CQI: Osteoporosis

COI: Osteoporosis
1. Identify Problem
2. Analyze Problem
3. Suggest Solution
4. Implement Solution
5. Evaluate Change

PDSA Cycle:
1. Plan: determine process change, gather baseline data
2. Do: Implement process improvement
3. Study: Evaluate effectiveness of intervention (follow up data)
4. Act: implement modified or refined intervention

Background:

Despite the fact that osteoporosis is common in older persons (nearly 50% of women and 30-45% of men over the age of 50 are osteopenic or osteoporotic), many patients are not assessed or treated for osteoporosis or falls and fracture reduction [1]. A white woman over the age of 50 has a 50% lifetime risk of having an osteoporotic fracture, a 25% risk of a vertebral compression fracture, and a 15% chance of a hip fracture, and a man over the age of 60 has a 25% risk of an osteoporotic fracture [2,3]. The older you are, the higher your risk. Up to 70% of patients over the age of 80 have osteoporosis. Fractures lead to decreased mobility, risk of recurrent falls, significant morbidity and pain, and mortality. Hip fractures are BAD – 12 – 20% of patients with a hip fracture will die within the year and 25% – 30% of patients will require long term skilled nursing care [4].

More surprising is how few of our older patients are evaluated or treated in the hospital setting, even when presenting with an osteoporotic fracture!! In one study, 114 patients with a hip fracture admitted to a tertiary care hospital were reviewed over a 5-year period. Only 6% were on adequate treatment for osteoporosis at discharge, and only 12% were on adequate treatment at 5 years! In addition, 22% of these patients had a new fracture within the 5-year follow up period [5]. Another study in 2000 found that only 21% of Medicare beneficiaries received any prescription treatment for osteoporosis after having a hip fracture, and that patients older than 74 with other comorbidities were the least likely to be treated [6].

What is osteoporosis? Osteoporosis in essentially a loss in total mineralized bone, in contrast to osteomalacia in which there is a decrease in the ratio of bone mineral to the organic matrix. Bone is constantly in a state of flux, being remodeled and rebuilt. Osteoclasts, stimulated by Parathyroid hormone, cause bone resorption. Parathyroid hormone also stimulates osteoblasts which in turn also stimulate osteoclastic action. Calcitonin acts to inhibit this osteoclastic bone resorption. Multiple factors including calcium and vitamin D intake and absorption, estrogen status, medications, exercise and multiple toxins act to change the delicate balance of bone build up and break down which can then lead to osteoporosis. The slowing down of bone build up can lead to
the osteoporosis common in older age, and the acceleration of bone breakdown can lead to same result in the immediate postmenopausal state. Bone mass usually peaks in both men and women in their twenties with a net loss of about .5% per year thereafter. For women, bone loss can accelerate to as much as 5% per year during the first five years of menopause. After the age of 70, men begin to have the same decline in bone density as women related to decrease in new bone formation [7].

Defining osteoporosis: The WHO has defined osteoporosis as a “systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk”. The definition points out that bone structure is as important as total bone mass. The practical definition used is based upon a total T score (see below) of < -2.5 or a history of an osteoporotic type fracture (hip fracture with minimal trauma, vertebral compression fracture, wrist fracture with minimal trauma).

Who gets osteoporosis: Age is one of the largest risk factors for osteoporosis and fractures. In addition, age is related to fracture risk – so older people get osteoporosis, and in addition are much more likely to have a significant fracture compared to a younger person with the same bones. Other risk factors for osteoporosis include the estrogen deficiency associated with menopause, testosterone deficiency in men, family history and genetics, female sex, low calcium/vitamin D intake, poor exercise, smoking alcohol, low body weight, anorexia, hyperthyroidism, hyperparathyroidism, prednisone use, liver or renal disease. Chronic use of medications such as heparin and antiepileptics are associated with osteoporosis. In addition, malignancies, especially multiple myeloma, can present with osteopenia and fractures. Prolonged immobility and low calcium intake combined with poor vitamin D intake and sun exposure can compound the problem in the frail elderly nursing home population. In addition, patients who have experienced a stroke leading to hemiplegia have a significant increase in osteoporosis and hip fracture on the involved side, likely related to accelerated osteoporosis of bone in an immobilized state combined with an increased risk of falls after a CVA [8].

