OSTEOPOROSIS TREATMENT BASED ON FRACTURE RISK: A QUALITY OF CARE STUDY

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

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ABSTRACT

Osteoporosis is a condition that decreases bone density and is more commonly found in elderly women due to estrogen depletion. The decrease in bone density puts patients at risk for fragility fractures, or fractures with minimal impact, which can drastically alter patients' lives. Primary prevention of these fractures is the goal with pharmacologic therapy for osteopenia or osteoporosis. There are many treatment options for osteoporosis and most are considered cost effective for patients with high fracture risk due to decreased bone density. Treatment decisions for osteopenia or osteoporosis are now based upon a fracture risk assessment tool in addition to T-score values. Studies have demonstrated that adherence to pharmacologic therapy to decrease fracture risk and maintain bone density is an issue with the majority of patients. Most patients are not staying on treatment for greater than one year for a variety of reasons. A practice improvement project was conducted at an internal medicine private practice clinic that serves 10,000 patients in a Midwestern community. The project included retrospective chart reviews and key informant interviews in order to gain expanded knowledge of the issue and provide recommendations for improvement.

Results showed inconsistent documentation of patient treatment preferences and provider treatment decisions. Additional areas for improvement included patient and provider follow up of treatment decisions as well as patient education regarding the disease process and benefits of treatment. Results and recommendations for improvement were disseminated to providers at the clinic with feedback solicited. An electronic medical record change was implemented in order to improve documentation of treatment decisions regarding elevated fracture risk.

The results of the project may not be transferrable due to small sample size and area of focus at one Midwest clinic. However, themes regarding clinical decision-making and

documentation of osteoporosis treatment emerged that likely exist at other primary care clinics. Further research is needed in order to evaluate effectiveness of electronic medical record intervention at the clinic. Other opportunities for further research involve expanding the topic to larger healthcare organizations and other areas of the country for comparison.

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To my chair, Dr. Mykell Barnacle, I would like to thank you for your guidance and time that you dedicated to the project. Without your help and encouragement, the project would not have been possible. To my committee members, Dr. Tina Lundeen, Dr. Kelly Buettner-Schmidt, and Dr. Daniel Friesner; thank you for your time and expertise in the guidance and acceptance of my project.

DEDICATION

I would like to dedicate the completed dissertation to my father, Michael Lillestol. Your passion for the diagnosis and treatment of osteoporosis is what drove me to complete this practice improvement project.

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CHAPTER ONE. BACKGROUND AND SIGNIFICANCE

Osteoporosis Defined

Osteoporosis is a condition that decreases the density of bones resulting in weaker bones and greater risk of fragility fractures. Fragility fractures occur with less force than may be expected in the fracture of a normal bone, usually including falls from standing height or less. Risk factors for the development of osteoporosis include aging, estrogen deficiency, low calcium and vitamin D intake, and certain disorders (Bolster, 2015).

Fragility Fractures

Prevention of fractures from osteoporosis is imperative because they can devastate the lives of patients. One out of five of people who suffer a hip fracture die within a year of the fracture and the risk of death persists for up to five years following the fracture. Hip fractures often result in the loss of physical functioning and independence for patients. Thirty-three percent of patients are totally dependent for activities of daily living in nursing homes following hip fractures. Vertebral fractures can also dramatically change lives, leading to back pain, height loss, physical deformity, immobilization, increased time in bed, and reduced lung functioning. Not only can fragility fractures drastically alter lives, there is also a socioeconomic impact. Fragility fractures increase costs for hospital and surgical care and indirectly result in loss of productivity for patients with loss of independence and need of nursing home or institutional care. If actively employed, these fractures can result in a loss of workdays and productivity (International Osteoporosis Foundation, 2015). Osteoporosis and subsequent fractures can be reduced with adequate calcium and vitamin D intake, weight bearing exercise, and pharmacologic therapy (Bolster, 2015).

Dual-Energy X-ray Absorptiometry

Since patients with osteoporosis are usually asymptomatic until a fracture occurs, diagnosis is achieved with dual-energy x-ray absorptiometry (DXA) screening or with DXA confirmation after a fragility fracture. DXA measures bone mineral density (BMD) and providers can diagnose a patient with osteopenia or osteoporosis based on results. DXAs also predict fracture risk and can be used to monitor treatment response (Bolster, 2015).

Results of DXA scans are given using three values, T-score, Z-score, and fracture risk assessment score. T-scores represent the standard deviations that the patient's bone density differs from a young, healthy individual of the same sex and ethnicity with peak bone mass. T-scores of < -1.0 to > -2.5 signify osteopenia and ≤ -2.5 signify osteoporosis. Z-scores represent the number of standard deviations the patient's BMD differs from someone of the same age and sex. Z-scores should be used for children, pre-menopausal women, and men less than 50 years old. Z-scores ≤ -2.0 should be evaluated for secondary causes of bone loss. Historically, osteoporosis treatment decisions were based on T-score values alone, however, it has been realized in recent years that T-score values are not the optimal way to measure fracture risk, because many fragility fractures occur in people outside the T-score ranges, most occurring within the osteopenia range (Bolster, 2015). According to the National Osteoporosis Risk Assessment study, there were 2259 post-menopausal women who sustained fragility fractures and had a follow-up DXA scan one year later; 82% of these women had a T-score value above -2.5 and 67% had a T-score value above -2.0.

Fracture Risk Assessment Tool

The University of Sheffield developed the fracture risk assessment tool (FRAX) in 2008 to incorporate risk factors for osteoporosis with or without femoral neck BMD to calculate a

patient's 10-year risk of fragility fractures (Bolster, 2015). The decision for treatment of osteopenia is now based on FRAX scores in addition to T-score values. FRAX scores can be calculated either with or without BMD testing (DXA score).

Osteoporosis Guidelines and Screening Recommendations

According to the National Osteoporosis Foundation's "Clinician's Guideline for the Prevention and Treatment of Osteoporosis" (2014) patients with a total fracture risk of ≥ 20% or a hip fracture risk of ≥ 3% and a T-score value between -1.0 and -2.5 should have pharmacologic therapy recommended because it is considered cost effective for the primary prevention of fragility fractures. In addition to these recommendations, there are two other scenarios patients should be initiated on treatment. The first is if there is a prior or current history of clinical or asymptomatic vertebral fractures or hip fractures. In addition, if a patient's T-score is below -2.5, treatment should be initiated unless otherwise contraindicated (Cosman et al, 2014).

According to the United States Preventative Services Task Force (USPSTF) (2016), screening for osteoporosis using DXA scans is recommended for women greater than 65 years of age. Women 50-64 years old should have DXA screening recommended if their FRAX score is greater than or equal to 9.3%. The reason for the 9.3% is that the fracture risk is equal to a 65-year-old woman who has no additional risk factors. There is currently no recommendation for osteoporosis screening in men. Currently, the USPSTF (2016) has no recommendation for frequency of DXA rescreening due to lack of sufficient evidence. The interval for rescreening should be based on clinical judgement, but the American Family Physician's guidelines entitled, "Diagnosis and Management of Osteoporosis" (2015) recommend screening no more than every one to two years. The recommendations by the USPSTF (2016) are graded level "B", meaning that clinicians should recommend or provide the service based on high certainty that the net

benefit for the population is moderate. The USPSTF determines the net benefit based on available evidence that is sufficient to determine the effect of the recommended service, however, confidence is constrained due to factors such as the sample size, quality, or quantity of studies, inconsistency of results from studies, limited generalizability to primary care, or lack of coherence among the evidence (USPSTF, 2017).

Project Introduced

Many patients think of osteoporosis as a "silent disease" and do not see the benefit in receiving medication for primary fragility fracture prevention. Adherence to pharmacologic therapy remains the largest treatment issue for providers. Studies have demonstrated that after one year of therapy only 40% of patients remain on the medication and after two years only 20% remain on the medication (International Osteoporosis Foundation, 2015a).

For the practice improvement project, attention was focused on an independent internal medicine clinic serving around 10,000 patients in a Midwestern community. Retrospective chart reviews and key informant interviews were conducted to identify treatment patterns of patients with significant fracture risk (≥ 3% hip fracture risk and or ≥ 20% major fracture risk). The focus of the project was to increase awareness of providers and identify contributing factors to inadequate treatment in the targeted population. Providers at the participating clinic were included in the project, with the goal of inspiring sustainable change and improvement in osteoporosis management, ultimately decreasing morbidity and mortality of affected patients.

Significance of Practice Improvement Project

If patients with significant fracture risk are not receiving pharmacologic therapy, they may have an increased risk of fragility fractures, which can ultimately decrease their quality of life and increase mortality. The overall purpose of the practice improvement project was to

increase awareness of the lack of pharmacologic treatment of patients with significant fracture risk or identify patterns in current osteoporosis treatment and barriers to optimal osteoporosis management to providers at an independent internal medicine clinic that serves 10,000 patients in a Midwestern community. The goal is that with the awareness and recommendations for improvement the providers will make future practice changes and increase the proportion of patients on treatment.

Congruence of the Project to the Organization's Strategic Goals

The internal medicine clinic where the project was conducted specializes in internal medicine services for the adult patient. The clinic staff provides primary, preventative and specialty services. One of the clinic's commitments to their patients is, "We'll offer a preventive approach to help you achieve and maintain the highest quality of health possible for you." With the commitment in mind, prevention of fragility fractures from osteoporosis is something that is taken very seriously within the organization.

In discussion with one of the clinic's physician owners who has a strong interest in osteoporosis, a project focusing on osteoporosis management was one of high importance. The clinic's office manager was also a very important part of the project and contributed by providing the researcher with necessary access and data throughout all stages of the project.

Project Objectives

Objective One: Complete a retrospective chart analysis to determine gaps, barriers, and successes related to osteoporosis management at an internal medicine clinic in a Midwestern community.

Objective Two: Conduct key informant interviews with healthcare providers to supplement chart analysis findings regarding osteoporosis management.

Objective Three: Develop recommendations for improvement based upon retrospective chart analysis and key informant interviews.

Objective Four: Disseminate the findings of chart reviews and key informant interviews to providers at the internal medicine clinic and provider recommendations for improvement.

Objective Five: Implement an electronic medical record (EMR) change in order to improve documentation of non-treatment reasons and/or improve the proportion of patients receiving treatment in the future.

CHAPTER TWO. THEORETICAL FRAMEWORK

Theory of Power as Knowing Participation in Change

Nursing theories have many important implications for practice, including but not limited to furthering theory development, providing perspective about certain human behaviors, a means to interpret data, and they are inherently useful for guiding practice (Peterson & Bredow, 2013). The theory chosen to guide the project is the Theory of Power as Knowing Participation in Change by Dr. Elizabeth Barrett (2009). The theory defines power as "the capacity to participate knowingly in change as manifested by awareness, choices, freedom to act intentionally, and involvement in creating change (Barrett, 2009)." The definition also includes the theory's four dimensions of power. The theory also differentiates two types of power, power-as-control and power-as-freedom. Power-as-control is grounded in the laws of cause and effect and characterized by being hierarchal and predictable. Power-as-control is of finite quantity, in contrast to power as freedom, which is an open universe where power is not of finite quantity. Power-as-freedom is characterized by innovation, openness, and unpredictability. There are numerous examples of how knowledge is utilized in the world for both freedom or control, for example, money can be used in order to control others in a form of power, or it can be used for freedom such as charitable giving. In the same ways, power can be used for both control and freedom. Dr. Barrett defines power as the ability to participate knowingly in change; she sees power as a process to be lived rather than something to be acquired (Barrett, 2009).

