Prevalence of Osteoporosis

- 1.5 million fractures annually in the U.S.
- Overall lifetime risk for an osteoporotic fracture is about 1 in 2 for women and 1 in 5 for men
Epidemiology of Osteoporosis

- Approximately 8 million women were estimated to have osteoporosis in 2010
- Approximately 1 in 2 women over the age of 50 years will have an osteoporosis-related fracture in their remaining lifetime
- Approximately 2 million men were estimated to have osteoporosis in 2010
- Up to 1 in 5 men over the age of 50 years will have an osteoporosis-related fracture in his remaining lifetime
- Caucasian and Asian ancestry are risk factors for developing osteoporosis
- By 2025, the number of fracture due to osteoporosis is expected to increase to over 3 million

Incidence of Osteoporosis

Impact of Osteoporosis

- Every year, osteoporosis-related morbidity results in:
  - More than 430,000 hospital admissions
  - 180,000 nursing home admissions
  - 2.5 million office visits
- Majority of osteoporosis-related fractures occur in patients who have Medicare coverage
  - 75% of osteoporosis costs in these patients result from hip fractures
- Costs associated with osteoporosis are expected to rise to over $25 billion in 2025
Osteoporosis Overview

- Silent disease until complicated by fractures
  - Fracture can occur following minimal trauma
- Most common bone disease in humans
- Skeletal disorder characterized by low bone mass, deterioration of bone tissue and disruption of bone micro-architecture, compromised bone strength and an increased risk of fracture

Evaluating Bone Strength

- Bone strength reflects the integration of BMD and bone quality

\[
\text{Bone Strength} = \text{BMD} + \text{Bone Quality}
\]

WHO Diagnostic Classification of Osteoporosis

- Measured with Dual-Energy X-Ray Absorptiometry (DXA)
- BMD at hip or spine ≤ 2.5 standard deviations below young normal mean reference population
- Majority of fractures occur in patients with low bone mass

[Images of bone micro-architecture]
Osteoporosis

• Can be prevented and can be diagnosed and treated before any fractures occur
• Became increasingly clear that many patients are not having appropriate testing to diagnose osteoporosis

Fragility Fractures

• Osteoporosis can get worse over time, until your bones become fragile enough that they can fracture while doing every day activities

Economic Toll of Osteoporosis

• Major economic toll on nation
• Osteoporosis related fracture create a heavy economic burden, causing more than 432,000 hospital admissions, almost 2.5 million medial office visits and about 180,000 nursing home admissions annually in the US
• The cost to the health care system associated with osteoporosis related fracture has been estimated at $17 billion for 2005
• Due to the aging population, estimates the number of hip fractures and their associated costs to double or triple by year 2040
Major Recommendations to Clinicians

- Counsel on risk of osteoporosis and related fractures
- Check for secondary causes
- Advise on adequate amounts of calcium and vitamin D
- Recommend regular weight bearing exercise to reduce risk of falls
- Advise avoidance of tobacco smoking and excessive alcohol intake

Major Recommendations to Clinicians

- Bone mineral density (BMD) testing for women age 65 and older/men age 70 and older
- BMD testing when concerned based on risk factor profile in postmenopausal women and men age 50-69
- BMD testing to those who have had a fracture, to determine severity of disease

Major Recommendations to Clinicians

- Initiate therapy in those with hip or vertebral fractures
- Initiate therapy in those with BMD T scores ≤ -2.5 at femoral neck or spine by DXA, after appropriate evaluation
- Initiate therapy in postmenopausal women and men age 50 and older with low bone mass (T score between -1.0 and -2.5, osteopenia) at femoral neck or spine and 10 year hip fracture probability ≥ 3% or 10 year major osteoporotic fracture probability ≥ 20% based on FRAX
Major Recommendations to Clinicians

- Current pharmacologic options for osteoporosis prevention and/or treatment
  - Bisphosphonates (alendronate, ibandronate, risedronate, zoledronic acid)
  - Calcitonin
  - Estrogens and/or Hormone therapy
  - Parathyroid hormone (teriparatide)
  - Estrogen agonist/antagonist (raloxifene)
- BMD testing is typically performed 2 years after initiating therapy and every 2 years thereafter

Medical Impact of Osteoporosis

- Most fracture in older adults are due in part to low bone mass, even when they result from considerable trauma.
- Fractures may be followed by full recovery or by chronic pain, disability, and death.
Medical Impact of Osteoporosis

• Hip fractures result in 10-20% excess mortality within 1 year.
  – Hip fractures are associated with 2.5 fold increased risk of subsequent fractures
• Approximately 20% of hip fracture patients require long term nursing home care, and only 40% fully regain their pre fracture level of independence.
• Mortality is also increased following vertebral fractures, which cause significant complications including back pain, height loss and kyphosis.

Bone Remodeling

• The process of bone remodeling maintains a healthy skeleton
  – Occurs throughout life to repair fatigue damage and micro-fractures in bone
  – Removing older bone and replacing with new bone
• Bone loss occurs when this balance is altered, resulting in greater bone removal than replacement
  – Imbalance occurs with menopause and advancing age
  – With the onset of menopause, the rate of bone remodeling increases, magnifying the impact of the remodeling imbalance
  – The loss of bone tissue leads to disordered skeletal architecture and an increase in fracture risk.
Bone Loss

- A consequence of bone loss leaves architecturally weakened structure with significantly reduced mass.
- Rapid bone remodeling increases bone fragility and fracture risk.
- Bone loss leads to an increased risk of fracture that is magnified by other aging associated declines in functioning.
- Fractures result when weakened bone is overloaded, often by falls or certain activities of daily living.

Risk Assessment

- In general, the more risk factors that are present, the greater the risk of fracture.
- Many factors have been associated with an increased risk of osteoporosis-related fracture.

<table>
<thead>
<tr>
<th>Lifestyle Factors</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Low calcium intake</td>
<td>Vitamin D insufficiency</td>
<td>Excess vitamin A</td>
</tr>
<tr>
<td>High caffeine intake</td>
<td>High salt intake</td>
<td>Aluminum (in antacids)</td>
</tr>
<tr>
<td>Alcohol (1 or more drinks/day)</td>
<td>Inadequate physical activity</td>
<td>Immobilization</td>
</tr>
<tr>
<td>Smoking (active or passive)</td>
<td>Falling</td>
<td>Thinness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Miscellaneous Conditions and Diseases</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholism</td>
<td>Emphysema</td>
<td>Muscular dystrophy</td>
</tr>
<tr>
<td>Amyloidosis</td>
<td>End stage renal disease</td>
<td>Parenteral nutrition</td>
</tr>
<tr>
<td>Chronic metabolic acidosis</td>
<td>Epilepsy</td>
<td>Post transplant bone disease</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>Idiopathic scoliosis</td>
<td>Prior fracture as an adult</td>
</tr>
<tr>
<td>Depression</td>
<td>Multiple sclerosis</td>
<td>Sarcoidosis</td>
</tr>
</tbody>
</table>
Risk Assessment

• A prior fracture at any skeletal site double future fracture risk

It is also important to evaluate risk factors for falling.
• The most important of these seem to be a personal history of falling, along with muscle weakness and gait, balance and visual deficits.

Risk Factor for Falls

• Environmental factors
  – Lack of assistive devices in bathrooms
  – Loose throw rugs
  – Low level lighting
  – Obstacles in walking path
  – Slippery outdoor conditions

• Medical risk factors
  – Age
  – Anxiety and agitation
  – Arrhythmias
  – Dehydration
  – Depression
  – Female gender
  – Impaired transfer and mobility
  – Malnutrition
  – Medications causing oversedation (narcotics, anticonvulsants, psychotropics)
  – Orthostatic hypotension
  – Poor vision and use of bifocals
  – Urgent urinary incontinence
Risk Assessment

- This set of risk factors increases risk independently of BMD and can be combined with BMD measurements and used to assess an individual patient’s risk of future fracture.

