OH 25-lab value, and diagnosis after DEXA scan.

Extraneous variables interfere with or obfuscate the relationship between the dependent and independent variables. Examples are similar to those listed above with a concern for patient compliance with supplement intake and education on their diagnosis. Patients may have compliance concerns with vitamins and medications. According to a study by Porthouse (2005), patient non-compliance with taking bisphosphonates resulted in a 60% drop out rate. Relationships between variables are multi-faceted and will directly impact each other based on the individual patient.

Population Sampling and Parameters

The population at highest risk for osteoporosis and vitamin D deficiency (vitamin D OH 25 lab value below 32 ug/dL) is the elderly population (Lawrence, 2008). Population assessment included residents of all ages meeting the outlined criteria residing in the southwestern part of the US. Population assessed was male or female, over the age of 50 years, had a documented positive or negative history of steroid use and exercise history, had undergone bone density testing using a DEXA scan, and had vitamin D OH 25 laboratory testing over the previous two-year period. The rationale for using the above-mentioned criteria is the increased risk of vitamin D OH 25 deficiency and osteoporosis in this target group (Leyland, 2012). Patients were not asked to undergo testing for the purpose of this study. Data utilized was retrospective data, and readily available to the primary investigator.

Although the target population for this capstone project was older adults, the risk was minimal for any harm or discomfort. The investigator focused on the outcomes of the relationship between vitamin D OH 25 blood levels and DEXA scan results through chart reviews, not by generating new data. The investigator ensured that personal identifiers were not collected linking individuals to the collected data. All data was reported as aggregate

data. The setting was an existing medical practice owned by the primary investigator. The practice was established in 2010 and focuses on rheumatology with a specific specialty in osteoporosis. The primary investigator owns a DEXA scanner and often tests vitamin D levels. Referrals from partners and other practices are sent to the primary researcher. Data was readily available to the investigator for this reason.

Protection of Human Rights

The protection of human rights is the responsibility of all health care providers, and patients are of primary concern at all times. According to Zaccagnini and White (2011), when conducting nursing research, nurses must protect subjects right to privacy, self-determination, confidentiality, fair treatment, and protection from harm. No unauthorized persons had access to this capstone project's data. Confidentiality was assured through a set of coding activities instituted by the primary investigator whereby no patient identifiers were on any of the instruments used to collect data for the study (see Appendix A). Due to the nature of data collection for chart reviews, the primary investigator kept an Excel spreadsheet on a password protected computer with patient name and chart number and the de-identified code used on the chart review instruments to determine which patients' charts had been reviewed. Only the primary investigator had access to the data.

Instrumentation Reliability and Validity of Intended Statistics

Reliability is the degree of consistency or dependability with which an instrument measures the attribute it is designed to measure (Polit, 2011). Literature review supported the findings and show consistency with results. The researcher chose this study due to her experience with the increased incidence of vitamin D deficiency in relation to osteoporosis

and osteopenia. Data will be kept for three years following the study and is available for review at request.

Validity is a quality criterion referring to the degree to which inferences made in a study are accurate and trustworthy (Polit, 2011). Evidence of validity will be shown throughout the study with evidence-based research in comparison to research findings. All data collected will remain in a database for a period of three years for validity purposes. Two researchers verifying the data on three occasions accomplished validity and reliability. The primary researcher verified data on the first and third occasion and an assistant verified the data on a second occasion.

Instrumentation was created for this capstone project (see appendix A) and was utilized for all patients included in the study and included information such as gender, age, diagnosis, vitamin D level, exercise history, and steroid use. The primary investigator for this capstone project designed the instrument. A power analyses of 0.80 was used and a confidence interval of 95% was achieved using the independent variable vitamin D when compared to the dependent variable of osteoporosis, osteopenia and normal bone. A population of 78 was desired after performing the power analyses and a population of 91 was achieved.

Data Collection and Procedure Protocol

This quality improvement (QI) project utilized a quantitative retrospective study design comparing outcome data on patients who have previously undergone a bone density test using a DEXA scan and vitamin D OH 25 laboratory testing over the previous three-year period. Blood values were categorized as vitamin D deficient or normal. Data collected wherein nominal measurement is the lowest form of measurement and involves using

numbers (Polit, 2011). Variables measured included a dependent variable of the diagnosis of osteoporosis and multiple independent variables, the diagnosis of vitamin D lab value, age, exercise history, gender, and past history of corticosteroid use.