The theory was chosen to guide the project because it involves an attempt to create change in a healthcare establishment to improve osteoporosis management. With Dr. Barrett's theory to guide the project, we can help more fully understand what we need to have the power to change knowingly. Through the needs assessment that was conducted at the internal medicine

clinic, the awareness portion of the theory was achieved by disseminating results of the chart analysis and interviews to the health care providers at the clinic. Providers at the clinic are committed to high-quality patient care, so a needs assessment, which reveals suboptimal osteoporosis care, would be important information to spur practice change. Through the needs assessment, information was gathered, identifying possible reasons for patients not receiving treatment. The findings were presented to the providers. The dissemination leads to the choices portion of Dr. Barrett's theory. The choices included the recommendations for improvement presented to providers. Freedom to act intentionally involves the providers at the clinic actively making the choice to change their practice based on these choices. The last portion of the theory revolves around creating change, which will come to fruition when providers actually make changes to their practice based on the choices and freedom to act intentionally. Dr. Barrett's theory was very beneficial for the guidance of the project. A breakdown of how the theory was used to guide the project can be found in figure 1.

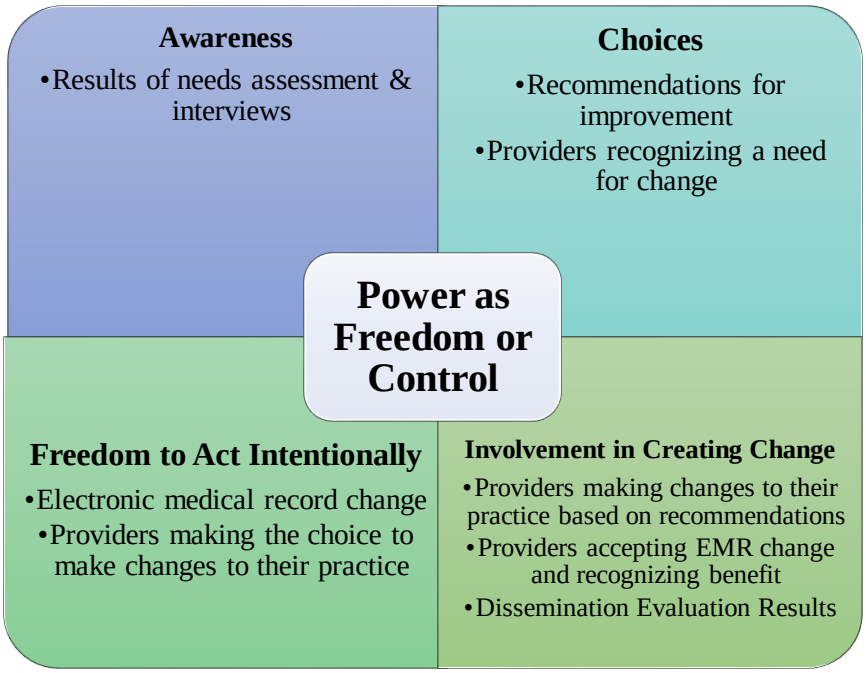

Figure 1. A graphic representing the application of Dr. Barrett's Theory of Power as Knowing Participation in Change.

CHAPTER THREE. LITERATURE REVIEW

Adherence to Treatment

The International Osteoporosis Foundation (2015) reports osteoporosis as the cause of more than 8.9 million fractures annually which equates to one fracture every three seconds. One out of three women over the age of 50 will experience an osteoporotic fracture as well as one out of five men the same age. A critical aspect of osteoporosis management is identifying and treating patients who are at the highest risk for fractures before they have sustained one. Successful osteoporosis management reduces the risk of first time fracture in 5 years from about 34% to 10%. Osteoporosis treatment to prevent fractures is a difficult task for many reasons, including cost, side effects, patient perception of efficacy and safety, perceived lack of benefit, preference of "natural" treatment in calcium and vitamin D, and complicated dosing instructions (Warriner & Curtis, 2009).

Another major reason behind the lack of pharmacologic treatment of osteoporosis is a generalized low public awareness of the morbidity and mortality associated with untreated osteoporosis and subsequent fragility fractures. In a review by Harvey et al. (2017), three areas of public awareness in relation to osteoporosis were identified as in need of improvement. The areas in need of improvement for the public were the importance of adherence to treatment, osteoporosis diagnosis and fracture risk, and benefits versus risk of pharmacologic treatment. Public awareness of the potential morbidity and mortality risk of untreated osteoporosis is another area that needs to be addressed to increase the overall adherence and acceptance of pharmacotherapy for patients with fracture risk.

There are a wide variety of treatment options for osteoporosis, which can reduce risk of vertebral fractures by 30 - 70%, non-vertebral fractures by 15 - 20%, and hip fractures by 40%.

The treatment options are cost effective and have proven rapid efficacy for prevention of these fractures. However, poor compliance is one of the main issues with treatment (International Osteoporosis Foundation, 2015a). A study by Zwaard et al. (2017), demonstrated that after one year of therapy, only 75% of patients remain on the medication and after five years of therapy only 45% remain on treatment. According to the study, the main reasons associated with patients not persisting with therapy included age less than 65 and a specialist being the main prescriber. The patients with a general practitioner as the main prescriber were more persistent with treatment (45%) than those with a specialist main prescriber (39%) after five years of therapy (Zwaard, 2017). The study demonstrates the importance of primary care providers being comfortable with the screening and management of osteoporosis as it has been associated with better adherence to treatment by patients.

An article by LaVallee et al (2016), titled "The Challenges in the Screening and Management of Osteoporosis" further explores possible reasons that patients may not be prescribed appropriate pharmacologic management for osteoporosis. There is a lack of confidence among primary care providers when it comes to determining patients needing pharmacologic therapy and how long to treat the patient with increased fracture risk. The decision regarding length of therapy was further complicated when information about possible risks of atypical femur fractures and osteonecrosis of the jaw were released, as these risks indicated a need for drug holidays from the commonly used bisphosphonates. The length and choice of therapy is an especially difficult problem to address because of the lack of access to specialty care since osteoporosis is such a common disease process. Primary care providers also seem to struggle with the interpretation of DXA scan results and recommending the proper course of treatment (LaVallee et al., 2016). Overall, primary care providers need to become more

comfortable and confident in the screening and management of osteoporosis if we want our patients to adhere to treatment.

Several patient factors also contribute to the lack of pharmacologic therapy for the treatment of osteoporosis. These include a lack of understanding of the disease process, concern over using medication to treat a "silent" disease to prevent a possible future outcome, concern over possible side effects of the medication, and the cost of therapy. First, patients have a generalized poor understanding of the possible morbidity and mortality associated with untreated osteoporosis. It is up to providers to educate patients about the disease process as well as possible consequences of fragility fractures. Unfortunately, even after such discussions patients often still chose to "wait and see", treat with diet and exercise, or refuse treatment altogether (LaVallee et al., 2016).

Many patients have a hard time buying into the use of another medication to treat a disease that they feel is "silent" in nature. The patient decision to treat is especially difficult in the elderly who may already be taking many medications. These patients often believe that they can treat osteoporosis with diet and exercise alone and refuse the pharmacologic therapy. Often, having conversations with patients regarding the maintenance of independence and quality of life carries more weight than quoting statistics about morbidity and mortality (LaVallee et al., 2016).

Pharmacologic Treatment Options for Osteoporosis

There are many different treatment options for osteoporosis management. Bisphosphonates are the most commonly used agents. The reasons that bisphosphonates are used first-line and most commonly is because many insurance companies require that patients fail bisphosphonates or have a medical reason why the medications should not be utilized for that patient prior to covering the other types of treatment modalities. Bisphosphonates inhibit the

bone resorption activity of osteoclasts by attaching to hydroxyapatite binding sites located on bony surfaces (Rosen, 2017). They are available orally or intravenously and depending on the agent can be dosed daily, weekly, monthly, four times a year, or annually. The most common side effects from oral bisphosphonates are related to gastrointestinal issues such as esophageal ulcerations, perforations, and bleeding events. The medications must be taken with water and the patient must sit up for at least 30 minutes after taking the medication or taking in any other medication or food. Taking the medications this way reduced the risk of gastrointestinal upset and allowed for effective absorption. Other common side effects from these medications include muscular and joint pain (Jeremiah et al., 2015). The bisphosphonate agents include alendronate, risedronate, ibandronate, and zoledronic acid.

There are questions concerning length of therapy associated with bisphosphonates. Limited trial data is available for the long-term management with bisphosphonates. The length of treatment becomes more important and challenging with newly recognized rare side effects of bisphosphonates including osteonecrosis of the jaw and atypical femoral fractures (Bethel et al., 2017). The risk of these side effects is very rare, the estimated risk of osteonecrosis of the jaw for patients treated with zoledronic acid is 0.017 - 0.04% compared to placebo group risk of 0 - 0.02% (Ruggiero et al., 2014). Malden et al. (2012) derived an incidence of osteonecrosis of the jaw after exposure to oral bisphosphonates as 0.4 cases per 10,000 patient years. The risk of osteonecrosis of the jaw was more common when these medications were used to treat different types of bone cancer, when used for the treatment of osteoporosis at much lower doses, the risk was very rare (Udell, 2017). The risk of atypical femoral fractures is 0.13% in the following year in patients who have been treated for at least 5 years (Park-Wyllie et al., 2011).

Despite the rarity of these side effects, they have received a large amount of media focus (LaVallee et al., 2016). For these reasons, the American Society for Bone and Mineral Research (2016) published guidelines for long-term bisphosphonate treatment with the following recommendations. Reassessment of risk should be assessed after five years of oral or three years of injectable bisphosphonate therapy. Women considered high risk (older age, low hip T-score, high FRAX score, previous fragility fracture, fracture while on therapy) should continue treatment for up to ten years with oral agents or six years with intravenous agents with periodic reassessment. The risk of atypical femoral fracture and osteonecrosis of the jaw increases with the duration of therapy, but the rare event risk is outweighed by the benefit of fragility fracture risk reduction in high-risk individuals. Lastly, women not at high fracture risk should have a drug holiday of 2-3 years after 3-5 years of bisphosphonate therapy (Adler et al., 2016). As you can see, even though these side effects are considered rare, there are guideline recommendations in place to help providers minimize these risks as much as possible. Patients need to be aware of these recommendations and the research behind them so that they can be fully informed about their treatment decisions.

Selective estrogen receptor modulators (SERM) are another agent used in the treatment of osteoporosis. Raloxifene (Evista) selectively binds to estrogen receptors producing estrogenic and anti-estrogenic effects, it acts as an estrogen agonist in bone decreasing bone resorption and turnover (Epocrates, 2017). Raloxifene is an oral SERM agent approved for the use in osteoporosis management and is dosed once daily. Raloxifene has demonstrated a 35% reduction in risk of vertebral fractures in clinical trials and seems to be most useful in younger postmenopausal women. Raloxifene has been shown to increase risk of deep vein thrombosis, stroke, and hot flashes (Bethel et al., 2017).

Teriparatide (Forteo) is synthetic parathyroid hormone that is used in the treatment of osteoporosis in patients with high fracture risk who are intolerant to other osteoporosis therapy, or whom previous osteoporosis therapy has failed to increase BMD. Teriparatide is a daily injection administered subcutaneously. Teriparatide works in osteoporosis management by regulating bone metabolism, intestinal calcium absorption, and reabsorption of renal tubular calcium and phosphate (Epocrates, 2017). Teriparatide cannot be given for more than 2 years. After 2 years, the gains in BMD have been achieved and are secure. Longer treatment would result in the BMD regressing to pre-treatment levels. After the 2-year course of treatment, patients can be augmented with bisphosphonate therapy (Bethel et al., 2017).