Diagnosing osteoporosis: What we really want to know is fracture risk. We don’t really have a test that can 100% evaluate this risk. We use the Bone Mineral Density as a surrogate marker for bone strength. It is important to recognize that while important, this is still a surrogate marker for fracture. Older women, likely because of factors other than bone density such as bone structure and overall falls risk) have a much higher risk of fracture than younger women with the same BMD score. Laboratory data are of limited value for the diagnosis of osteoporosis. An appropriate evaluation to rule out secondary causes, especially in younger women or men, should be undertaken (workup for hyperthyroidism, hyperparathyroidism, estrogen or testosterone deficiency, malignancy, multiple myeloma, calcium and/or vitamin D deficiency). Other laboratory, such as the use of telopeptide, can be used as a marker for bone turnover, but may be more useful in the monitoring of the effects of treatments such as bisphosphonates aimed at reducing bone turnover than in the diagnosis of osteoporosis.

Methods to evaluate for osteoporosis: Although there are multiple diagnostic tests available including quantitative ultrasonography and computed tomography to evaluate bone density, the most commonly used and best validated testing involves the use of Dual Energy X-ray Absorptiometry (DEXA) scanning. It is important to recognize though that not all DEXA measurements are the same, and even though this is considered a “gold standard” in the diagnosis of osteoporosis, it is far from such. DEXA measurements can be done at the spine, at the hip, at the forearm or at the heel. The heel and the forearm sites are attractive for screening because of the speed and ease with which they can be done. But these sites have the least correlation with total fracture risk, and most recommend evaluating the site of most concern – the hip. DEXA evaluation at the hip has the best correlation with future risk of hip fracture [9]. In a systematic review from
Sweden, it is pointed out that the diagnosis of osteoporosis depends on the site tested. Of women over the age of 60, only 6% would be diagnosed with osteoporosis based upon the DXA reading at the hip only, compared to nearly 15% if the DXA measurement came from the lumbar spine [10]. Other sites commonly used include the vertebral spine. One must though consider underlying osteoarthritis in the spine when interpreting the results of DEXA at the spine – significant osteophyte formation in the spine can falsely elevate the bone density reading and score.

**How to interpret the BMD:** The T score is the standard deviation of the BMD from the average sex matched 35 year-old. The z score is less used, but is basically the standard deviation score as compared to age matched controls. The WHO defines osteoporosis as a T score of <= -2.5 and osteopenia as a T score of -1 - -2.5 range. For every one decrease in the T score for BMD, there is a double in the risk of fracture. In addition, every 1 SD decrease in BMD is equivalent to a 14 year increase in age in predicting risk for hip fracture [9]. It is important to remember that regardless of T score, patients with a prior osteoporotic type fracture can be up to five times more likely to have a future fracture.

**Fracture Reduction:** Remember, the goal is to PREVENT FRACTURE, not to just treat a number on the DEXA scan! Fracture reduction can be thought of involving the treatment of osteoporosis, decreasing the risk of break, and the reduction of falls.

1. **Osteoporosis treatment options:**

   1. **Calcium and Vitamin D:** less than half of adults take in the recommended amounts of calcium and vitamin D. Patients with malabsorptive problems, renal disease or liver disease may have further problems. Calcium and Vitamin D supplementation have been shown to reduce the risk of hip fracture in older adults [11]. Calcium should be given with meals for optimal absorption and adults should take in at least 1000 mg/day (ideally 1500 mg/day in postmenopausal women or those with osteoporosis). Vitamin D (25 and 1,25 D3) can be checked, but if the serum calcium level is normal most would recommend empiric treatment with additional vitamin D of at least 400 IU. In frail older patients with limited diets and sun exposure, the required amounts are most likely much higher, at least 600-800 IU daily.