The researcher chose a quantitative study because data was categorized as numerical. When presenting data or reading data the researcher found it simpler to present data in numeric form to prove research findings. Quantitative data is proof of a recorded lab value or proof that a patient has a tangible diagnosis of osteoporosis, osteopenia or normal bone quality. When a DEXA score is reviewed with a patient it is straightforward and unquestionable. Patients either have osteoporosis or they do not, and they either have vitamin D deficiency or they do not.

The researcher used an Excel spreadsheet to collect data (Polit, 2010). Using one-way analyses of variance (ANOVA) for this study the variables were analyzed. Once this was completed, multiple regression was utilized to analyze the variables individually. The variables were then separated into four categories: (1) patients with osteoporosis or osteopenia and low vitamin D levels, (2) patients with osteoporosis or osteopenia and normal vitamin D levels, (3) patients with normal bone and low vitamin D levels and (4) patients with normal bone and normal vitamin D levels.

The software used for data analysis was SPSS v. 22. Presentation was displayed in the form of one-way ANOVA analyses. Graphing was attempted but due to the multiple variables involved, graphing was not successful. Percentages were used for data presentation and ease of understanding for the reader.

Project Findings and Results

Objective

The objective of this capstone project and data analysis was to determine whether vitamin D deficiency was statistically significant for the diagnosis of osteoporosis and osteopenia. Other variables including exercise history, steroid use, gender, and age contributed to study findings. Involving these variables, the researcher was able to demonstrate the significance of vitamin D on osteoporosis and osteopenia using descriptive statistics. Descriptive statistics used were general statistics, one way ANOVA testing, and percentages. A key was utilized (see Appendix G) to simplify the terms entered into SPSS v. 22 for the ANOVA and a legend was developed (see Appendix H) to enter the data into SPSS v. 22.

One-way ANOVA testing was used to represent data. The ANOVA test is used to analyze the difference between two means. ANOVA tests analyze variation among groups, they are determined by the ratio of two variances. A p-value was set at 0.05 and would give the researcher a significance level of 95%. A result less than 0.05 would give the researcher 95% confidence that vitamin D is a significant contributor to the diagnosis of osteoporosis or osteopenia. The following one-way ANOVA test was run with vitamin D as the variable and showed a significance level of $p=0.026$.

Table 1 (ANOVA #1)

POPE

	Sum of Squares	df	Mean Square	F	Sig.

Between Groups	2.550	1	2.550	5.107	0.026
Within Groups	44.439	89	0.499		
Total	46.989	90			

This one-way ANOVA test was run with the variable age and was not statistically significant with a significance level of $p=0.5888$. This value is above the p-value set at 0.05.

Table 2 (ANOVA #2)

POPE

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1.022	3	0.341	0.645	0.588
Within Groups	45.967	87	0.528		
Total	46.989	90			

This one-way ANOVA test was run with the variable steroid use and was not statistically significant with a significance level of $p=0.364$. This value is above the p-value set at 0.05.

Table 3(ANOVA #3)

POPE

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	0.436	1	0.436	0.834	0.364
Within Groups	46.553	89	0.523		
Total	46.989	90			

This one-way ANOVA test was run using the variable gender and was not statistically significant with a significance level of $p=0.413$. This value is above the p -value set at 0.05.

Table 4 (ANOVA #4)

POPE

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	0.347	1	0.347	0.678	0.413
Within Groups	42.547	83	0.513		
Total	42.894	84			

This one-way ANOVA test was run using the variable exercise history and was not statistically significant with a significance level of $p=0.990$. This value is above the p -value set at 0.05.