Calcitonin-salmon (Fortical, Miacalcin) decreases osteoclast activity, inhibiting bone loss. It is indicated for the treatment of osteoporosis in women who are more than 5 years post-menopausal and have low bone mass. Calcitonin should be reserved for those who refused, cannot tolerate, or contraindicated for estrogen use. The drug is dosed daily as an intranasal spray (Bethel et al., 2017). In 2013, the United States Food and Drug Administration (FDA) showed an increased risk of malignancy in calcitonin treated patients. The data from the study was not sufficient to further analyze by the type of malignancy associated and a definitive causal relationship between calcitonin and malignancy could not be established. The FDA now recommends that health care providers assess each patient's need for osteoporosis therapy and weigh the risks versus benefits (United States FDA, 2015). Also, it has been demonstrated that calcitonin is not as potent or effective as other therapies for the treatment of osteoporosis (Epocrates, 2017). For these reasons, calcitonin is no longer commonly used in the treatment of osteoporosis.

Denosumab (Prolia) decreases bone resorption by inhibiting the activity of osteoclasts reducing bone resorption and turnover (Epocrates, 2017). Denosumab is indicated for increasing bone mass in men and post-menopausal women with osteoporosis. In particular, denosumab is indicated in those who have a high FRAX score, previous fragility fracture, multiple risk factors for fracture, those who are intolerant to other therapies, or who have failed other therapies. Denosumab is dosed subcutaneously every six months in the upper arm, upper thigh, or abdomen. Denosumab also can be used in those with renal insufficiency (Bethel et al., 2017).

Treatment Modality and Role in Adherence to Therapy

The type of treatment modality used for osteoporosis management plays a large role in patient adherence. One study by Durden et al. (2017), found that patients initiated with injectable therapy (34 - 41%) had greater persistence and adherence in a two-year period than those initiated with oral agents (20 - 31%). Patients who were receiving every 6-month injections had a statistically significantly higher adherence than those who were dosed more frequently, such as daily or weekly, whether it was oral or injectable agents. The study demonstrates the willingness of patients to adhere to treatment modalities that are less intrusive to their daily lives. The study also exhibits that patients feel a sense of accountability going to the clinic to receive injections that can increase compliance. Unfortunately, many of the treatment modalities that are dosed less frequently are more expensive. However, as more of injectable therapies become generic in the years to come they will be much more of a consideration (Durden et al., 2017).

Cost of therapy is another contributing factor why patients are not adherent to osteoporosis therapy. The most common therapy choice for osteoporosis is oral bisphosphonates. The main reason for the preference is that they are the most effective and best-tolerated therapy available in generic form, ultimately decreasing the cost. Also, as mentioned previously, many

insurance companies require that a patient fail these medications or have a medical reason not to utilize them prior to covering the more expensive therapies. Teriparatide and denosumab are becoming preferred treatment options for many patients and providers, however, the cost remains prohibitive. Teriparatide costs on average $2,855.87 for a 4-week supply and denosumab costs $1,132.96 on average every 6 months (GoodRx, 2017). Patients may be unwilling to pay these prices and reluctant to receive therapy. The biggest issue is for those on Medicare Part D who have met their limit for the year and find themselves in the "donut hole," in which they must pay for prescriptions out of pocket. Prior authorizations can be done to attempt to improve insurance coverage of these therapies, however, prior authorizations can be very time consuming and burdensome to providers. (LaVallee et al., 2016). Other conditions that immediately impact their health and quality of life may take priority in those situations.

Osteoporosis is a disease that can adversely affect patients' quality of life and increase mortality due to fragility fractures. Many issues remain for the treatment of osteoporosis to prevent these fractures. Increased awareness of these issues and improved confidence among primary care providers in the screening and management of osteoporosis can greatly impact the burden of osteoporosis for patients.

Osteoporosis Quality Indicators

The quality of osteoporosis management can be largely assessed by DXA screening rates at baseline for women >65 and DXA screening for those at-risk within 6 months of a fragility fracture (Cadarette et. al, 2010). Also included in osteoporosis quality assessments are the following: Treatment rates for those that meet diagnostic criteria for osteoporosis (T-score ≤ -2.5), those who have sustained a fragility fracture, and osteopenia patients who have high fracture risk based on the FRAX assessment tool (National Guideline Clearinghouse, 2013). To

assess quality of diagnosis and treatment of osteoporosis, the National Committee for Quality Assurance (NCQA) started tracking bone density measuring rates for women 65-85 on Medicare ever receiving a DXA scan. Most recently, in 2016 the rate for Health Maintenance Organization (HMO) Medicare was 73.8% and Preferred Provider Organization (PPO) Medicare was 79.3%. The NCQA also tracks osteoporosis management in women who have had a fracture. Testing and treatment of osteoporosis post-fracture is an in need of vast improvement in the field. Most recently, in 2016, the rate for HMO Medicare was 41.9% and PPO Medicare was 34.2%. The rates of baseline screening and post-fracture screening and treatment have significantly improved since initiation of these quality indicators, however, there is still need for improvement in both areas (NCQA, 2017).

CHAPTER FOUR. DESIGN AND IMPLEMENTATION

Initial Patient Population

In order to determine whether a project regarding osteoporosis treatment would be valuable, an initial EMR review was conducted by the office manager at the internal medicine clinic. The purpose of the review was based upon the impression of providers that patients with osteoporosis and treatment indications were not on sufficient pharmacologic therapy. A search of clinic patients who have had DXA scans was conducted for those that met the treatment guidelines of greater than or equal to 3% hip fracture risk or greater than or equal to 20% total fracture risk. The search was further narrowed down to those on treatment for osteoporosis and those who are not. The search revealed that of the internal medicine clinic's 286 patients who met the above criteria, only 137 (47.9%) patients were on treatment for osteoporosis. See figure 2 for depiction of these results.

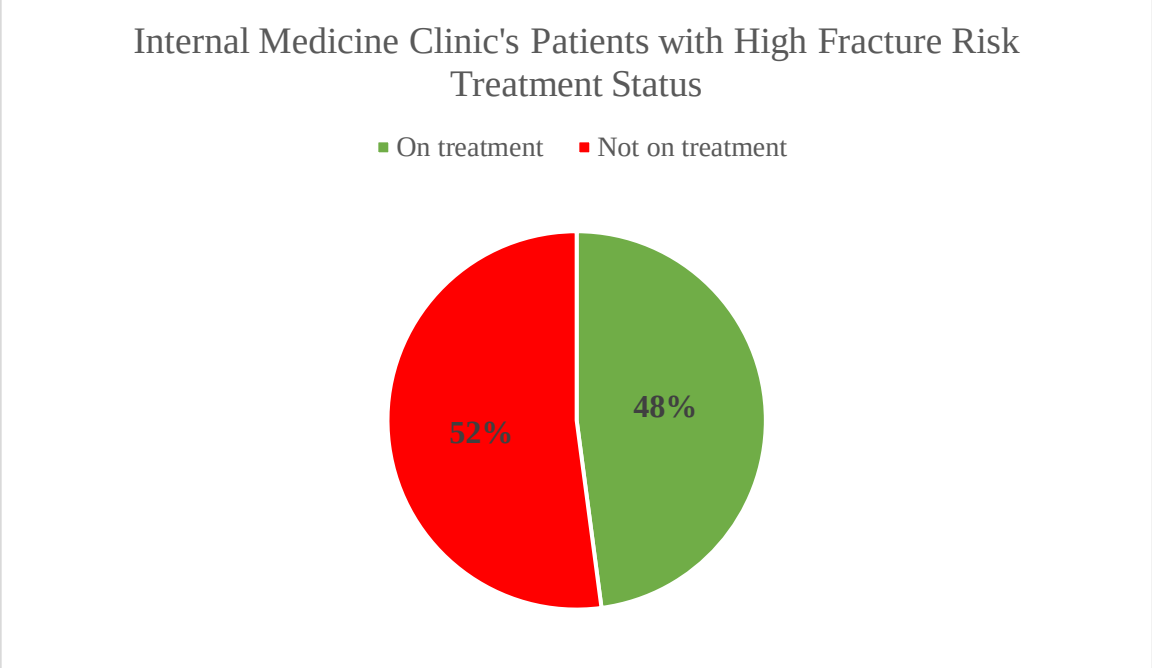

Figure 2. Internal medicine clinic patients with significant fracture risk treatment status for osteoporosis.

Methods

To further evaluate these findings, a retrospective data analysis was performed. Chart reviews were completed to attempt to identify the reasons most of the internal medicine clinic's patients with significant fracture risk are not receiving therapy for osteoporosis. EMRs were utilized in order to perform retrospective chart reviews.

Sample

The sample for these chart reviews was determined by an initial EMR review conducted by the clinic manager at the internal medicine clinic. It consisted of 149 patients at an internal medicine clinic in a Midwestern community with high fracture risk (≥ 3% hip fracture and/or ≥ 20% overall fracture risk) based on their most recent DXA scan that were not on pharmacologic therapy. The number of charts that needed to be reviewed to get an accurate sample for the whole population was determined by Don Dillman's *Mail and Internet Surveys, the Tailored Design Method* (2000). Based on the method, to get an accurate sample size of 149 charts (the number of patients not on treatment), 106 charts needed to be reviewed. The sample was selected via random sampling. One hundred and six charts provided an effect size of 50 - 50, 5% sampling error, and a 95% confidence interval.

Data Collection

The clinic has used the Centricity EHR system for eight years, which was the period that was reviewed as part of the retrospective chart review. Retrospective data prior to the implementation of the EHR system was not evaluated. Random sampling was achieved by putting all patient medical record numbers in numerical order and then reviewing every third chart in that order. In total, seven different providers' patients were included in the sample. No data was collected regarding how many patients per provider as it was considered identifiable

information. It can be assumed that no one provider was overrepresented in the sample, as each provider had approximately equal distribution of patients included.

Certain information was collected during the chart review process. Basic demographic data and FRAX criteria were collected. The demographic data included age, gender, height, weight, previous fracture, parental hip fractures, smoking status, glucocorticoid use, rheumatoid arthritis history, secondary osteoporosis status, alcohol usage, and femoral neck BMD (Centre for Metabolic Bone Diseases, 2017). Other data collected included which medications, if any, the patient had previously been on for osteoporosis, length of previous therapy for osteoporosis, insurance status, date of most recent DXA scan, and fracture risk and T-score from that scan. The reasons for patients not being on pharmacologic therapy for osteoporosis was separated into the following categories: 1) cost, 2) perceived lack of efficacy, 3) preference for "natural" treatment, 4) not clinically appropriate, 5) patient preference, 6) experienced side effects, 7) switch to alternate therapy, 8) drug holiday without restart, 9) lack of provider/patient follow up, 10) provider recommended calcium and Vitamin D treatment, 11) patient concern over side effects, 12) no recent annual exam, and 13) no recent DXA scan. Additionally, data was collected regarding whether or not the patient was offered pharmacologic therapy per documentation in the EMR.

Two interviews were conducted with healthcare provider key informants at the clinic to further evaluate the provider perspective on the issue. The first interview was with the key stakeholder physician who is an osteoporosis advocate within the clinic and the second informant was a physician assistant who specializes in women's health in the same clinic. The interviews lasted approximately 15 minutes each. The questions asked during the interview process can be viewed in Appendix A.

Evidence-Based Intervention

A meeting for the internal medicine clinic's providers to attend was hosted. The results of the retrospective chart reviews and key informant interviews were presented at the meeting. Based on the results, a list of recommendations for improvement of treatment rates for patients with significant fracture risk was presented at the meeting. Adequate time for questions and discussion was provided. Not all the providers were able to attend the meeting, so an email was also sent following the meeting including the results of the EMR reviews and interviews with recommendations for improvement as well as topics that were discussed and relevant questions addressed at the meeting. After the presentation, an EMR change was implemented in order to improve documentation of non-treatment reasons and improve treatment rates of patients with significant fracture risk. The change is encountered when providers enter "Osteoporosis" or "Osteopenia" in the assessment section of patient visit notes. Once the diagnosis is selected, a patients' most recent DXA information is auto-populated into the note, a patient's current osteoporosis treatment plan is also populated and a pop-up window for the provider to select a patient's treatment status and reasons for non-treatment. The provider then chooses the appropriate response for the situation and the data is populated into the note.

Timeline of Project Phases

Chart reviews were completed in August-September 2017. Key informant interviews were completed in January 2018. Statistical analysis of results was completed in January 2018. The written dissertation was completed in February 2018. Dissemination to providers was completed in March 2018. Defense of the dissertation was completed in March 2018.

Resources

The main resource that was utilized for the project was the internal medicine clinic's EMR system. The system utilized is Centricity. The office manager provided EMR access for the researcher could complete the retrospective chart reviews. Access to providers at the clinic was also necessary for key informant interviews and dissemination of results. No budget was necessary for the project.

Logic Model

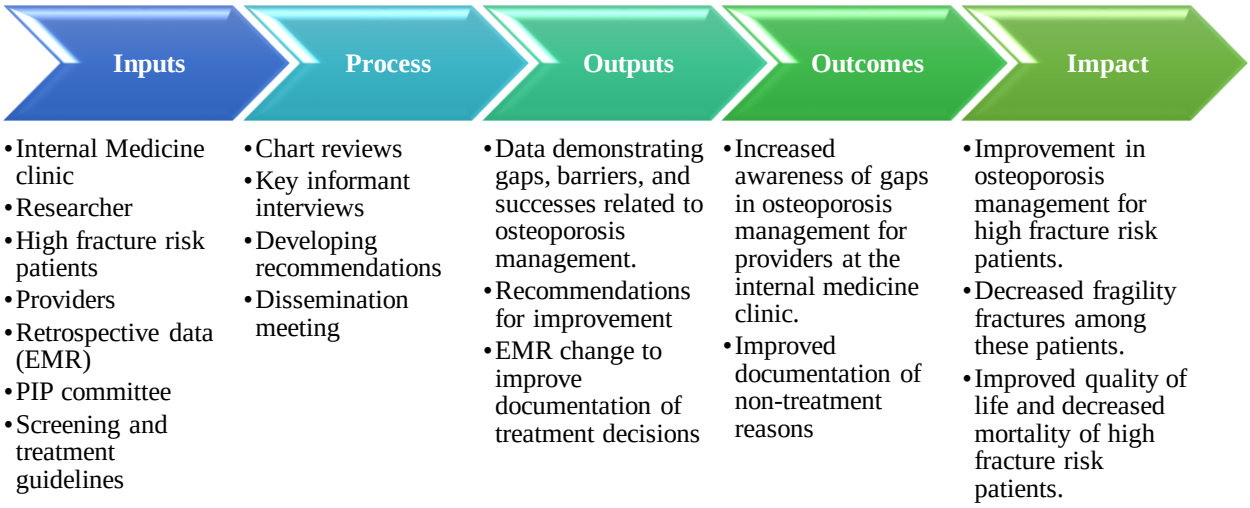

Figure 3. A logic model representing the evaluation plan.

Evaluation of Objectives

Objective One: Complete a retrospective chart analysis to determine gaps, barriers, and successes related to osteoporosis management at an internal medicine clinic in a Midwestern community. Demographic data, FRAX criteria, and DXA scan results were collected along with

details regarding previous pharmacologic therapy used and reasons for no treatment or discontinuation of therapy.

Objective Two: Conduct key informant interviews with clinic personnel to supplement chart analysis findings regarding osteoporosis management. Key informants included two providers at the internal medicine clinic and lasted approximately 15 minutes each. See Appendix A for questions asked during key informant interviews. Findings were written up in a question and answer format and evaluated for themes and differences.

Objective Three: Provide recommendations for improvement of osteoporosis management based upon retrospective chart analysis and key informant interviews. Recommendations for improvement were given to providers at the internal medicine clinic during the dissemination of results meeting. Feedback was asked of providers on practicality of recommendations and discussion encouraged. Evaluation was achieved utilizing the Dissemination Evaluation form that can be found in Appendix D.

Objective Four: Disseminate the findings of chart reviews and key informant interviews to providers at the internal medicine clinic. The dissemination process occurred in a 30-minute meeting with providers from the internal medicine clinic as well as be sent out via email form for providers unable to attend.

Objective Five: Implement an EMR change in order to improve documentation of non-treatment reasons and/or improve the proportion of patients receiving treatment. Feedback from providers was asked at the dissemination meeting regarding the change and perceived benefit.

Protection of Human Subjects

The participants in the project included 286 internal medicine clinic patients who had significant fracture risk. These participants were not directly involved in person for any portion

of the project. The project consisted of chart reviews, interviewing healthcare provider key informants, disseminations of results, and recommendations for improvement. The biggest risk to participants in the project was confidentiality since private health information was reviewed.

There was no recruitment of subjects for the project. Since the project consisted of retrospective chart reviews of existing data with minimal risk to subjects, informed consent was waived. The research did not adversely affect the rights or welfare of participants involved. Risk to participants was minimized by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Privacy Rule. The researcher received formal training under the act and operated under the constraints of the rule. No identifiable private health information was utilized for the purposes of the project and no HIPAA violations were encountered during any portion of the practice improvement project.

The purpose of the project was to examine and bring awareness of the lack of pharmacologic therapy in patients with significant fracture risk to providers at the internal medicine clinic as well as implement an EMR change to improve documentation of treatment decisions. The goal was that with the increased awareness and EMR change, providers would changes to their practice based on recommendations suggested. If the percentage of patients with significant fracture risk on pharmacologic therapy increases, there may be fewer fragility fractures, which should increase quality of life and decrease mortality among the population.

Since osteoporosis is a disease found more frequently in women, they were included in the project. Minorities were also included in the project sample; however, race and ethnic data were not collected for any portion of the project. Since the project only involves chart reviews, interviews with healthcare provider key informants, dissemination of results, and recommendations for change the risk to women and minorities was minimal. Since the internal

medicine clinic utilized for the project specializes in providing internal medicine services for the adult patient, there were no children included in the project.

Approval for protocol #PH17267 was received on July 27, 2017 from the North Dakota State University Institutional Review Board. The approval letter can be found in Appendix C. The project fell under the expedited review category for North Dakota State University.

Disclosure of Relationships

The researcher involved in this project had vested interest in the clinic involved. Upon completion of her graduate degree, she will be working in the clinic where the project took place. The key stakeholder physician involved in this project is the researcher's father. Because a retrospective review of EHR data was the primary point of interest for the study, it is unlikely that this relationship influenced the results. The key stakeholder physician owns a pharmaceutical research company which researches medications utilized in the treatment of osteoporosis. Although, it is unlikely that many of these research participants were included in this study, it is possible and could influence the results. The key stakeholder physician is perceived as a local expert in the field of osteoporosis management for the community in which the project took place. He has over 35 years of experience in the diagnosis and treatment of osteoporosis. With this expertise in mind, it was felt to be valuable for the physician to serve as a key informant for the project. All of these factors could have played a role in the perception of this practice improvement project and therefore must be disclosed.

CHAPTER FIVE. RESULTS

Sample

The sample for the project was pre-determined by the internal medicine clinic's initial chart query. The initial population data can be seen in the project design section of the paper. The total sample population was 286 patients with increased fracture risk (total fracture risk of ≥ 20% or hip fracture risk of ≥ 3%). Since the project was focused on identifying reasons patients are not receiving pharmacologic therapy, chart reviews were limited to those not currently on treatment. Based on Don Dillman's *Mail and Internet Surveys, the Tailored Design Method,* to get accurate data in a sample size of 149, 106 charts were reviewed (2000). One hundred and six charts provided an effect size of 50 - 50, 5% sampling error, and a 95% confidence interval. Random sampling was utilized in order to decide which charts were to be reviewed. Table 1 provides a breakdown of the basic demographic data collected from retrospective chart reviews of the population.

Table 1
Demographic data for retrospective chart reviews

Total (N)	286
Total on pharmacologic therapy	137 (47.9%)
Total not on pharmacologic therapy	149 (52.1%)
Distribution male vs. female	Male – 12 (8.1%) Female – 137 (91.9%)
Age	78.04 $\bar{x}$ Range 57 - 92 7.88 s
Insurance Provider	Medicare – 101 (95.3%) Private Insurance – 3 (2.8%) Medicaid – 1 (0.9%)
Body Mass Index	26.90 $\bar{x}$ Range 16.37 – 44.40 5.12 s

Retrospective Chart Review Results

Each chart was reviewed and most recent DXA scan results were collected including Femoral Neck BMD, T-score, and FRAX scores. Table 2 provides a breakdown of the average scores for the sample of charts reviewed.

Table 2
DXA scan distribution results for sample of patients reviewed

DXA Result Component	Average	Range	Standard Deviation
Femoral Neck BMD	0.73 g/cm2	0.48 g/cm2 - 0.892 g/cm2	0.08 g/cm2
Femoral Neck T-score	-2.2	(-1.0) – (-3.4)	0.53
Overall Fracture Risk	18.37%	8.20% - 37.50%	0.06
Hip Fracture Risk	5.69%	2.60% - 27.30%	0.04

In order to understand the data more fully, the patient distribution of osteopenia diagnosis versus osteoporosis diagnosis can be viewed in Figure 4. Seventy-two percent of patients were diagnosed with osteopenia and 28% with osteoporosis based on T-score values.

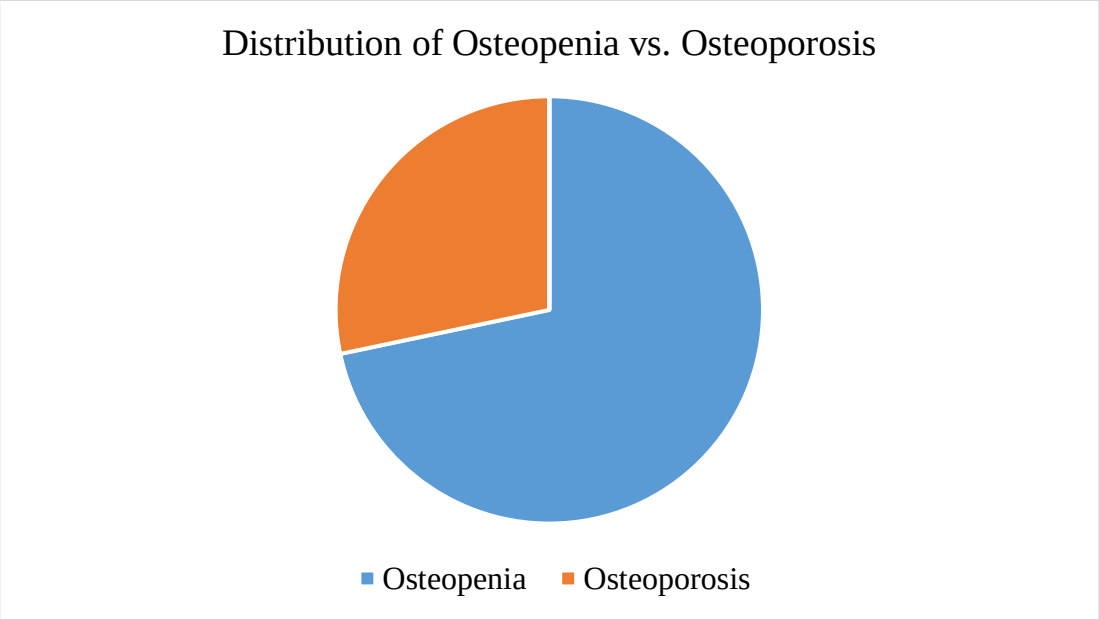

Figure 4. Sample distribution comparison of patients with osteopenia vs. osteoporosis based on T-score

FRAX criteria were collected during chart reviews including, previous fracture, smoking status, parental hip fracture, secondary osteoporosis, glucocorticoid use, rheumatoid arthritis history and alcohol use. FRAX criteria information can be located in Tables 3 and 4.

Table 3
Other FRAX criteria of patient sample

Variable N=106	Yes		No	
	n	Percentage	n	Percentage
Previous Fracture?	35	33.02%	71	66.98%
Parental Hip Fracture?	6	5.66%	100	94.34%
Glucocorticoid Use	6	5.66%	100	94.34%
Rheumatoid Arthritis History	4	3.77%	102	96.23%
Alcohol (≥ 3 U/day)	1	0.94%	105	99.06%

Table 4
Smoking Status of patient sample

Never		Current		Former	
		N=106			
n	Percentage	n	Percentage	n	Percentage
77	72.64%	6	5.66%	23	21.70%

During chart reviews, information was collected regarding medications patients have utilized previously for osteoporosis treatment. The average number of medications previously used for the sample was 0.519 with a range of 0-4 and a standard deviation of 0.831. Many patients in the sample studied had never utilized treatment previously so that is why the average is less than 1. To further evaluate these findings each individual medication patients had utilized previously was listed and the distribution of different medications utilized previously in the population can be seen in Figure 5. In addition, the length of each medication use was collected, and the mean was calculated for the population as a whole. The data is depicted in Figure 6.

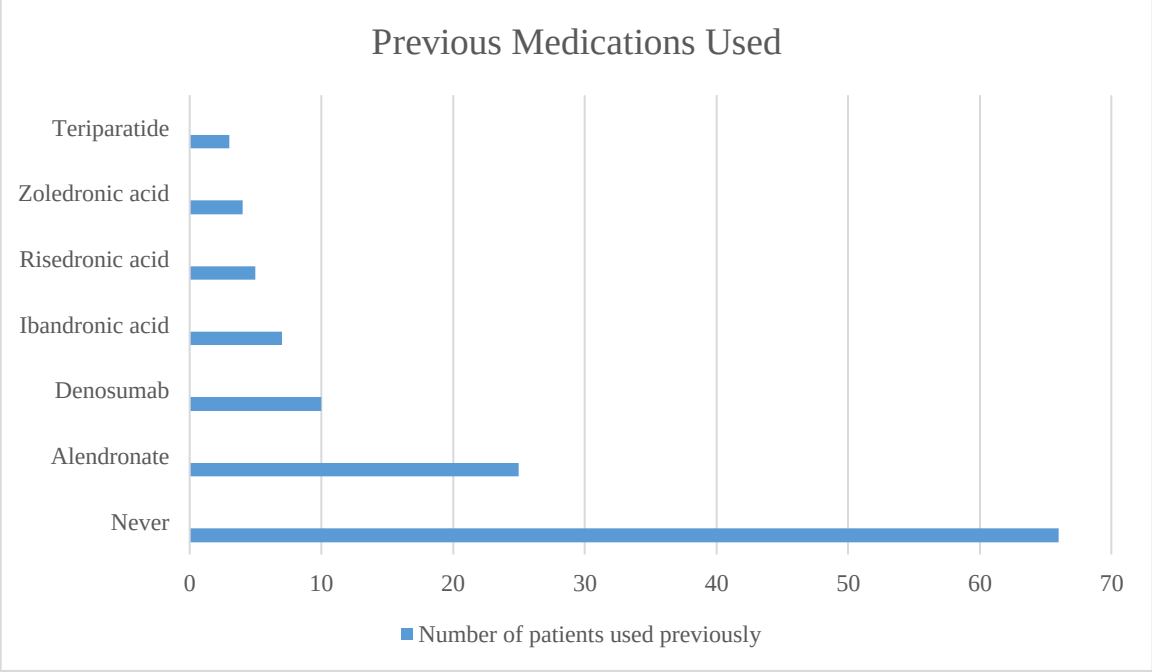

Figure 5. Previous medications used for patients with high fracture risk not currently on pharmacologic therapy obtained from retrospective chart reviews.

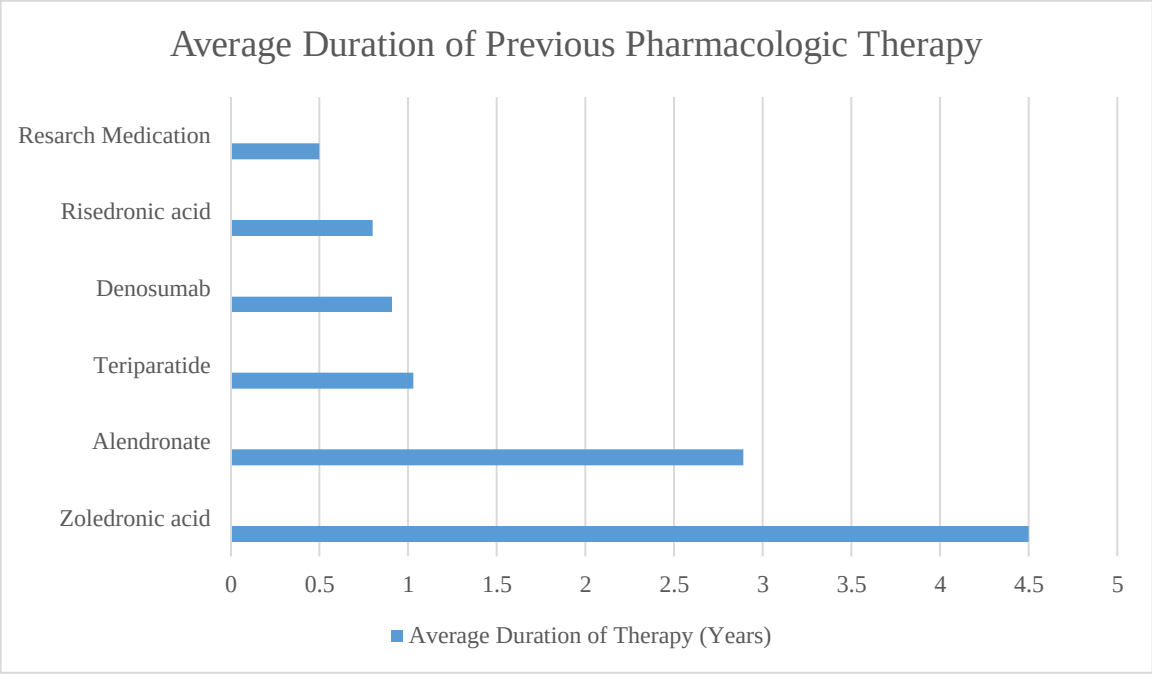

Figure 6. Average duration of previous pharmacologic therapy for patients with high fracture risk not currently receiving treatment obtained from retrospective chart reviews.

Possible reasons for patients not being on pharmacologic treatment for their elevated fracture risk was gathered from retrospective chart reviews. Most of the information was gathered from progress notes, phone notes, previous medications used, and results letters. Not all information was easily found via chart reviews. The depiction of these results can be viewed in Figure 7.

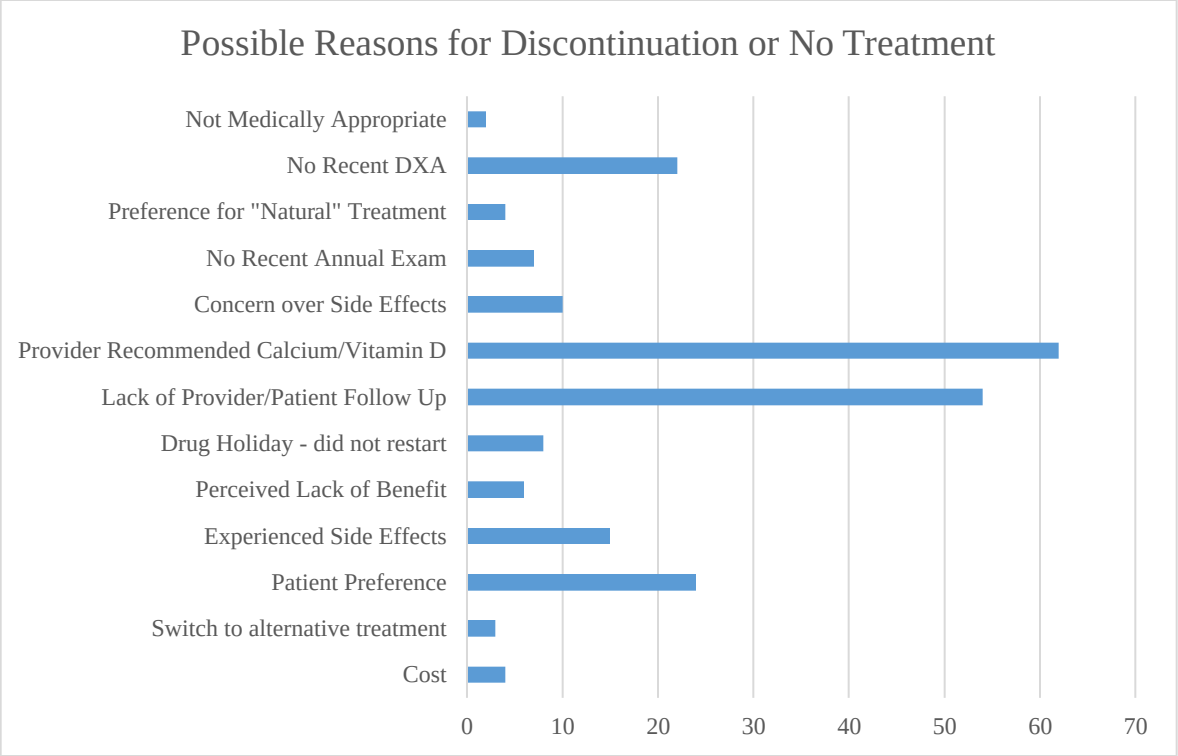

Figure 7. Reasons for discontinuation or no treatment gathered from retrospective chart reviews.

Based on information gathered during the chart reviews, whether or not patients were offered pharmacologic treatment based on their fracture risk score was collected. The information came from progress notes, results letters, and whether patients had previously been on therapy or not. The depiction of these results can be seen in Figure 8.

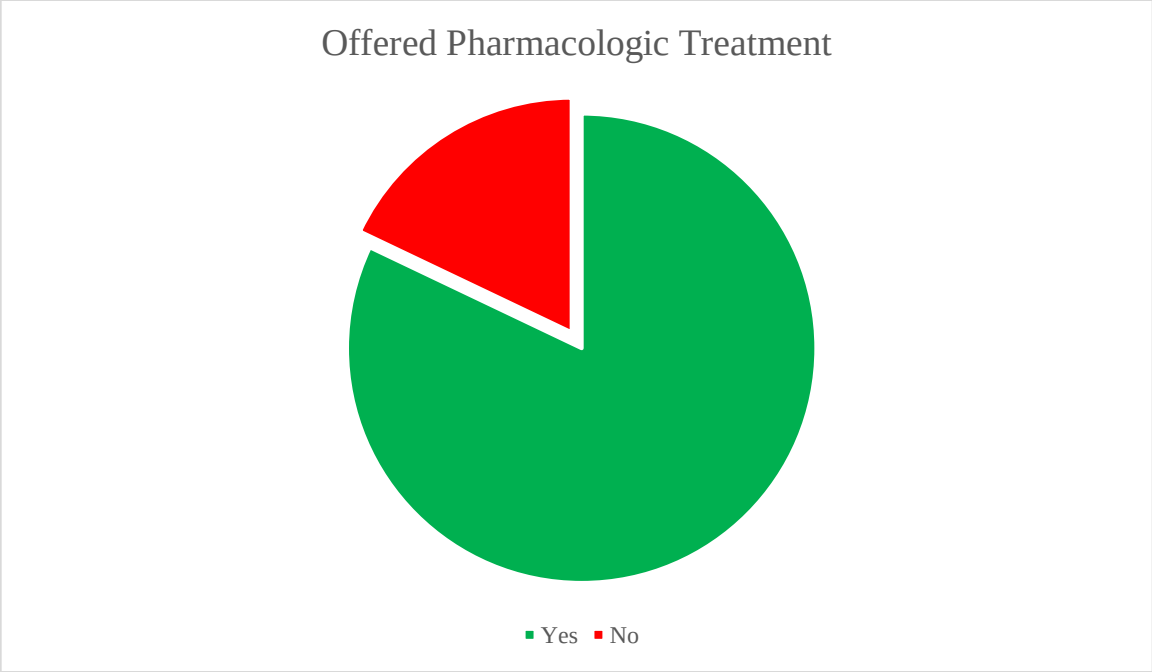

Figure 8. Representation of patients with high fracture risk not currently receiving therapy of whether or not they were offered pharmacologic therapy obtained from retrospective chart reviews.