<table>
<thead>
<tr>
<th>WHO 10 Year Fracture Risk Assessment Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current age</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Prior osteoporotic fracture</td>
</tr>
<tr>
<td>Femoral neck BMD</td>
</tr>
<tr>
<td>Low body mass index</td>
</tr>
<tr>
<td>Oral glucocorticoids ≥ 5mg/dL of prednisone for ≥ 3 mo (ever)</td>
</tr>
</tbody>
</table>

WHO Fracture Risk Algorithm in US (FRAX)

- Calculates 10 year probability of a hip fracture and 10 year probability of major osteoporotic fracture
  - Takes into account femoral neck BMD and clinical risk factors

Risk Assessment

- One-half of patients presenting with hip fractures have suffered a prior fracture
Laboratory Tests

• Complete blood cell (CBC) count
• Serum Chemistry studies (calcium, phosphorus, total protein, albumin, liver enzymes, alkaline phosphatase, creatinine, and electrolytes)
• 24 hour urinary calcium excretion
• Serum 25 (OH) vitamin D level
• Parathyroid hormone (PTH) level

Diagnosis of Osteoporosis

• Established by measurement of bone mineral density (BMD)
  – Correlates with bone strength and is an excellent predictor of future fracture risk
• Dual-energy x-ray absorptiometry (DXA) measurement of hip and spine
  – Used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk and monitor patients by performing serial assessments
  – Reported by Z score or T score
    • Z score — compared to expected BMD for patient’s age and sex
    • T score — compared to “young normal” adults of the same sex

Diagnosis of Osteoporosis

• Normal
  – BMD is within 1 SD of a “young normal” adult
  – T score at -1.0 and above
• Low bone mass (Osteopenia)
  – BMD is between 1.0 and 2.5 SD below that of a “young normal” adult
  – T score between -1.0 and -2.5
• Osteoporosis
  – BMD is 2.5 SD or more below that of a “young normal” adult
  – T score at or below -2.5
  – Patients in this group who have already experienced one or more fractures are deemed to have severe or established osteoporosis.
Indications for BMD Testing

• Women age 65 and older and men age 70 and older, regardless of clinical risk factors
• Younger postmenopausal women and men age 50-69 with risk factors
• Women in the menopausal transition if there is a specific risk factor associated with increased fracture risk (low body weight, prior low trauma fracture, high risk medication)
• Adults who have a fracture after age 50
• Adults with a condition or taking medication associated with low bone mass or bone loss
• Anyone being considered for pharmacologic therapy for osteoporosis
• Anyone being treated for osteoporosis, to monitor treatment effect
• Postmenopausal women discontinuing estrogen

Medicare covers BMD testing

• For individuals age 65 and older
  – Estrogen deficient women at clinical risk for osteoporosis
  – Individuals with vertebral abnormalities
  – Individuals receiving, planning to receive, long term glucocorticoid therapy in a daily dose of ≥ 5 mg prednisone or equivalent for ≥ 3 months
  – Individuals with primary hyperparathyroidism
  – Individuals being monitored to assess response or efficacy of osteoporosis drug therapy
DXA Scan Results

- Cost effective to treat individuals with a prior hip or vertebral fracture
- And those with a DXA femoral neck T score ≤ -2.5
- Spine T score ≤ -2.5 also warrants treatment

Vertebral Fracture Assessment (VFA)

- Independent of BMD, age, and other clinical risk factors, radiographically confirmed vertebral fractures are a strong predictor of new vertebral fractures
  - They also predict other fractures
  - VFA imaging of thoracic and lumbar spine using central DXA scanners should be considered at time of BMD assessment when presence of vertebral fracture not previously identified.
Universal Recommendations

• Adequate intake of calcium and vitamin D
  – At least 1,200 mg of calcium per day
  – Intake of 800-1,000 IU of vitamin D per day
• Lifelong participation in regular weight-bearing and muscle-strengthening exercise
  – Walking, jogging, Tai-Chi, stair climbing, dancing, tennis
• Avoidance of tobacco use
• Identification and treatment of alcoholism
  – Moderate alcohol intake has no negative effect on bone
• Treatment of other risk factor for fracture

Pharmacological Therapies

• FDA-approved osteoporosis treatments have been shown to decreased fracture risk in patients who have had fragility fracture and/or osteoporosis by DXA.
• Pharmacotherapy may also reduce fractures in patients with low bone mass (osteopenia) without fractures.