Table 5 (ANOVA)

POPE

	Sum of Squares	df	Mean Square	F	Sig.
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Between Groups	.011	2	.006	.010	.990
Within Groups	46.978	87	.540		
Total	46.989	89			

Table 6 (Statistics)

	POPE	VITD	EXER	STER	AGE	GENDER
N Valid	91	91	85	90	91	91
Missing	0	0	6	1	0	0
Mean	0.9890	0.4396	0.4353	0.7000	0.8681	1.5385
Std. Error of Mean	0.07575	0.05232	0.05410	0.06787	0.03566	0.08882
Std. Deviation	0.72256	0.49908	0.49874	0.64390	0.34022	0.84732
Variance	0.522	0.249	0.249	0.415	0.116	0.718
Range	2.00	1.00	1.00	2.00	1.00	3.00
Minimum	.00	.00	.00	.00	.00	.00
Maximum	2.00	1.00	1.00	2.00	1.00	3.00

The table above represents statistical analysis with mean of variables, standard deviation and variance.

Table 7 (Patients analyzed)

Osteoporosis/osteopenia and vitamin D deficient	35 patients
Osteoporosis/osteopenia and normal vitamin D	33 patients

Normal bone and vitamin D deficient	5 patients
Normal bone and normal vitamin D	18 patients

Of the 91 patients analyzed, 12 patients were men and 79 patients were women. 39% of patients had both osteoporosis or osteopenia and vitamin D deficiency. 36% of patients had osteoporosis or osteopenia and did not have vitamin D deficiency. 5% of patients had normal bone and were vitamin D deficient. 20% of patients had normal bone and normal vitamin D lab value. These results show that the majority of patients evaluated in the study were diagnosed with osteoporosis or osteopenia and also had low vitamin D levels.

Results of the one-way ANOVA test using variables of diagnosis and vitamin D levels showed a significance of 0.026 for vitamin D when compared to the control group diagnosis. A significance of 0.026 was below the p-value of 0.05 indicating a 95% confidence of accuracy and leaving a 5% possibility of error. A significance of .0588 for gender, 0.364 for age, 0.990 for steroid use and exercise 0.413 was found when compared to the control group. All other variables were not statistically significant to osteoporosis or osteopenia. These results show that vitamin D was the only variable that was statistically significant to the diagnosis of osteoporosis and osteopenia. The other variables had no statistical significance in this study but the project investigator found clinical significance in these other variables.

Results of the multiple regression test verified statistical significance with only one variable, which was vitamin D. A confidence interval is the measure of reliability of an estimate. If the value between the ranges of a confidence interval can equal 1, the researcher can assume the result is likely to occur. A narrow window with the ability to achieve 1 gives the researcher more confidence in the significance of their results. Multiple regression testing

was run using all of the variables and comparing the variables to each other. The results showed the statistical significance of vitamin D on osteoporosis and osteopenia. The variables when compared to each other showed no statistical significance. The variable vitamin D deficiency resulted in a confidence interval of 0.290 and 2.082. Confidence intervals of diagnosis of osteoporosis and osteopenia were 0.236-4.645. All other variables showed a confidence interval that did not achieve 1. All other factors could have been 0 and were not statistically or clinically significant in this study. Vitamin D was the only variable that showed a confidence interval between 0 and 1.

The standard deviation measures the amount of variation from the average. Standard deviations were as follows: osteoporosis, osteopenia and normal bone had a standard deviation of 0.72256, vitamin D levels had a standard deviation of 0.49908, exercise had a standard deviation of 0.49874, steroid use had a standard deviation of 0.64390, age had a standard deviation of 0.34022 and gender had a standard deviation of 0.84732.

Table 8 (Parameter Estimates)

		Estimate	Std. Error	Wald	df	Sig.	95% Confidence Interval	
							Lower Bound	Upper Bound
Threshold	[POPE = .00]	.023	1.089	.000	1	.983	-2.111	2.157
	[POPE = 1.00]	2.440	1.125	4.707	1	.030	.236	4.645
Location	[VITD=.00]	1.186	.457	6.725	1	.010	.290	2.082
	[VITD=1.00]	0 ^a	.	.	0	.	.	.
	[EXER=.00]	.724	.461	2.472	1	.116	-.179	1.627
	[EXER=1.00]	0 ^a	.	.	0	.	.	.

[STER=.00]	-.115	.785	.022	1	.883	-1.653	1.423
[STER=1.00]	.038	.799	.002	1	.962	-1.528	1.605
[STER=2.00]	0 ^a	.	.	0	.	.	.
[AGE=.00]	.765	.634	1.455	1	.228	-.478	2.008
[AGE=1.00]	0 ^a	.	.	0	.	.	.
[GENDER=.00]	-.313	.921	.115	1	.734	-2.118	1.493
[GENDER=1.00]	.485	.762	.406	1	.524	-1.008	1.979
[GENDER=2.00]	-.260	.735	.125	1	.724	-1.701	1.181
[GENDER=3.00]	0 ^a	.	.	0	.	.	.

Analyses of the results showed a statistical significance between osteoporosis or osteopenia and vitamin D deficiency. Vitamin D was the only variable that contributed to the diagnosis of osteoporosis and osteopenia. All other variables did not contribute to the diagnosis. The p value is the measure of how likely the data is to be accurate. A p-value of 0.05 gives the researcher 95% confidence that the results are accurate and not a matter of chance. The p value was set at 0.05 and the statistical significance was 0.026 between the diagnosis of osteoporosis or osteopenia and vitamin D levels. This significance level was below the p value, showing a confidence level of 95%. The results showed that exercise, age, gender, and steroid use were not statistically significant factors in osteoporosis and osteopenia, but found to have clinical significance.

The effect size is the size of the experimental effect; they allow the researcher to compare the magnitude of experiments to each other (Polit, 2010). The effect is essentially the difference between the two means. The effect size was calculated using 0.9890 (means of

control group POPE) subtracted by 0.4396 (means of experimental group VITD) divided by 0.07575 (the standard deviation) =0.964. The effect size is therefore, 0.964. This result was close to one, indicating a larger affect of the experimental on the control. When variables were compared to each other using correlation testing, there was no statistical significance.

Limitations

One limitation of the project was that although the other factors when compared to vitamin D were not statistically significant, some were more significant than others. Age, exercise history, and gender were more significant than steroid use history. Another limitation was that there was a large sample of women in the project as compared to men. Osteoporosis commonly affects women more often than men, however the population sampling may suggest that an increased provider awareness may be needed for the proper screening of men.

Patients may have had previously corrected vitamin D levels with a diagnosis of osteoporosis or osteopenia. Vitamin D levels may have been corrected over a period of three months. Osteoporosis and osteopenia would take much longer for correction.

Another limitation may have been that a larger sample size could have achieved stronger results. The results of the study, however, indicated a strong correlation between vitamin D deficiency and osteoporosis and osteopenia.

Smoking history was not included in the study for several reasons. Smoking history can be documented as present or past history. Patients achieve their highest bone turnover rate during their twenties and thirties; therefore, if patients smoke during this time, bone quality can be affected. This smoking history documentation proved difficult to acquire and was therefore excluded from the study.

Other variables to include in a future study may be family history of osteoporosis and osteopenia, menopausal age, and supplementation such as calcium. These factors may have increased or decreased the statistical significance depending on the findings.

Recommendations

The results of this analysis show that vitamin D deficiency is a statistically significant factor in osteoporosis and osteopenia. The factor of vitamin D deficiency had a higher statistical significance than exercise history, steroid use, gender, and age. All patients undergoing bone density testing should have a vitamin D OH 25-lab value. All patients should be educated and screened for the prevention of vitamin D deficiency and also osteoporosis and osteopenia. Patients diagnosed with osteoporosis or osteopenia are at risk for vitamin D deficiency and should have a vitamin D OH 25 lab draw completed once they are diagnosed with osteoporosis or osteopenia. Patients undergoing bone density testing every other year should have a vitamin D level drawn at least once yearly. If patients are deficient in vitamin D, they should be treated with an appropriate dosage of vitamin D and rechecked with a blood test after three months of treatment.

This capstone project demonstrates the importance of primary preventative medicine as an integral part of nursing. New data was generated as a result of this study. Prevention should start at the primary care level and patients should be screened yearly for vitamin D levels and osteoporosis and osteopenia, at minimum. Patients screened should include post-menopausal women, smokers, caffeine users, rheumatology patients, fracture patients, a strong family history of osteoporosis, and the elderly over the age of sixty-five years.

Implications For Change

New protocols developed within the primary investigator's practice include screening all new and existing patients for the date of their last bone density test and vitamin D OH 25 lab value. Patients are scheduled for a follow-up visit to review results within two weeks of their study completion. Patients are educated on how to read a bone density and understanding their T-Score. The T-Score indicates the strength of the bone when compared to a healthy 30-year old. T-Scores above -1 indicate normal bone, between -1 and -2.5 indicate osteopenia and below -2.5 indicate a diagnosis of osteoporosis. Patients are given a copy of their bone density test on request and educated on prevention. Most patients will undergo a one-time physical therapy visit for teaching on the prevention of osteoporosis and osteopenia. Patients are given literature for educational purposes and scheduled for a follow-up visit within one year if results are positive or indicate osteopenia with a possible vertebral fracture and two years if results are normal. An indication for testing prior to two years would be new onset fracture or new exposure to long term steroids such as prednisone. Having this research available may educate patients and family and allow them to benefit from a study performed by their own provider.

Future studies may include adding more variables such as smoking history, age of menopause and fracture history. Another study could include evaluating the impact of calcium and vitamin D or calcium independently. Research can be used to change practice guidelines and apply new protocols and recommendations.

This study may be useful for conference involvement such as the National Osteoporosis Foundation (NOF), the American Association of Nurse Practitioners (AANP), the American Osteopathic Board of Orthopedic Surgery (AOBOS), the American Osteopathic

Academy of Orthopedics (AOAO), the American Academy of Orthopedic Surgeons(AAOS) and the American College of Rheumatology (ACR).

Conclusion

The purpose of this capstone project was to evaluate osteoporotic and osteopenic patients, and investigate “What is the relationship between reduced serum levels of vitamin D OH 25 compared to normal serum levels of vitamin D OH 25, in the incidence of osteoporosis or osteopenia?” The goals of the study were met and it was determined that there was a relationship between vitamin D deficiency and osteoporosis or osteopenia, which was statistically significant. Using one-way ANOVA testing, multiple regression and percentages, the researcher showed that vitamin D was statistically significant to osteoporosis and osteopenia. Results of the one-way ANOVA test showed a significance of $p=0.026$ for vitamin D when compared to the control group diagnosis. Results of the multiple regression test verified statistical significance with only one variable, which was vitamin D deficiency. This study showed that vitamin D deficiency as a variable was more significant to osteoporosis and osteopenia than the other variables such as exercise history, steroid use, age, and gender.

Prevention of osteoporosis and osteopenia can reduce the risk of comorbidities such as fracture. Identifying pertinent variables and treating patients for vitamin D deficiency can reduce the risk of fracture. Osteoporosis and osteopenia have impacted patients and their families across the U.S. and across the world. Primary preventative medicine plays an important part in treating patients and identifying the issue before disease occurs.

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Appendix A

Retrospective Chart Review Instrument

Patient identifier number: _____

Date of bone density test: _____

Bone density test or result on file: Y N

Patient bone density: normal range osteopenic osteoporotic

Vitamin D OH 25 level: _____

Patient age: _____

Male _____ Female _____

History of steroid use: Y _____ N _____

Current weight bearing exercise sessions per week: _____

Appendix B

Cost Analysis

Item	Cost
Vitamin supplementation	\$5-\$20 depending on size of bottle
Calcium supplementation	\$4-\$15 depending on size of bottle
DEXA Scan per patient	\$60 cash price/co-pay if billed to insurance
Hologic™ DEXA scanner	\$50,000
Medication to treat osteoporosis	Varies depending on medication
Educational brochures from the Arthritis Association	\$20/pack of 30 brochures
Primary researchers time commitment	260 hours
Employee hours	20 hours/\$11 per hour

Appendix C

Timeline for Capstone Project

STEPS	Goals	Due Date
STEP I: Problem Recognition NR701/706A/707	Identified Need Problem Statement-PICO PICO Approval Literature Review	Fall 2012 Spring 2013 Spring 2013 Spring 2013
STEP II: Needs Assessment NR703/704/707	Identify population/community Identify sponsor& stakeholders Organizational assessment Assess available resources Desired outcomes Team selection Cost/Benefit analysis Define scope of project	Winter 2012 Winter 2012/Spring 2013
STEP III: Goals, Objectives, & Mission Statement NR707/711/721	Goals Process/outcome objectives Develop mission statement	
STEP IV: Theoretical Underpinnings NR701/707/721	Theories of change Theories to support project framework	Fall 2013 Fall 2013
STEP V: Work Planning NR707/721/722	Project proposal Project management tools Milestones Timeline Budget	Fall 2013 Summer 2013 Spring 2013 Summer 2013
STEP VI: Planning for Evaluation NR706B/707/722	Development evaluation plan Logic model development	Fall 2013 Fall 2013
STEP VII: Implementation NR706B/706C/707/722	IRB approval Threats and barriers Monitoring implementation phase Project closure	Summer 2013 Summer 2013/Fall 2013 Fall /Winter2013 Spring 2014
STEP VIII: Giving Meaning to the Data	Quantitative Data	Summer 2014

NR702		
STEP IX: Utilizing & Reporting Results	Written dissemination Oral dissemination Electronic dissemination	Summer 2014 Summer 2014 Summer 2014
NR706C		

Appendix D

CITI Training

LEARNER DEPARTMENT EMAIL INSTITUTION EXPIRATION DATE**COLLABORATIVE INSTITUTIONAL TRAINING
INITIATIVE (CITI)****HUMAN RESEARCH CURRICULUM COMPLETION REPORT Printed on
02/09/2014**

SUMMER TILGNER (ID: 3218849) Nursing stilgner@regis.edu Regis University

SOCIAL BEHAVIORAL RESEARCH INVESTIGATORS AND KEY PERSONNEL**COURSE/STAGE: PASSED ON: REFERENCE ID:****REQUIRED MODULES**Introduction History and Ethical Principles - SBE The Regulations - SBE Assessing Risk -
SBE Informed Consent - SBE Privacy and Confidentiality - SBE Regis University

Basic Course/1 11/25/2012 9228460

11/25/2015



For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D. Professor, University of Miami Director Office of Research
Education CITI Program Course Coordinator

DATE COMPLETED

11/25/12 11/25/12 11/25/12 11/25/12 11/25/12 11/25/12 11/25/12

Appendix E



Academic Grants

3333 Regis Boulevard, H-4
Denver, Colorado 80221-1099303-458-4206
303-964-5528 FAX
www.regis.edu

IRB – REGIS UNIVERSITY

March 25, 2014

Summer Tilgner
297 S. Lake Havasu Avenue #200
Lake Havasu City, AZ 86403**RE: IRB #: 14-143**

Dear Ms. Tilgner:

Your application to the Regis IRB for your project, "The Effects of Vitamin D Levels on Osteoporosis/Osteopenia," was approved as an exempt study on March 25, 2014. This study was approved per exempt study category of research 45CFR46.101.b(#4).

The designation of "exempt" means no further IRB review of this project, as it is currently designed, is needed.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval.

Sincerely,

Patsy McGuire Cullen, PhD, PNP-BC
Chair, Institutional Review Board
Professor & Director
Doctor of Nursing Practice & Nurse Practitioner Programs
Loretto Heights School of Nursing
Regis University

cc: Dr. Colleen McCallum



ORTHOPEDIC INNOVATIONS

Theron C. Tilgner, D.O. LLC
Margaret Holmes, FNP/PA.C

Appendix A

Letter of Support-Dr. Theron Tilgner

Regis University IRB Committee:

01/01/2014

The intent of this letter is to confirm my acknowledgement and support of the study proposed before you by investigator Summer Y Tilgner FNP. My intention is to help on this research project as needed. I am aware of a possible increased time commitment and am prepared to participate as necessary. In addition, we will follow guidelines/requirements as determined by the Regis University Human Subjects Institutional Review Board (IRB). Please feel free to call with any questions or concerns.

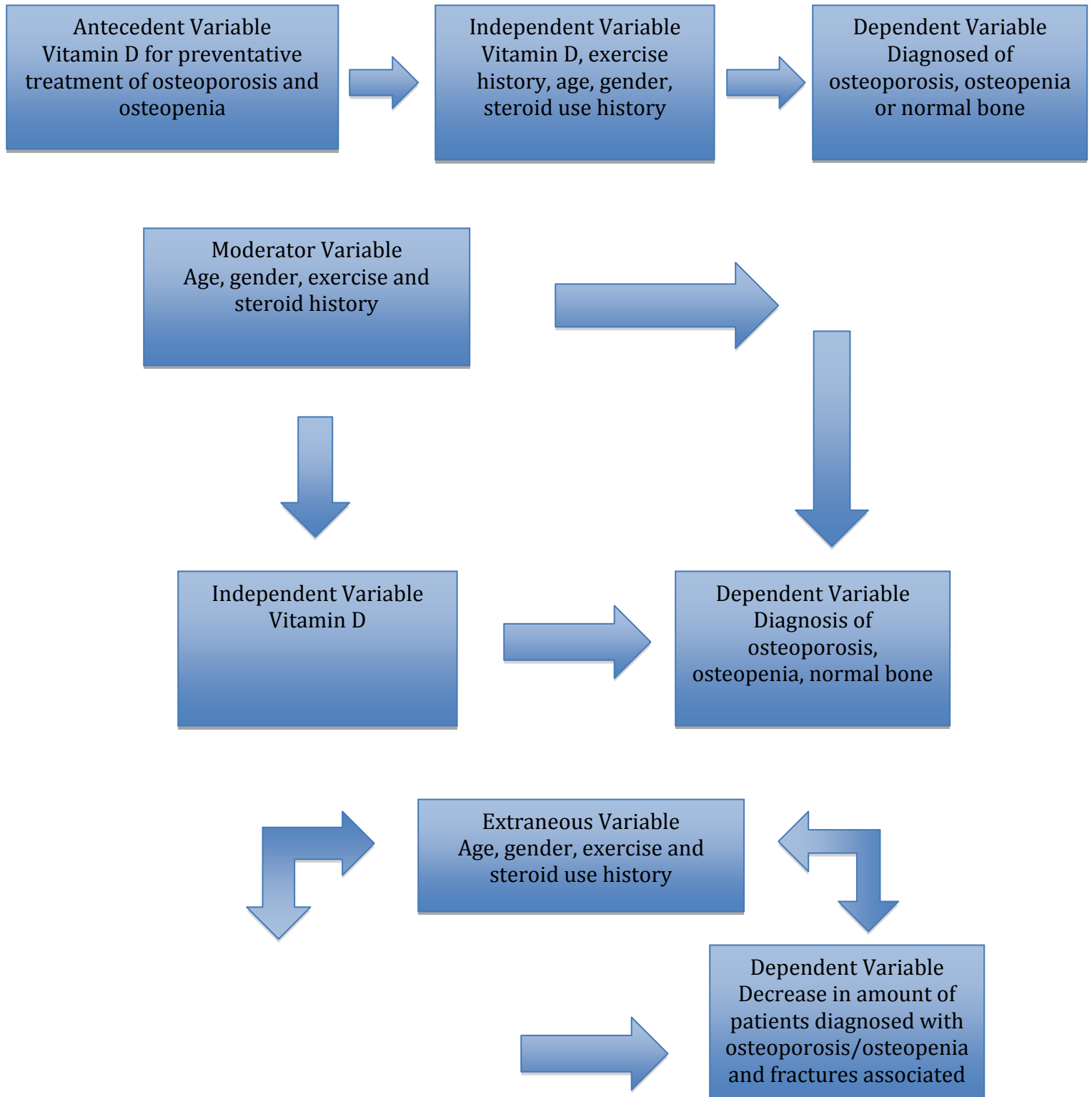


Dr. Theron Tilgner
297 S. Lake Havasu Ave, St. 108
Lake Havasu City, Arizona
86403

297 S. Lake Havasu Ave., Suite 108 • Lake Havasu City, AZ 86403
(928) 854-3333 • (928) 854-3335

Appendix F

Process Model



Appendix G

Key

POPE: Osteoporosis, osteopenia and normal bone

VITD: Vitamin D deficiency and normal lab

EXER: Exercise history

STER: Steroid use

AGE: Age in categories

GENDER: Gender male or female

Appendix H

Legend

1. Diagnosis (POPE):

Osteoporosis=0

Osteopenia=1

Normal=2

2. Exercise (EXER):

No=0

Yes=1

Unknown=2

3. Steroid Use (STER):

No=0

Yes=1

Unknown=2

4. Gender (GENDER):

Male=0

Female=1

5. Vitamin D Levels (VITD)

Normal Lab=0

Vitamin d deficient=1

6. Age (AGE):

50-60=0

60-70=1

70-80=2

80-90=3

90+=4