In order to further analyze these findings, characteristics from each group were gathered. See table 5 in order to view the average age, overall fracture risk, and hip fracture risk for the patients offered pharmacologic therapy and the patients not offered pharmacologic therapy to decrease their fracture risk.

Table 5
Breakdown of patients not offered and offered pharmacologic therapy average age along with fracture risk scores

Not Offered Pharmacologic Therapy			Offered Pharmacologic Therapy		
Average Age	Average Overall FRAX Score	Average Hip FRAX Score	Average Age	Average Overall FRAX Score	Average Hip FRAX Score
79.4	15.18%	4.04%	77.655	19.03%	6.05%

A comparison was made regarding whether patients had received previous pharmacologic therapy or not and their T-score values and FRAX scores. These results can be viewed in Table 6.

Table 6
T-score and FRAX score comparison between patients who have received previous pharmacologic therapy and patients who have not

No Previous Pharmacologic Therapy			Previous Pharmacologic Therapy		
Femoral Neck T-score	Overall FRAX Score	Hip FRAX Score	Femoral Neck T-score	Overall FRAX Score	Hip FRAX Score
-2.09	17.05%	4.95%	-2.33	20.56%	6.96%

Formal statistical analyses could have been utilized in order to more extensively evaluate the 106 patient charts in the population sample. However, with no valid null hypothesis, these results would have provided little to no additional benefit for the evaluation of these results. Upon the advice of a consulted biostatistician, more formal and extensive statistical analysis were not utilized in the results of the project. It was determined that descriptive statistics were a more appropriate method to use.

Key Informant Interview Results

Two interviews were conducted with providers at the clinic, one was an internal medicine physician with over 30 years of experience, and the other was a physician assistant with over 15 years of experience. The interviews lasted around 15 minutes each. These providers see many elderly women in their practice, so most patients encountered were typical patients with elevated fracture risk and low BMD due to aging and estrogen depletion. However, it was estimated that about 5% of patients were "atypical" patients with low BMD due to secondary causes, such as long-term corticosteroid use or alcoholism.

When interviewing providers regarding osteoporosis/osteopenia treatment based on fracture risk, it was clear that FRAX scores were crucial in treatment decisions. Both providers utilize FRAX scores in their decision-making in addition to femoral neck BMD for comparison to previous DXA scans and T-score values to diagnose osteopenia or osteoporosis. Both providers preferred to use denosumab first-line because it is easy to make sure that the patient is

actually taking the medication since they have to come to the clinic for injections. Some insurance companies require patients to have tried to use a bisphosphonate previously or have a medical reason why it is contraindicated to use bisphosphonate therapy. In these scenarios, usually alendronate is used first-line for these providers. The providers agreed that many patients would say that they are taking their osteoporosis medications when they are not actually taking them, which drives the preference for denosumab first-line. The key informant physician would like to use teriparatide more often; however, it is very difficult to get insurance companies to cover the medication. In addition to the medication component, approach to therapy also consisted of weight bearing exercise, calcium and Vitamin D supplementation.

The most common reasons encountered by these providers for their patients being unwilling to use or stopping therapy are cost, concern over side effects, experienced side effects, or perceived lack of benefit. There are also factors out of their control that contribute to patients' feelings about these medications including false information obtained from the internet or friends and family. Patients also frequently do not consider potential benefits from receiving therapy for their osteoporosis to prevent fractures. Providers at the clinic try to reassess patients' willingness to utilize medication to treat their low BMD or elevated fracture risk at the next visit following the DXA scan, annual visits, or with repeat DXA scans. If patients are completely unwilling to use pharmacologic therapy and do not anticipate changing their mind, providers and patients may opt to not continue with DXA screening.

Medical reasons that these providers may feel it is inappropriate to utilize pharmacologic therapy to decrease fracture risk include upcoming major dental work due to osteonecrosis of the jaw risk, however, it is usually only a consideration when the patient is on the injectable therapies and due for an upcoming injection. In those situations, the providers will hold their

injection for 3 months after the dental work is complete. Neither provider will typically hold any of the oral agents in relation to dental work. Other reasons include chronic kidney disease stage IV and patients on hemodialysis. However, these reasons are usually only issues with bisphosphonate therapy and do not apply to teriparatide or denosumab.

A patient's age is considered when starting or discontinuing therapy for these providers. Typically, when a patient is above 90, the decision to stop treatment is considered. It is very much considered by every unique patient situation. If a patient is a healthy, active 90 year old then discontinuing therapy would not be ideal. On the other hand, if a patient were older than 90 and bedbound in a nursing home with many other comorbid conditions, then discontinuing treatment would be very likely.

Dissemination Evaluation Results

A meeting was held with providers at the internal medicine clinic to disseminate results of retrospective chart reviews and key informant interviews. The meeting lasted approximately 15 minutes and five of the six main providers at the clinic were able to attend. The executive summary document in Appendix E was utilized for the dissemination meeting along with spoken description of the results by the researcher. Each of the providers filled out the dissemination evaluation form listed in Appendix D.

All five providers said that the information presented at the meeting would influence their practice. Comments on this question included improvement of documentation of non-compliance reasons, changes to process for updating problem list, and improvement of patient education. The second question asked if the providers could identify a performance or quality gap that would improve treatment compliance of osteoporosis patients. All providers answered yes to this question as well. Comments included patient education, improving documentation, updating

problem list, updating medication list, and improvement in identifying high fracture risk patients. The last question of the dissemination evaluation form asked if the providers had any final comments regarding the topic. Four out of five providers said yes to this question. Comments included treatment of osteopenia is not well covered by insurance, DXA audit would be a good idea, good information to remember, helps with patient compliance, well-written, nice job, and useful information. The key informant physician, who is the researcher's father, was present at the dissemination meeting. With this in mind, the results could have been influenced due to this relationship, so it must be disclosed.

CHAPTER SIX. DISCUSSION AND CONCLUSION

Interpretation of Results

The samples utilized for the study were individuals with increased fracture risk as defined previously. Specifically, targeted were those people who, according to the EMR system, were not currently receiving treatment to maintain their BMD. Not surprisingly, 91.9% of the sample was women, which is consistent with prevalence data since osteoporosis is most common among females. The average age of the sample was 78.04 with a range of 57-92. Osteopenia and osteoporosis are more common in the elderly population, so these ages were consistent with that fact. Also, 95.3% of the people in the study were covered via Medicare health insurance, which typically starts coverage at the age of 65. No one in the sample was uninsured.

When the DXA scan results were broken down and analyzed, it was interesting to see that all of the patients in the sample had a T-score value of -1.0 of less, which puts them at least in the osteopenia range. To further analyze these results, 72% of the sample was diagnosed with osteopenia and 28% had osteoporosis based on their T-score values. Since the patients also had increased fracture risk, according to the National Guideline Clearinghouse "Diagnosis and Treatment of Osteoporosis" guidelines (2013) as well as the "Clinician's Guideline for the Prevention and Treatment of Osteoporosis" (2014) all of the patients in the sample should be considered for treatment based upon the information listed above (Cosman et al, 2014).

The average overall FRAX score was 18.37, which is less than the overall FRAX threshold of $\geq 20\%$. Only 29.25% of the patients in the sample met the overall FRAX score threshold. The guidelines still suggest that these patients are considered high risk for fractures and can be considered for pharmacology treatment due to the hip FRAX score elevation. 99.05% of the sample met the fracture risk criteria based on the hip FRAX threshold of $\geq 3\%$. Given this

information, the majority of patients in the sample had minimal elevation in their fracture risk. Providers may not have been as aggressive with treatment recommendations due to the minimal elevation and the majority of patients only meeting one and not both of the FRAX thresholds.

Previous medications utilized by the sample of patients were analyzed in a variety of ways. As previously demonstrated, the majority of patients in the sample had never been on treatment to decrease their fracture risk. Alendronate and denosumab were the most common medications that patients had utilized previously, if they had been on therapy. However, the medication with the best adherence for length of treatment was zoledronic acid, which is an intravenous infusion given once yearly at 4.5 years followed by alendronate which was right under 3 years. All of the other therapies averaged around 1 year or less of total treatment time. With exception to zoledronic acid, these results contradict other studies that have been done regarding length of treatment via type of method. The previous studies have shown that the less frequently the medication has to be taken, the longer patients typically will take them (Durden et al., 2017). Zoledronic acid is only administered once per year and was used with the longest duration on average, one would expect that denosumab would be the next longest duration of use due to administration frequency of twice per year. In comparison, alendronate is administered once per week, but was second in average duration of use length.

One patient in the sample had been on a research medication previously. The key stakeholder physician owns a research company that has done research on osteoporosis medications previously. Limited information was available about this research medication. It is unknown if the patient was on placebo or the active medication and what DXA requirements were part of the study, etc. There is a possibility that other patients in the sample were in

investigational studies for osteoporosis, although, this was not specifically documented via the chart reviews except on the one occasion.

Reasons for patients discontinuing or not ever being on treatment were the hardest part of the data to analyze. The main reason for the difficulty was lack of documentation for these reasons. When previous drugs were discontinued via the EMR system, the most common response was "Course Completed." While course complete is true in a sense, there was likely more to the story regarding why patients stopped their treatment. If providers did not discuss the reason in their progress notes, then it was very hard to understand why these medications were stopped. While the commonly studied reasons of experiencing side effects, concern over possible side effects, cost, and preference for natural treatment were all encountered a handful of times with clear documentation, this was the exception and not the rule during these chart reviews.

The biggest factor identified for not starting or continuing pharmacologic treatment was that providers did not officially recommend that the patients start on pharmacologic therapy, and instead recommended that patients remain on their calcium and vitamin D supplement only. This type of recommendation was commonly encountered with patients whose fracture risk was mildly elevated. Often in these scenarios, providers would send results letters to these patients stating that since their fracture risk is mildly elevated they could consider treatment, however, it is also reasonable for them to remain on their calcium and vitamin D and recheck a DXA scan in 2 years. In these situations, providers were not recommending treatment even though these patients had significant fracture risk and were at least in the osteopenia range. These recommendations by the providers are in contrast with guidelines that recommend patients should be considered for treatment if they have significant fracture risk because it is cost effective (Cosman et al, 2014) (National Guidelines Clearinghouse, 2013).

Lack of provider or patient follow up was a large contributor for why many patients were potentially not on therapy. As stated above, many situations were encountered during the reviews of providers sending results letters to patients and stating that the patient's fracture risk was elevated, and they would qualify for treatment to decrease fracture risk, however, staying on calcium and vitamin D and rechecking DXA scan in 2 years would also be a reasonable option. The letters often ended with statements similar to, "if you are interested in starting therapy please contact my office." After these letters, osteoporosis or fracture risk was often not readdressed until the next annual visit or repeat DXA scan. In some situations, neither the patient or provider had followed up regarding the potential availability of treatment and the lack of follow up contributed to why the patient was not on therapy. Both parties bore some responsibility in order for follow up to occur. The patient was told to contact the office if they were interested, however, there was often a missing education component regarding why the therapy may be beneficial in the first place. If a patient is given a letter without mention of the potential benefits of starting a new prescription, the patient would likely choose conservative treatment. In many cases, patients stayed on calcium and vitamin D supplement and repeated the DXA at a later time since that is the most convenient option and they were not fully aware of the benefits of the aforementioned option.

As can be seen in the results, 82% of the sample patients were offered pharmacologic therapy to decrease their fracture risk. However, as stated previously, many times they were offered therapy but also told that it was reasonable to stay on calcium and vitamin D and recheck a DXA in 2 years. Ambiguous messages can be confusing to patients since they were not likely educated regarding potential benefits of starting therapy for their mildly elevated fracture risk. Also included in the percentage were patients who had previously been on therapy, since at one

point they were offered and accepted therapy for the condition. Given the background information, the fact that 82% were offered therapy is somewhat misleading. To gain further insight into the data, the mean age and fracture risk scores were evaluated for patients who were previously offered therapy and those who were not. The patients offered therapy were, on average, younger and had higher fracture risk percentages than those who were not. The data is rather intuitive because patients who were younger at the onset of osteopenia or osteoporosis have more time for future risk of fractures and likely less other co-morbid conditions that would contraindicate therapy. Also, the patients that were offered therapy had higher fracture risk on average, making providers more aggressive with their treatment recommendations.

To further analyze offering pharmacologic therapy to patients, data was compared concerning patients who had been on pharmacologic therapy previously and those who had not. T-scores for patients who had never been on therapy were higher than those who had been previously treated. FRAX scores were higher for the patients who had received previous therapy. Again, the data was rather predictable because patients whose T-scores and fracture risk were higher would make providers more aggressive with their treatment recommendations and these patients were more likely to be on therapy previously.

Other potential reasons commonly encountered were regarding frequency of annual exams and follow up DXA scans. “No recent annual exam” or “No recent DXA scan” were marked as potential contributing reasons for no treatment when an annual exam was not done in the last 3 years or a DXA scan was not repeated since 2013 or before. The reasons why some of the patients were not having annual exams is not fully clear, though there are some patients at the clinic that come for more specialized care and not for primary care. The researcher excluded these patients from the sample whenever that situation was clear, however, it is possible that a

few remained in the sample despite efforts to remove them. Since osteoporosis is typically a "silent" disease until a fracture occurs, sometimes the only time it gets addressed for patients is at annual exams when discussing preventative health services, such as DXA scans. Since DXA scans are essential for evaluation of treatment, if a patient had not had an annual exam in the last 3 years it was counted as a potential contributor for why a patient was not receiving treatment. On the same note, if a patient had not had a recent DXA scan it was more likely that they were not on treatment because there was no reminder to address the condition. It is possible that due to patient age or previous denial of treatment, the patient's provider or the patient themselves have deemed it unnecessary to continue checking BMD levels, however, these reasons were not obvious from the chart reviews.

Overall, the healthcare provider key informant interviews aligned with data obtained from chart reviews. One contradiction was regarding follow up for reassessment of therapy. While the providers were optimistic in their opinion that treatment decisions reassessment would ideally get addressed at the next visit, data from chart reviews contradicted that information. Their opinions regarding barriers to therapy and patients' reasoning for stopping or never starting therapy were consistent with information found in chart reviews.

Overall, the dissemination evaluation had a positive response from providers. They were very accepting of the EMR change to improve documentation of non-treatment reasons. Also, the providers found an easy solution to solving the issue with osteopenia or osteoporosis not being in the patient's problem list. The DXA scan technician now has an added duty of inputting the appropriate diagnosis based on the DXA results at the time of the scan. The nurses will also be educated to ensure that injections given for osteopenia or osteoporosis is listed on the patient

medication list at the time of the injection encounters. Providers also acknowledged a need to input the medication on the patient's list at the time of ordering.

There were some less positive findings that emerged during the dissemination. Providers are hesitant to spend any additional time on patient education regarding treatment to reduce fracture risk, due to the many medical conditions that are being treated at any given visit. Also, the office manager and providers stated that treatment for patients with osteopenia and high fracture risk is not very well covered by insurance companies.

Limitations

Several limitations must be considered when evaluating the results of the practice improvement project. The project was conducted at an independent internal medicine clinic in the Midwest. Quality measures that exist at larger organizations are not formally in place at the clinic or at most independent facilities. Each provider had a different approach to how they treated and educated patients about DXA scan results and osteoporosis treatment. In addition, since internal medicine is the specialty of focus within the clinic, many of the patients are of advanced age and have complex medical backgrounds. With the individuality in mind, the results are not transferrable to other clinics, even small independent clinics.

Another consideration is the population used for the project. Since the clinic is internal medicine in focus, most patients who receive care there are also primary care patients of the clinic. However, some patients seek care at the clinic for more specialized care of certain conditions, such as diabetes mellitus type II, and have a primary care provider elsewhere. The issue arose a few times during retrospective chart reviews. Even though the patient had a separate primary care provider, they had a DXA scan at the clinic being studied and appeared in the sample size because there was not a DXA scanner available at the other clinic. Whenever the

researcher saw what appeared to be this type of situation, the patients were excluded from the sample, however, it is possible that some remained in the sample despite efforts to remove them.

One more limiting factor to consider, is that the researcher only evaluated the patients who were not currently receiving pharmacologic therapy for their fracture risk. The results might have been much different if all patients with significant fracture risk were included in the sample. The patients included in the sample could have been more resistant to receiving therapy in the first place since they were not currently receiving anything, which could have skewed the results a certain way.

The biggest limiting factor of the research was the ability of the researcher to find information in the EMRs. The specific reason(s) for patients not being on treatment was the hardest to find. All medications that were previously discontinued for osteoporosis management were viewed and the reason for discontinuation was evaluated. Despite an embedded EMR feature prompting the reason for medication discontinuation, little valuable information was found in this area. Occasionally, nursing or the provider would write reasons for discontinuation in this section which made the information very easy to find. The most common reason for discontinuation identified was “course complete”, which is likely the default response when discontinuing any medication.

Another limitation which was originally mentioned by the key stakeholder physician involved in the project is that patients often tell you that they are taking these medications for osteoporosis when in reality they may not be taking them. There is no way to verify that patients are being honest, so the results of the chart review are based upon the fact that the patients who are documented as being on therapy are actually taking the medication. Also, the results of the project relied on a thorough medication review of the nursing staff and providers in order to

assure medication lists are up to date with what the patients are currently taking. The up to date medication reviews also assumes that the patient is knowledgeable in what they are taking when these reviews are happening. With all of these considerations in mind, it is possible that in an ideal world with perfect charting, these results would have been much different.

Recommendations

The first recommendation which was implemented at the conclusion of the project was an update to the EMR system to improve documentation of treatment decisions for patients with significant fracture risk with the goal of improving treatment rates of these patients within the clinic. A change was incorporated into the system when providers enter osteoporosis (ICD-10: M80-81) or osteopenia (ICD-10 M85.8) diagnosis codes in the assessment section of their clinic visit notes. The template for these diagnosis codes already fills in the most recent DXA scan information including fracture risk, however, a new area was added to ask providers why patients with significant fracture risk are not receiving pharmacologic therapy.

A second recommendation to the clinic involved putting osteoporosis or osteopenia into patients' problem lists. During the retrospective chart reviews, the author found nine different patients whose DXA scan report showed either osteoporosis or osteopenia and the diagnosis was not listed in the active problem list. These lists are crucial to have up to date in the clinic setting. At a patients' annual visit, the provider often looks at these lists and makes sure to cover each of them if possible at the visit. If the patient does have osteoporosis or osteopenia and the diagnosis is not included in the problem list, it is likely not going to get as much focus at annual visits, which is usually the only time osteoporosis gets discussed. Because it is a silent disease, a patient will not usually come into the clinic with a complaint of osteoporosis unless they have sustained

a fracture. Also, osteoporosis often gets discussed at annual visits because as part of preventative healthcare, DXA scans are usually only ordered or recommended at annual visits.

A third recommendation was also based on findings from the retrospective chart reviews. The original sample was based on patients' medication lists and whether or not they were receiving therapy for osteoporosis. It was noted during the reviews in eleven separate instances that patients were included in the non-treatment sample, however, once the review started they were found to have received an injection of denosumab in the previous 6 months. These patients were subsequently moved to the treatment portion of the sample. The recommendation to the clinic involved ensuring that patients' medication lists are up to date, even if they are only receiving these injections every 6 months and not taking a medicine daily. It is important not only as the primary care provider to be aware that your patient is receiving these injections, but to every other provider who may take care of the patient during the half lives of the medication in order to evaluate for drug interactions. When nursing staff is administering these medications in the clinic, they should be double checking that the medication is present on the patients' list each time.

Lastly, while it was not always clear from documentation why patients were not receiving treatment for their osteoporosis or significant fracture risk, the common reasons for patients stopping or refusing therapy were definitely found in the review. Patient education is something that can always be improved. It was suggested by the key stakeholder physician for the project to have an osteoporosis champion, of sorts, within the clinic. The provider would serve as patient educator for those with significant fracture risk who should be receiving pharmacologic therapy and are resistant to the recommendation. The goal of the intervention would be to avoid fragility fractures and associated morbidity and mortality by increasing or maintaining a patient's BMD

level. The ideal patients for the provider to see would be those who are resistant due to lack of information, knowledge of the disease process, or who have received false information. The designated osteoporosis education provider is something that the clinic was very interested in pursuing in the future.

Implications for Practice

Retrospective chart reviews demonstrate the importance of up-to-date and accurate medication and problem lists for our patients. The chart reviews proved to be more difficult than originally anticipated due to lack of documentation for discontinuation reasons, as well as medication lists that did not accurately reflect what patients are taking. In a busy clinic life, it is easy to see how some of these minor issues with charting and medication reconciliation can fall prey to other day to day activities. Despite the competing priorities of primary care, out of date records can vastly impact treatment decisions.

In addition to the recommendations made above, the FRAX tool has much more value than just assessing for fracture risk with a BMD measurement. FRAX can be utilized with or without the BMD information. Providers can start calculating the measurement on high risk men and women far before they have their first DXA scan. According to the International Osteoporosis Foundation, postmenopausal women ages 50-64 should be considered for a DXA scan if they have a total osteoporotic fracture FRAX score of $\geq 9.3\%$. Many women and men in this age group are likely not having their FRAX score calculated, thus missing some high-risk individuals who may benefit from earlier intervention to prevent fragility fractures. Primary care could help their patients a great deal by incorporating FRAX into their practice at earlier stages.

Implications for Future Research

To further evaluate the results of the project, another study would need to be done. The study would involve the total sample size of patients with high fracture risk, including those that are currently on pharmacologic therapy according to the EMR system. Broadening the sample for the project would give a more in-depth picture as to why patients discontinued previous agents and how long they have been on the current modality they are using. Also, in future studies more attention could be focused on specific medications and the reasons associated with each one for discontinuation

Any future studies would be conducted after the EMR system improvement was implemented and the recommendations for improvement were presented to the providers and staff. The changes would allow better documentation regarding reasons for declining or discontinuing certain agents to retrieve better quality data. Having a follow up study after the EMR change had taken place would also help to evaluate if the EMR system reminder for patients with high fracture risk actually improved treatment rates and documentation processes in the clinic.

Expanding the topic to larger health systems in the area who may have different quality measures in place would be interesting to compare to smaller independent organizations. Ultimately, comparing different areas of the United States regarding adherence to treatment and fracture risk would provide a lot of insight into the topic, although that is out of the scope of the project.

The key stakeholder physician involved in the project from the beginning has decades of experience working with patients with osteoporosis. In his hospital experience, he noticed a large area of need for patients to be worked up for osteopenia or osteoporosis and potentially started

on treatment following fragility fractures by their primary care providers. He noticed that the diagnostic work-up post fragility fracture is an area that is missed often and recommended the idea for a practice improvement project initially. A different project focus was chosen due to the complexity of working with several different organizations. However, much research has been done on the topic area and a need for improvement has been demonstrated. Further examination regarding why patients may be missed during transition of care from hospital or emergency room follow-ups could be a great area for practice improvement in relation to osteopenia and osteoporosis management. Individuals should be worked up for osteoporosis and potentially started on treatment in order to reduce the risk of future, potentially devastating fractures following discharge from the hospital or ED after a fragility fracture.

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APPENDIX A. KEY INFORMANT INTERVIEW QUESTIONS

- For typical osteoporosis patients with significant fracture risk- what is your approach to therapy?
    - How many truly atypical patients do you see per year?
- What are your most commonly used types of pharmacologic treatment for osteoporosis?
- What are the most common reasons that you see in patients who are unwilling to use pharmacologic therapy to treat their osteoporosis?
- What barriers to optimal therapy do you commonly encounter in practice?
- What are some reasons that you as a provider would not clinically recommend for a patient with high fracture risk to utilize pharmacologic treatment?
- What portion of DXA scan results do you use in your treatment decisions?
- How often do you reassess patients' willingness to use pharmacologic therapy for osteoporosis?
- What factors out of your control impact how you care for and treat a patient with osteoporosis and high fracture risk?

APPENDIX B. COLLABORATION AGREEMENT

ima | Healthcare
Internal Medicine Associates

1707 Gold Drive South
Suite 101 • Goldmark Office Park
Fargo, North Dakota 58103
701.280.2033 • Fax: 701.232.5578
www.imahealthcare.com

June 22nd, 2017

NDSU Institutional Review Board
NDSU Department 4000
PO BOX 6050
Fargo, ND 58108-6050

To whom it may concern:

This letter is to indicate the intent of IMA Healthcare to collaborate in Dr. Mykell Barnacle's research, "Osteoporosis Treatment Based on Fracture Risk: A Quality of Care Indicator." In this research, IMA Healthcare's personnel will provide access to electronic medical records and key informants. All of IMA Healthcare's personnel have been trained in the protection of human subjects, and the approved NDSU IRB protocol will be followed when conducting the research.

If you have any concerns or questions, please contact me at: (701) 280-2033.

Sincerely,

Michael Lillestol, MD, FACP
IMA Healthcare

APPENDIX C. NDSU IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

June 27, 2017

Dr. Mykell Barnacle
Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH17267, "Osteoporosis Treatment Based on Fracture Risk: A Quality of Care Study"

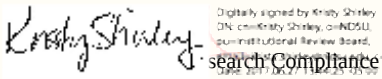
Co-investigator(s) and research team: Karissa Emerson
Certification Date: 6/27/2017 Expiration Date: 6/26/2020
Study site(s): IMA Healthcare
Sponsor: n/a

The above referenced human subjects research project has been certified as exempt (category #2 and 4) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the revised protocol submission (received 6/23/2017).

Please also note the following:
• If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
• The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
• Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
• Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.
Sincerely,



search Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 7012318995 | Fax 7012318098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX D. DISSEMINATION EVALATION TOOL

Title: Osteoporosis- Dissemination of Retrospective Chart Reviews / Interview Results

Presenter: Karissa Emerson, DNP-S

Date:

Will the information presented today influence your practice in any way? ☐ Yes ☐ No

If yes, please explain:_____

_____

_____

_____

Is there a performance or quality gap that you can identify that would improve the treatment compliance of osteoporosis patients? ☐ Yes ☐ No

If yes, please explain:_____

_____

_____

_____

Do you have any final comments regarding the topic? ☐ Yes ☐ No

If yes, please explain:_____

_____

_____

_____

APPENDIX E. EXECUTIVE SUMMARY FOR DISSEMINATION TO CLINIC

OSTEOPOROSIS TREATMENT BASED ON FRACTURE RISK: A QUALITY OF CARE STUDY

RESULTS

72% of sample had diagnosis of osteopenia

Most commonly encountered reasons for no treatment were lack of follow up by patient or provider, provider recommending calcium and vitamin D due to minimal fracture risk elevation, no recent DXA (>3 years), patient preference, experienced side effects, concern over side effects, drug holiday, cost, and perceived lack of benefit.

82% were offered therapy to reduce fracture risk and they were younger and had higher fracture risk on average

62.3% of patients had never been on therapy previously, on average these patients had lower fracture risk and T-scores than patients who had been on therapy prior.

11 times denosumab was given in the previous 6 months, but not in patient's medication list

9 times DXA indicated osteoporosis/osteopenia but it was not listed in problem list

Best adherence (4.5 years) shown with zoledronic acid followed by alendronate (3 years).

INTRODUCTION

Osteoporosis is a condition that decreases the density of bones resulting in weaker bones and greater risk of fragility fractures. Fragility fractures occur with less force than may be expected in the fracture of a normal bone, usually including falls from standing height or less. The majority of fragility fractures occur in patients in the osteopenia range (-1.0 - -2.4) of bone mineral density.

Treatment decisions for osteopenia or osteoporosis are now based upon a fracture risk assessment tool (FRAX) in addition to T-score values due to the importance of reducing a patient's risk of fracture before they sustain one.

Studies have demonstrated that adherence to pharmacologic therapy to decrease fracture risk and maintain bone density is an issue with the majority of patients. Most patients are not staying on treatment for greater than one year for a variety of reasons, most commonly cost, side effects, patient perception of efficacy and safety, perceived lack of benefit, preference of "natural" treatment in calcium and vitamin D, and complicated dosing instructions.

Guidelines suggest consideration of treatment for patients with significant fracture risk (≥3% hip fracture risk and/or ≥20% overall fracture risk) and a T-score of less than -1.0 in order to reduce the risk of fragility fractures.

PROJECT DESIGN

286 patients with high fracture risk at an internal medicine clinic in a Midwestern community.

Retrospective chart reviews and key informant interviews were conducted to identify treatment patterns of patients with significant fracture risk.

52.1% (n= 149) of the sample was not currently receiving pharmacology therapy to reduce their fracture risk and were the total population reviewed.

Certain information was collected during the reviews including demographic data, FRAX criteria, previous medications used, length of previous therapy, insurance status, date of most recent DXA scan, and fracture risk and T-score from that scan.

LIMITATIONS

Patients receiving specialized care at the clinic with primary care provider elsewhere.

Only reviewed patients not currently receiving therapy.

Ability to find information in the electronic medical records.

Required up to date patient medication lists.

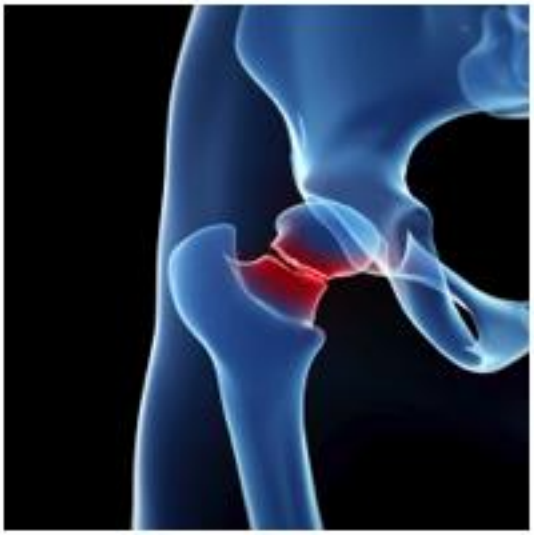
RECOMMENDATIONS FOR IMPROVEMENT

EMR update to improve documentation of treatment decisions for patients with high fracture risk.

When reviewing DXA scan results, ensure that appropriate diagnosis is in patient's problem list.

Nursing to review patient's medication list during injection encounters to make sure it is listed.

Patient education regarding osteopenia/osteoporosis treatment to reduce fracture risk.



APPENDIX F. EXECUTIVE SUMMARY

Background and Significance

Osteoporosis is a condition that decreases the density of bones resulting in weaker bones and greater risk of fragility fractures. Fragility fractures occur with less force than may be expected in the fracture of a normal bone, usually including falls from standing height or less. Risk factors for the development of osteoporosis include aging, estrogen deficiency, low calcium and vitamin D intake, and certain disorders Prevention of fragility fractures related to osteoporosis is imperative because they can devastate the lives of patients. Patients may lose independent functioning, have chronic pain, or even die as a result of these fractures. Fragility fractures increase costs for hospital and surgical care and indirectly result in loss of productivity for patients with loss of independence and need of nursing home or institutional care. Osteoporosis and subsequent fractures can be prevented with adequate calcium and vitamin D intake, weight bearing exercise, and pharmacologic therapy.

Many patients think of osteoporosis as a "silent disease" and do not see the benefit in receiving medication for primary fragility fracture prevention. Adherence to pharmacologic therapy remains the largest issue with treatment for providers. Historically, osteoporosis treatment decisions were based off T-score values alone, however, it has been realized in more recent years that T-score values are not the optimal way to measure fracture risk, because many fragility fractures occur in people outside the T-score ranges, most occurring within the osteopenic range.

Osteoporosis is the cause of more than 8.9 million fractures annually which equates to one fracture every 3 seconds. One out of three women over the age of 50 will experience an osteoporotic fracture as well as one out of five men the same age. A critical aspect of

osteoporosis management is identifying and treating patients who are at the highest risk for fractures before they have sustained one. Successful osteoporosis management reduces the risk of first time fracture in 5 years from about 34% to 10%. Osteoporosis treatment to prevent fractures is a difficult task for many reasons, including cost, side effects, patient perception of efficacy and safety, perceived lack of benefit, preference of "natural" treatment in calcium and vitamin D, and complicated dosing instructions.

Project Summary

For the practice improvement project, attention was focused on an independent internal medicine clinic serving around 10,000 patients in a Midwestern community. A retrospective data analysis was performed. Chart reviews were completed to attempt to identify the reasons most of the internal medicine clinic's patients with significant fracture risk are not receiving therapy for osteoporosis. Two interviews were conducted with healthcare provider key informants at the clinic to further evaluate the provider perspective on the issue. A meeting for the internal medicine clinic's providers to attend was hosted. The results of the retrospective chart reviews and key informant interviews were presented at the meeting. Based on the results, a list of recommendations for improvement of treatment rates for patients with significant fracture risk was presented at the meeting.

Results

Results showed inconsistent documentation of patient treatment preferences and provider treatment decisions. Additional areas for improvement include patient and provider follow up treatment as well as patient education regarding the disease process and benefits of treatment. Results and recommendations for improvement were disseminated to providers at the clinic with feedback solicited. An electronic medical record change was implemented in order to improve

documentation of treatment decisions regarding osteoporosis or osteopenia. Patients with high fracture risk were flagged, prompting a response regarding reasons for discontinuation of previous therapy or why the patient is not currently on therapy.

Recommendations

Recommendations to the facility included improvement of documentation for provider or patient treatment decisions regarding elevated fracture risk. An electronic medical record change was implemented in order to improve the documentation process. Patient education was also in need of improvement, so a provider who was designated as a patient education expert regarding pharmacology treatment to reduce fracture risk was recommended.