What is Osteoporosis?

**OSTEOPOROSIS** is defined as “reduced bone strength leading to an increased risk of fracture”. Osteoporosis, or “porous bones”, occurs when the body loses too much bone, makes too little bone or both. Loss of bone is a painless process – there are no warning signs or symptoms until a fracture occurs. The most common sites for osteoporosis-related fractures are the spine, hip and wrist.

How Common is it?

Osteoporosis is progressively more common after the age of 50, and 1 of 2 women (50%) and 1 of 5 men (20%) will experience an osteoporosis-related fracture in their lifetime. A fracture at any age can be a life-changing event, but especially so for older persons. Obvious consequences of fractures include acute pain and loss of mobility, but anxiety and depression may follow if independence is lost due to chronic pain and/or an inability to return to work or usual activities. Hip fractures are the most serious consequence of osteoporosis because of complications from the fracture or surgery to treat the fracture. Within 6 months after a hip fracture, 20% of patients will die from complications related to the fracture, and another 20% will need permanent nursing home care. Only about half of patients will be able to return to fully independent living after a hip fracture.

Why Does it Occur and What Factors Increase Risk of Fractures?

Men and women begin losing bone in their early to mid-forties. Factors that increase the rate of bone loss and risk of fracture include inadequate calcium and vitamin D intake, cigarette smoking, a very low body weight, aging, and menopause (especially early menopause). Other risk factors include a family history of osteoporosis, lack of weight bearing activity, daily alcohol excess, excessive loss of calcium in the urine, certain diseases and a variety of medications (such as prednisone and similar cortisone-like steroids, some anti-epilepsy drugs, certain antidepressants, proton pump inhibitors to treat heartburn and indigestion, among others). Fractures occur when an increased mechanical force (a fall, or other trauma or mechanical strain – such as lifting, pulling or twisting) overcomes bone strength. Fracture risk is directly related to bone density, and is greatest in patients with osteoporosis. The best way to determine fracture risk is to include a bone mineral density (BMD) test measurement with other risk factors for bone loss in a fracture risk assessment tool such as FRAX® (http://www.shef.ac.uk/FRAX/). FRAX® was developed by the World Health Organization and calculates the 10-year probability of both a hip fracture and a major osteoporotic fracture (i.e., spine, hip, forearm or shoulder fracture) in helping to guide treatment decisions.
**How is it Diagnosed?**

Osteoporosis is diagnosed in the presence of a fragility fracture (defined as a fracture from a standing position, regardless of how one falls). In the absence of a prior fracture, the BMD is an excellent test to help estimate the risk of a future fracture. The BMD measures the degree of bone loss, and is used as a guide to initiate therapy and to monitor the response to treatment. BMD can be measured by several techniques. The most widely-accepted is dual-energy x-ray absorptiometry (DXA). DXA is a safe, painless test that takes just a few minutes to perform at the spine and the hip. A patient’s BMD result is reported as gender-matched standard deviations from both healthy young (i.e., T score) and age-matched (i.e., Z score) adults. T scores between -1.0 and -2.5 reflect low bone density and are called “osteopenia”, and a T score of -2.5 or below is consistent with “osteoporosis”. Patients with osteoporosis are candidates for drug therapy as they have a higher overall risk of fracture. Of note, “osteoporosis” can be diagnosed with a T score in the osteopenia range when associated with other risk factors that result in a high FRAX® score. However, FRAX® is not intended for use in persons who have BMD T scores in the osteoporosis range or for those who have had a previous hip or spine fracture, as they are already candidates for treatment.

**Rare Adverse Events from Osteoporosis Treatment**

There are two safety concerns about osteoporosis medications that are extremely rare, but deserve mention.

**Osteonecrosis of the Jaw (ONJ)**

ONJ manifests as exposed bone, slow to heal, resulting from an invasive dental procedure such as a tooth extraction. ONJ is not associated with routine procedures such as dental cleaning or treatment of cavities. The incidence is very rare, estimated at 1 out of 10,000 to 100,000 people being treated for osteoporosis. ONJ must not be confused with other jaw symptoms (clicking, locking, or osteoarthritis pain of the mandible jaw joint) not associated with osteoporosis medications.

Patients are sometimes inappropriately advised to avoid osteoporosis medications because of impending dental work. The benefits of osteoporosis treatment far outweigh the risk of ONJ.

**Atypical Fractures of the Femur (AFF)**

Fractures of the proximal upper leg (femur) bone may occur spontaneously or with minimal trauma in patients with osteoporosis. They occur in a specific area (subtrochanteric region) below the hip joint of the femur. Just like ONJ, these are very rare, estimated to be at the same rate of 1 out of 10,000 to 100,000 cases. Healing can occur slowly and fractures can also happen in both hips. If either ONJ or AFF is suspected, it is important to have further investigation and consider alternate treatments.
Individualized Fracture Risk

What is my risk of breaking a bone?

Age: ______

Hip Bone Mineral Density (T score): ______

- Prior fracture
  (if with no symptoms, an x-ray of your back may be needed to check for spine fractures)
- Parent had a fracture
- Current smoker
- Intake of more than 2 drinks of alcohol a day
- Taking steroid medications
- Falls frequently

Based on these risk factors, we estimate that your fracture risk is:

- Low Risk
- Moderate Risk
- High Risk

FRAX SCORE

% Major Osteoporotic Fracture Risk

% Hip Fracture Risk

- Drug therapy is recommended if the FRAX scores are >= 20% for major osteoporosis fractures, >=3% for hip fracture risk in the US (may vary by country)

- Commonly used drugs reduce these fracture risk by approximately 50% (see table for drug efficacy on next page)
## Medication Options

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<th>Medication</th>
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<th>How it is Given</th>
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<tr>
<td><strong>Alendronate</strong></td>
<td>Decreases bone breakdown, decreases fracture risk</td>
<td>1 pill once weekly 30 minutes before breakfast and other medications</td>
<td>Heartburn, stomach pain, bone pains, joint or muscle pains; caution if decreased kidney function, don't use after certain stomach surgeries</td>
<td>🟢🟢🟢🟢🟢</td>
</tr>
<tr>
<td><strong>Risedronate</strong></td>
<td>Decreases bone breakdown, decreases fracture risk</td>
<td>1 pill once weekly (Actonel 35 mg) or once monthly (Actonel 150 mg) 30 minutes before breakfast and other medications, or 1 pill once weekly after breakfast (Atelvia)</td>
<td>Heartburn, stomach pain, bone pains, joint or muscle pains; caution if decreased kidney function, don't use after certain stomach surgeries</td>
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</tr>
<tr>
<td><strong>Ibandronate</strong></td>
<td>Decreases bone breakdown, decreases fracture risk</td>
<td>1 pill once monthly 1 hour before breakfast</td>
<td>Heartburn, stomach pain, bone pains, joint or muscle pains; caution if decreased kidney function, don't use after certain stomach surgeries</td>
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<tr>
<td><strong>Zoledronic Acid</strong></td>
<td>Decreases bone breakdown, decreases fracture risk</td>
<td>Intravenous (IV) infusion once yearly</td>
<td>Mild to moderate flu like symptoms, generalized bone, joint, or muscle pains; caution if decreased kidney function</td>
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<tr>
<td><strong>Denosumab</strong></td>
<td>Decreases bone breakdown, decreases fracture risk</td>
<td>Subcutaneous injection (‘shot’) every 6 months</td>
<td>Bone pain, joint or muscle pains, and rare risk of skin rash/problems, and low blood calcium</td>
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<tr>
<td><strong>Raloxifene</strong></td>
<td>Decreases bone breakdown, decreases spine (not hip) fracture risk</td>
<td>1 pill daily</td>
<td>Hot flashes, rare blood clots</td>
<td>🟢🟢</td>
</tr>
<tr>
<td><strong>Calcitonin</strong></td>
<td>Decreases bone breakdown, no benefit to prevent fractures</td>
<td>Nasal spray once daily, or subcutaneous injection (‘shot’) once daily</td>
<td>Nasal irritation, injection site reaction</td>
<td>🟢</td>
</tr>
<tr>
<td><strong>Teriparatide</strong></td>
<td>Increases bone formation and bone density, decreases fracture risk</td>
<td>Subcutaneous injection (‘shot’) once daily using an injection pen device</td>
<td>Injection site reaction, leg cramps</td>
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</tbody>
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### Efficacy:

- ✓ ✓ ✓ ✓ ✓ is the most efficacious in decreasing fracture risk

*Efficacy is based on fracture risk reduction data (spine, non-spine and hip) as well as other endpoints.*
Non-Pharmacologic Options

<table>
<thead>
<tr>
<th></th>
<th>How it Works</th>
<th>Recommended Dose/Frequency</th>
<th>Side Effects</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium (-Carbonate or Citrate)</td>
<td>Main mineral component of bone</td>
<td>1000 mg daily (diet + supplement) in divided dose for all adults; 1200 mg daily in divided dose for postmenopausal women and men age &gt;70 years</td>
<td>Bloating, constipation, gas</td>
<td>✔️ ✔️</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Increases calcium absorption</td>
<td>1000-2000 IU daily or higher doses in special situations</td>
<td>Generally well tolerated</td>
<td>✔️ ✔️</td>
</tr>
<tr>
<td>Exercise</td>
<td>Slight increase in bone density</td>
<td>30 minutes daily of weight bearing activity (walking or walking equivalent - treadmill, elliptical, etc.)</td>
<td>Muscle sprains if too much</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Efficacy: ✔️ ✔️ is the most efficacious in decreasing fracture risk

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Balancing Benefits vs Risks

10-Year Probabilities

80 year old with a FN T-score of -3.0, a maternal history of hip fracture and a prior fracture

- **Fx Risk Untreated (60%)**
  - Includes 0.01% Atypical Femur Fracture Risk
- **Fx Risk Treated (30%)**
  - Includes 0.5% Atypical Femur Fracture Risk
- **Atypical Fracture Risk (0.01%)**
- **ONJ Treated (0.01%)**
- **Fatal MVA (0.11%)**
- **Murder (0.06%)**

Treatment Summary

- Medication: ________________________________________________________________
- Calcium: Dietary sources: _____________ mg Supplements: _____________ mg
- Vitamin D: ________________________________________________________________
- Exercise: ____________________ minutes daily / weekly
- Fall Prevention
- Follow up DXA / labs in _____________ months
- Return visit in _____________ months