   2. **Calcitonin:** likely better than nothing, but probably not as effective as bisphosphonates. Given as 200 IU nasally, alternating nares daily. There is some evidence that intranasal calcitonin can have some benefit in decreasing the pain associated with vertebral compression fractures in the acute setting – do not let this prevent you from providing optimal treatment with a bisphosphonate for these patients!

   3. **Bisphosphonates:** these drugs act to decrease bone resorption. Multiple studies have demonstrated a significant benefit in the reduction of hip and vertebral fractures [12,13]. Multiple agents exist, although alendronate and risedronate are some of the more studied and used options. Intravenous formulations such as pamidronate and zolendronate are also available, although most often used for osteoporosis associated with multiple myeloma and hypercalcemia associated with malignancy. Newer agents such as ibandronate take advantage of the incredibly long action of these agents and are given just once monthly. It is important to remember that those at highest risk for fracture (the older patients and those with existing vertebral fractures) were the patients who derived the most benefit from treatment. There have been recent reports of Bisphosphonate associated osteonecrosis (BON) of the jaw, usually related to significant dental disease and procedures and more commonly
seen with IV pamidronate and zolendronate although case reports with the oral bisphosphonates are emerging [14].

**Contraindications include renal failure and significant esophageal erosions/disease:** GERD, benign strictures, and other usual GI diseases are not an absolute contraindication to their use. To limit the toxicity associated with direct esophageal irritation of these agents, recommendations include taking these medications in the morning, drinking a large glass of water afterwards, and not lying down for at least 30 minutes after intake. Multiple studies have demonstrated that the GI side effects for these agents are no higher than seen with placebo.

4. **Estrogen replacement:** proven benefits in the treatment of osteoporosis with a reduction in bone resorption. Not currently recommended for the management of osteoporosis alone given the concerns over increased cardiac risk, venous thrombotic events and cancer.

5. **Selective Estrogen Receptor Modulators:** Raloxifene has FDA recommendation for the management of osteoporosis. Like estrogen, it acts to decrease bone resorption. Unlike estrogen it has no demonstrated increase in cancer (likely decreases the risk of breast cancer) or cardiac issues. It can cause an increase in the vasomotor symptoms associated with menopause leading to poor patient tolerance.

6. **Parathyroid Hormone:** Teriparatide. Currently approved for the treatment of osteoporosis. Although prolonged PTH exposure causes worsening of osteoporosis by increasing osteoclastic bone breakdown, intermittent PTH is associated with an overall improvement in bone density. This again emphasizes the complex nature of osteoporosis where optimal bone strength relies upon just the right balance of bone build up and bone tear down. The data looks promising with evidence to suggest improved BMD and decreased fracture use with its use [15, 16, 17]. There are a few caveats to usage. Long term use carries a potential increase in the risk of osteosarcoma in animal studies, therefore it is recommended only for 2 years. In addition, it is administered subcutaneously, and is extremely expensive. It is an option for those with severe osteoporosis who cannot tolerate a bisphosphonate, or who have been on such agents for an extended amount of time. Optimal effect also requires bone uptake. Studies looking at using intermittent PTH in combination with bisphosphonates have been disappointing, possibly because of the block in adequate uptake due in part to the bisphosphonate [18]. Current recommendations include stopping any bisphosphonate prior to PTH use (possibly up to a year before PTH treatment).

2. **Reducing the risk of break: Hip Protectors:** Multiple studies have demonstrated that hip protectors, padding that fits underneath clothing to essentially act as a cushion, are effective at preventing hip fractures and likely cost effective [19,20]. The problem is getting people to be aware that they are available, actually getting them at facilities where they may have the greatest impact, and most of all actually getting them and keeping them on patients.