Bisphosphonates

• Generic name: Alendronate
• Brand name: Fosamax
• Use in prevention and treatment of osteoporosis
  • Prevention: 5 mg daily and 35 mg weekly tablets
  • Treatment: 10 mg daily tablet, 70 mg weekly tablet
• Reduces the incidence of spine and hip fractures by about 50% over 3 years in patients with a prior vertebral fracture
Bisphosphonates

- Generic name: Ibandronate
- Brand name: Boniva
- Use in Treatment: 2.5 mg daily tablet, 150 mg monthly tablet, 3 mg every 3 months by IV injection
- Reduces the incidence of vertebral fractures by 50% over 3 years

Bisphosphonates

- Generic name: Risedronate
- Brand name: Actonel
- Prevention & Treatment: 5 mg daily tablet, 35 mg weekly tablet, 150 mg monthly tablet
- Increases bone mass in men with osteoporosis and prevention & treatment of osteoporosis in men and women who are either initiating or taking glucocorticoids
- Reduces the incidence of vertebral fractures by 45% and non vertebral fracture by 36% over 3 years, with significant risk reduction occurring after 1 year of treatment in patients with prior vertebral fracture

Bisphosphonates

- Generic name: Zoledronic acid
- Brand name: Reclast
- Prevention & Treatment: 5 mg IV infusion over 15 minutes once yearly for treatment and once every 2 years for prevention
- Prevention and treatment of osteoporosis in men and women on glucocorticoid therapy
- Prevention of new fractures in patient who have recently had a low trauma hip fracture
- Reduces the incidence of vertebral fracture by 70%, hip fractures by about 40% and non vertebral fractures by about 25% over 3 years
Bisphosphonates

• Side effects
  – Gastrointestinal problems
    • Difficulty swallowing, inflammation of esophagus and gastric ulcer
  – Osteonecrosis of jaw
    • Risk is rare for at least up to 5 years
  – Visual disturbances
  – Atrial fibrillation
    • Zoledronic acid when compared to placebo
    • Atypical femur fractures

Calcitonin

• Brand name: Miacalcin or Fortical
• Treatment of osteoporosis in women who are at least 5 years postmenopausal
• Single daily intranasal spray (200 IU) or Subcutaneous injection administration

Immunologic/Monoclonal

• Generic name: Denosumab
• Brand name: Prolia
• Treatment of osteoporosis in post menopausal women
  • Who are at high risk for fracture
  • Who have multiple risk factors
  • Who other osteoporosis medication do not work well
Estrogen/Hormone Therapy

- Estrogen brand names: Climara, Estrace, Premarin, Vivelle
- Hormone brand names: Activella, Prempro, Premphase
- Prevention of osteoporosis, relief of vasomotor symptoms and vulvovaginal atrophy associated with menopause
- 5 years of hormone therapy reduces the risk of clinical vertebral fractures and hip fractures by 34% and other osteoporotic fractures by 23%.

Estrogen Agonist/Antagonist (SERMs)

- Generic name: Raloxifene
- Brand name: Evista
- Prevention & Treatment
  - Reduces the risk of vertebral fracture by 30% in patients with prior vertebral fracture and by 55% in patients without prior vertebral fracture over 3 years
  - Reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis
  - Increases the risk of deep vein thrombosis to a degree
  - Also increase hot flashes

Parathyroid Hormone

- Generic name: Teriparatide; Brand name: Forteo
- Anabolic (bone building) agent
- Increases bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture
- Treatment of osteoporosis in postmenopausal women and men at high risk for fracture
- Treatment in men and women at high risk of fracture with osteoporosis associated with glucocorticoid therapy
- Subcutaneous injection, 20µg daily
- Decreases the risk of vertebral fracture by 65% and non vertebral fractures by 53%
Effectiveness of Treatment

• It is important to ask patients whether they are taking their medications and to encourage continued and appropriate compliance with their osteoporosis therapies to reduce fracture risk.
• It is important to review their risk factors and encourage appropriate calcium and vitamin D intakes, exercise, fall preventions, and other healthy lifestyle measures.
• Recommendation for repeat BMD assessment every 2 years

Risks of Treatment or Risks of Not Treating
Physical Medicine and Rehabilitation

- Provide training for safe activities of daily living (posture, transfers, lifting, and ambulation)
  - Assistive device may be beneficial for improved balance with mobility
- Evaluate home environment for risk factors for falls and intervene where appropriate
- Advise patients to avoid forward bending and exercising with trunk in flexion
- Avoid long term immobilization & Recommend partial bed rest only
- In patients with acute vertebral fractures or chronic pain after multiple fracture, the use of trunk orthoses may provide pain relief by reducing loads on fracture sites and aligning vertebra
  - However, long-term bracing may lead to muscle weakness and further de-conditioning.

Osteoporosis Treatment Gap

In one study, 3 out of 4 post menopausal women in the US did not receive treatment during the year following a fragility fracture
Osteoporosis Treatment Gap

Fracture Liaison Service (FLS)

- Osteoporosis related fractures are related for significant human and financial costs
  - Approximately 2 million fractures are caused by osteoporosis each year
  - Despite the alarming incidence of fractures each year, less than 25% of older women who suffer from a fracture will receive appropriate screening and/or treatment this year.
- However, provider performance around osteoporosis and post fracture quality measures are low despite the existence of several quality measures from the National Committee for Quality Assurance and Centers for Medicare and Medicaid Services.

Fracture Liaison Service (FLS)

- The solution to closing this nearly 75% post fracture care gap in the US is the implementation of fracture liaison service (FLS) programs.
  - The FLS model of care is a coordinated preventative care model which operates under the supervision of a bone health specialist and collaborates with the patient’s primary care physician and has shown to improve patient outcomes and significantly reduce the incidence of secondary fractures for more than 15 years of operation in the US and internationally.
Fracture Liaison Service (FLS)

**FLS Effectiveness**

<table>
<thead>
<tr>
<th>Model</th>
<th>Proportion receiving BMD testing</th>
<th>Proportion receiving osteoporosis treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status Quo</td>
<td>13%</td>
<td>8%</td>
</tr>
<tr>
<td>Type D</td>
<td>No study on BMD testing</td>
<td>8%</td>
</tr>
<tr>
<td>Type C</td>
<td>43%</td>
<td>23%</td>
</tr>
<tr>
<td>Type B</td>
<td>60%</td>
<td>41%</td>
</tr>
<tr>
<td>Type A</td>
<td>79%</td>
<td>46%</td>
</tr>
</tbody>
</table>

Ganda K et al. Osteoporosis International 2013 Feb; 24 (2); 393-406.
Osteoporosis Canada. “Make the FIRST break the LAST with Fracture Liaison Services.”

**FLS Effectiveness**

1. Identification – robust outreach and in reach for case finding
2. Investigation – which will need local DXA access
3. Initiation – of treatment and with support education
4. Adherence – to medications and other interventions in the long term
Components of FLS Program

- Physician and Administrative Champions
- FLS Coordinator
- Database to identify patients at risk
- Access to DXA
- Performance reporting and evaluation

Our FLS Program

- Administrative Champion – Jerry Blanton
- Administrative Support Staff – Claire Bosma, Cherilyn Bogan
- Health Care Champion – Dr. Anthony Czaplicki
- FLS Coordinators – Rhiannon Anderson & Linda Mitchell
- Nurse Navigator – Michele Jarboe
Goals of a FLS program

- Overall goal – promote good bone health for patients of all ages through osteoporosis prevention strategies and treatment to lower risk of osteoporosis fractures.
  - Reduce # of secondary fractures
  - Increase # of DXA scans in patients at risk for fractures
  - Increase 3 of patients on anti-osteoporosis treatment who are at risk for fragility fractures and standardize treatment of osteoporosis
  - Improve cost effectiveness

Impact of Osteoporosis

- Every year, there are 2 million bone breaks that are no accident, but signs of osteoporosis!