3. **Falls Reduction:** Again, even if your bones are thin, you are less likely to actually have a fracture if you do not fall. Falls are a marker of frailty. We know that hip fractures are associated with an increased risk of mortality and placement, but this is in part because hip fractures indicate that the patient is frail. Falls and hip fractures are tied in a complex manner, both leading to the other, but tied with osteoporosis and age, and both associated with mortality and morbidity. Falls
reduction begins with recognizing the patient at risk, asking patients routinely about falls or fear of falling, evaluating gait, recommending exercise and balance/strengthening exercises, and reviewing prescription, over the counter, and herbal medication use.

**Current Guidelines:** Based upon the U.S. Preventive Task Force Recommendations for Screening and Treatment of Osteoporosis

1. Test Bone Mineral Density in all women over age 65, younger postmenopausal women with at least one risk factor, and postmenopausal women with a history of fracture.

2. Treat patients with a T score of <-2 and no risk factors, a T score of <-1.5 if one or more risk factors present, and anyone with a prior vertebral or hip fracture

**Who is left out?** OLDER MEN. Current recommendations do not include what to do with elderly men. As we care for more and more men over the age of 80, guidelines for the screening and treatment will need to be in place. Current evidence again suggests that older men are at a significant risk for osteoporosis and fractures, and that they benefit from treatment with a reduction in fracture risk as well [21]

**The Problem:** We are in contact with many older patients on the geriatric service with a known history of fractures, falls or osteoporosis who continue to go without adequate assessment or treatment for osteoporosis.

**Analyze the Problem:** Use the audit sheet to do a baseline chart review of patients on the inpatient geriatric service to determine how many patients who are at risk for osteoporotic fractures are actually treated or assessed for osteoporosis.

**Suggest a Solution:** Elderly patients on the geriatric inpatient service are often admitted for reasons other than fractures, but are a high risk population for osteoporotic fractures and the morbidity and mortality associated with this disease. Treatment with calcium, vitamin D and bisphosphonates have been shown to be effective and well tolerated in this population. The inpatient setting is a unique opportunity to begin treatment on patients with whom we have close contact. The initiation of treatment on patients prior to discharge could be incredibly effective at decreasing future fractures and increasing the rates of recommended treatment. Should there be a prompt in a geriatric POE order set? A prompt on the CIS note or discharge sheet? Are there other systems changes that would lead to increased awareness and thus increased treatment in this patient population?

**Implement the Solution:** Based upon your discussions in the beginning of this project, implement a simple awareness project as a systems change and follow this for 2 weeks.

**Evaluate the Change:** Complete a second chart audit of the geriatric patients on the inpatient service with the attached audit sheet. Will the systems change be sustainable? Are there refinements to the initial plans suggested by the team? Has this changed your individual practice?
<table>
<thead>
<tr>
<th>MR #</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Fracture on admission?</td>
<td></td>
</tr>
<tr>
<td>Prior Fracture or history of osteoporosis?</td>
<td></td>
</tr>
<tr>
<td>Osteopenia on x-ray?</td>
<td></td>
</tr>
<tr>
<td>Prednisone use (now or past?)</td>
<td></td>
</tr>
<tr>
<td>Other risk factors (myeloma, smoking, heparin long term?)</td>
<td></td>
</tr>
<tr>
<td>Falls?</td>
<td></td>
</tr>
<tr>
<td>BMD ever done or ordered?</td>
<td></td>
</tr>
<tr>
<td>Calcium on admission?</td>
<td></td>
</tr>
<tr>
<td>Calcium at discharge?</td>
<td></td>
</tr>
<tr>
<td>Vitamin D on admission?</td>
<td></td>
</tr>
<tr>
<td>Vitamin D at discharge?</td>
<td></td>
</tr>
<tr>
<td>Bisphosphonate on admission?</td>
<td></td>
</tr>
<tr>
<td>Bisphosphonate at discharge?</td>
<td></td>
</tr>
<tr>
<td>Other treatment?</td>
<td></td>
</tr>
<tr>
<td>Documented clear reason why bisphosphonate contraindicated?</td>
<td></td>
</tr>
</tbody>
</table>
References: