

Understanding Osteoporosis

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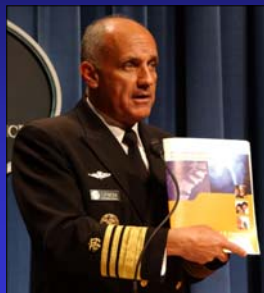
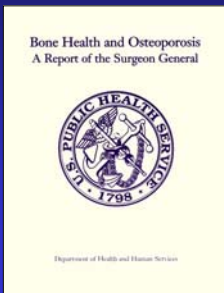


Learning Objectives

- Understand the public health impact of osteoporosis
- Describe methods to identify the risk and the importance of fracture reduction
- Describe the treatments for fracture reduction currently available.

Everyone has a Role to Play in Improving Bone Health

This report is a starting point for national action



NYSOPEP The New York State Osteoporosis Prevention and Education Program



- Established in 1997
- Evidence-based education
- 6 regional centers
- Visit the website www.NYSOPEP.org

Definition of Osteoporosis

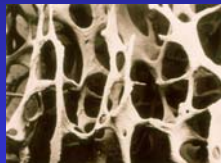
A skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture. Bone strength primarily reflects the integration of bone quality and bone density.

National Institutes of Health (USA)

Consensus Statement on Osteoporosis Prevention, Diagnosis, and Therapy, 2000

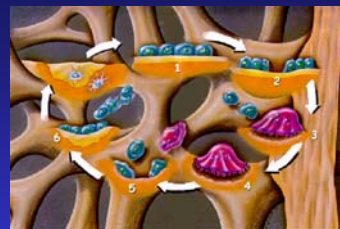


Normal Bone



Osteoporosis

Bone is alive!



There is a cycle of breaking down and rebuilding bone called *bone remodeling*

Osteoporosis

- 44 million people have osteopenia or osteoporosis¹
 - 34 million people have osteopenia or low bone density
 - 10 million people have osteoporosis
- Osteoporotic fractures are more common than heart attack, stroke, and breast cancer combined²⁻⁴

1. U.S. Department of Health and Human Services, Office of the Surgeon General, 2004.
2. Riggs BL, et al. Bone. 1995; 17(5)(Suppl):508S-511S.
3. American Heart Association. Heart and Stroke Facts/1996 Statistical Supplement.
4. Cancer Facts & Figures, 1996. American Cancer Society.

Osteoporosis: A Growing Concern for Health Plans

- Baby boomers and now at risk
 - Osteoporosis is under-diagnosed
 - Osteoporosis is under-treated
- "...Fractures...are by far the most important consequence of poor bone health since they can result in disability, diminished function, loss of independence, and premature death."

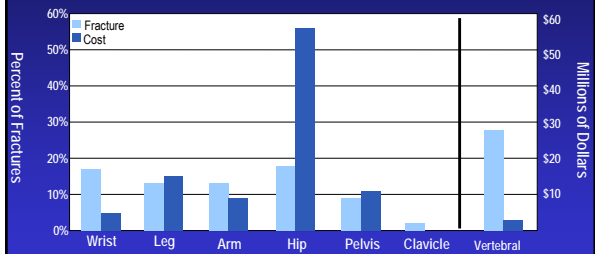
*U.S. Department of Health and Human Services, Office of the Surgeon General, 2004.
Available at: <http://www.surgeongeneral.gov/library>.

Projected Prevalence of Osteoporosis and/or Low Bone Mass of the Hip in U.S. Women and Men ≥ 50 Years Old

	2002	2010	2020
Women			
Osteoporosis	7,800,000	9,100,000	10,500,000
Low bone mass	21,800,000	26,000,000	30,400,000
Men			
Osteoporosis	2,300,000	2,800,000	3,300,000
Low bone mass	11,800,000	14,400,000	17,100,000
Both sexes			
Osteoporosis	10,100,000	12,000,000	13,900,000
Low bone mass	33,600,000	40,400,000	47,500,000
Either	43,600,000	52,400,000	61,400,000

America's Bone Health, NOF 2002

Fragility Fracture Rates in a Managed Care Population



Adachi J, et al. Online publication of abstract presented at: Annual Meeting of the European Calcified Tissue Society.

The Osteoporosis Continuum



Spine Fractures May Cause:

- ♦ Pain
- ♦ Loss of height
- ♦ Stooped posture
- ♦ Difficulty breathing
- ♦ Stomach pains/digestive discomfort
- ♦ Loss of self-esteem
- ♦ Increased risk for spine and other non-spine fractures (including hip fracture)



Hip Fractures have Serious Consequences

- ♦ Only 1 in 10 return to full activity
- ♦ 1 in 5 need a skilled nursing facility within a year
- ♦ 1 in 4 become disabled
- ♦ Many become isolated and depressed
- ♦ 1 in 5 die within a year of the fracture

It is important to identify people at risk in order to prevent fracture

- Risk factor identification
- Bone density testing
- Prior fracture

It is never too early or too late to prevent fractures

Promoting Bone Health

- ♦ Follow a bone-healthy diet
 - ♦ Well-balanced, adequate calcium & vitamin D
- ♦ Engage in regular physical activity
- ♦ Avoid harmful behaviors
 - ♦ Smoking and excessive alcohol consumption
- ♦ Assessing for and treating secondary causes

Risk Factors That Individuals Cannot Change

- ♦ Family history of osteoporosis and/or fracture
- ♦ Older age
- ♦ Being female
- ♦ Ethnicity (esp. Caucasian, Asian or Hispanic)
- ♦ Menopause at an early age
- ♦ Certain medications and/or medical conditions that may lead to bone loss or increase the risk for osteoporosis

Certain Diseases/Conditions

- ♦ Diseases that cause poor intestinal absorption (Crohn's disease, celiac disease, liver disease)
- ♦ Diseases associated with immobility or bed rest for more than 6 months (stroke, Parkinson's disease, multiple sclerosis)

Certain Medications

- ♦ Steroid medications used for more than 3 months (Cortisone, Prednisone)
- ♦ Excess thyroid hormone replacement
- ♦ Antiseizure medications (Dilantin or phenytoin, Depakote)
- ♦ Some cancer treatments

Risk Factors That Individuals Can Change

- ◆ Low lifetime calcium and/or vitamin D intake
- ◆ Lifetime lack of exercise
- ◆ Tobacco use
- ◆ Excessive alcohol use
- ◆ Being underweight
- ◆ Hormonal imbalance

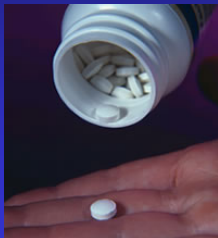


Vitamin D, Calcium and Fractures

- Four studies in elderly patients have found that supplementation with both calcium and vitamin D, resulted in fracture reductions (24-43% in hip and 22-54% in all non-spine fracture). In WHI, compliant women had a 29% reduction in hip fracture.
- One study of vitamin D alone found that there was no effect on fracture, although less than half the people took the vitamin D
- There was a 22% reductions in fracture after 100,000 IU vitamin D were given every 4 months for two years.

Vitamin D and Falls

Based on a review of 5 studies, if we treat 15 people over the age of 65 with Vitamin D supplementation (~800 IU) we will prevent one fall.



Exercise has the potential to:

- ◆ Increase bone density in youth and young adulthood
- ◆ Maintain and may modestly increase bone density in adulthood
- ◆ Prevent and minimize kyphosis
- ◆ Increase muscle mass
- ◆ Improve balance and agility
- ◆ Reduce the risk for fall-related fractures

Secondary Prevention

- ◆ Activities that block the progression of osteoporosis to a fracture
- ◆ Early detection of those at risk
- ◆ Prevent the disability from the disease by treatment of those at sufficient risk



Bone Mineral Density Tests

- ◆ Requires a prescription with a diagnosis
- ◆ Dual X-ray Absorptiometry
 - ◆ Gold standard: hip and spine
 - ◆ Painless, noninvasive
 - ◆ Safe: low dose x-ray
 - ◆ Can determine mineral content of bone



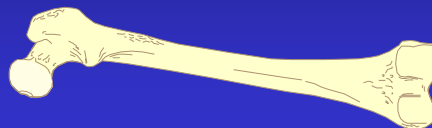
Who Should get a BMD test?

- ♦ All women by the age of 65
- ♦ All men by the age of 70
- ♦ Postmenopausal women or men who have clinical risk factors
 - ♦ Adulthood fractures, kyphosis, family history
 - ♦ Chronic diseases that increase risk of osteoporosis
 - ♦ Medications that increase risk
 - ♦ Active or recent smoking
 - ♦ Being very thin

Using T-scores to Define Bone Health

Diagnosis Based on Bone Density Test

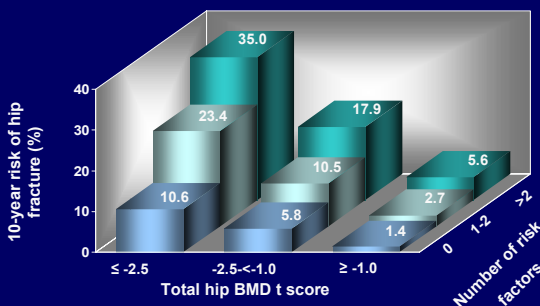
Osteoporosis (-2.5 and lower) **Low Bone Mass** (Between -1.0 and -2.5) **Normal Bone Mass** (-1.0 and above)
 ... -3.5 ... -3.0 ... -2.5 ... -2.4 ... -2.0 ... -1.5 ... -1.1 ... -1.0 ... 0.0 ... +1.5 ... +2.0 ...



The Future of BMD Testing

- The move to absolute risk
- Relative Risk: Ms Smith had a bone density evaluation. Her T-score is -2 which increases her risk of fracture by 4 times.
- 4 times what and over what time?
- Absolute risk: Defines the risk of an event specifically for that person over a reasonable time.

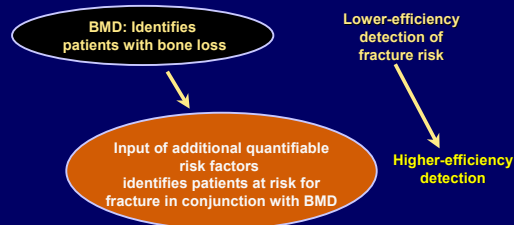
Ten-Year Risk of Hip Fracture by BMD and the Number of Risk Factors



Taylor et al. J Am Geriatr Soc. 2004;52:1479.

Identifying High-Risk Patients

Combination of BMD and risk factors leads to improved risk identification



Clinical Risk Factors¹

- Age
- Weight or BMI
- Femoral neck T-score*
- Previous low trauma fracture after age 50
- Current cigarette smoking
- Secondary osteoporosis (e.g. RA)
- High alcohol intake (> 2 units/day)**
- Family history of hip fracture (M or F)
- Prior or current glucocorticoid use

1. WHO Report. 2007. In production. Subject to change upon release of finalized WHO Report.

When is Medication Needed?

SHOULD TREAT people with:

- ♦ prior clinical vertebral or hip fracture
- ♦ prevalent vertebral deformity
- ♦ BMD in the osteoporosis range (T- score < -2.5)

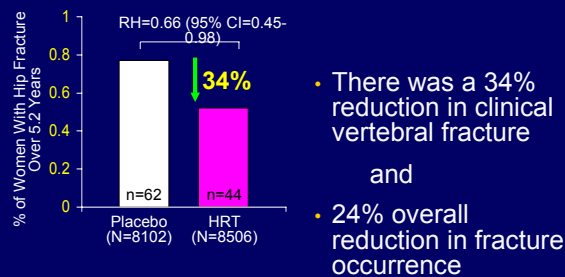
MAY TREAT people with BMD T-scores between -1.5 and -2.5 depending on number and severity of risk factors:

- ♦ prior adulthood fracture (non-spine, non-hip)
- ♦ older age
- ♦ family history of fracture
- ♦ low body weight
- ♦ high bone turnover
- ♦ medications/diseases
- ♦ smokers

U.S. FDA-Approved Medications for Osteoporosis

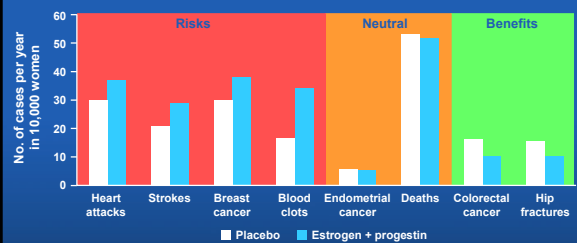
- ♦ **Antiresorptive medications-** reduce bone loss
- ♦ Bisphosphonates:
 - ♦ alendronate sodium (Fosamax) or (Fosamax Plus D)
 - ♦ ibandronate sodium (Boniva)
 - ♦ risedronate sodium (Actonel) or Actonel and Calcium
- ♦ estrogen therapy (ET) or hormone therapy (HT)
- ♦ raloxifene hydrochloride (Evista)
- ♦ salmon calcitonin (Miacalcin)
- ♦ **Anabolic agents-** build bone
- ♦ teriparatide or parathyroid hormone (Forteo)

WHI HRT Study: Incidence of Fractures



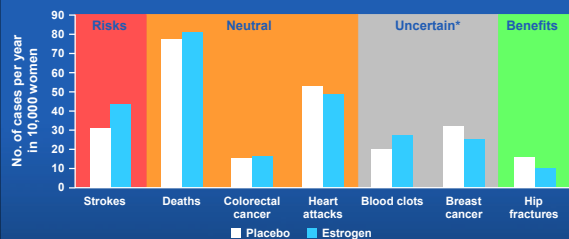
Adapted from: Writing Group for the Women's Health Initiative. *JAMA*. 2002;288:321-333.

WHI: Risk-Benefit Assessment



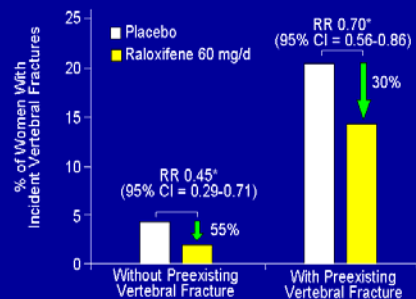
DSMB = data and safety monitoring board.
Women's Health Initiative. At: http://www.whi.org/updates/update_hrt2002.php. Accessed January 2006.

WHI: Risk-Benefit Assessment



Women's Health Initiative. At: http://www.whi.org/updates/update_hrt2004.php. Jan 2006.

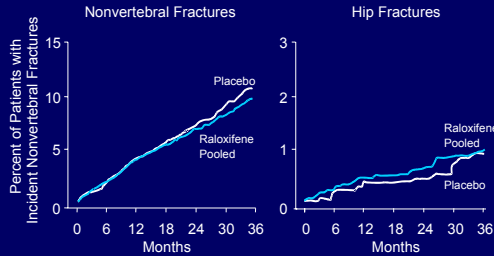
Effect of Raloxifene in Women With or Without Preexisting Fractures MORE Trial - 3 Years



Adapted from: Ettinger B, et al. *JAMA*. 1999;282:637-645.

*Rounded off in paper

Effect of Raloxifene on Nonvertebral and Hip Fracture



Ettinger B. JAMA. 1999;282:637-645.

Calcitonin (Miacalcin)

A hormone usually administered by nasal spray approved for osteoporosis treatment in women five or more years after menopause

Benefits

- ✓ Prevents bone loss in the spine but least potent of all the medicines
- ✓ Reduces risk of spine fracture in the older woman (less than other medications)
- ✓ No proof that it reduces fractures anywhere else
- ✓ May have pain relief properties following spine fracture

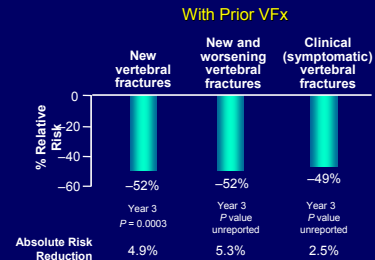
Possible Side Effects

- ✓ Runny nose, nose bleeds, nose pain

Bisphosphonates Approved for Treating Postmenopausal Osteoporosis

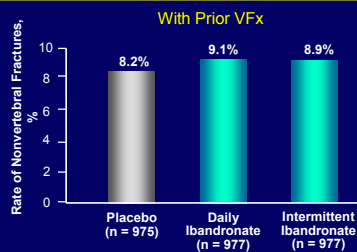
FOSAMAX PLUS D™ (alendronate sodium/cholecalciferol) Tablets and FOSAMAX® (alendronate sodium) Tablets	Actonel (risedronate sodium tablets)	Boniva (ibandronate sodium) tablets or injection
INDICATION • Increases BMD • Reduces incidence of hip and spine fractures	INDICATION • Increases BMD • Reduces incidence of vertebral fracture and a composite end point of nonvertebral fracture	INDICATION • Increases BMD • Reduces incidence of vertebral fracture
DOSING FOSAMAX PLUS D 70 mg/2800 IU once weekly FOSAMAX 70 mg once weekly or 10 mg/day	DOSING 5 mg/day or 35 mg once weekly Actonel with calcium 35 mg and 500 mg calcium	DOSING 2.5 mg/day or 150 mg once monthly Injection 3 mg every 3 months administered over 15-30 seconds
ADMINISTRATION Take at least 30 min before first food of the day. Do not lie down for at least 30 min after dosing.	ADMINISTRATION Take at least 30 min before first food of the day. Do not lie down for at least 30 min after dosing.	ADMINISTRATION Take at least 60 min before first food of the day. Do not lie down for at least 60 min after dosing.

Fracture Risk Reduction in Ibandronate Trials



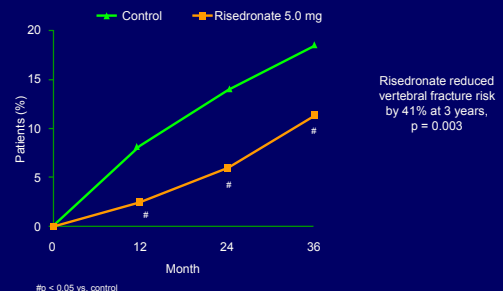
Boniva (ibandronate sodium) Tablets, Full Prescribing Information (NDA21-455). <http://www.rocheusa.com/products/Boniva/P1.pdf>. Accessed on March 31, 2005

Clinical Osteoporotic Nonvertebral Fractures vs Placebo in Ibandronate Trials

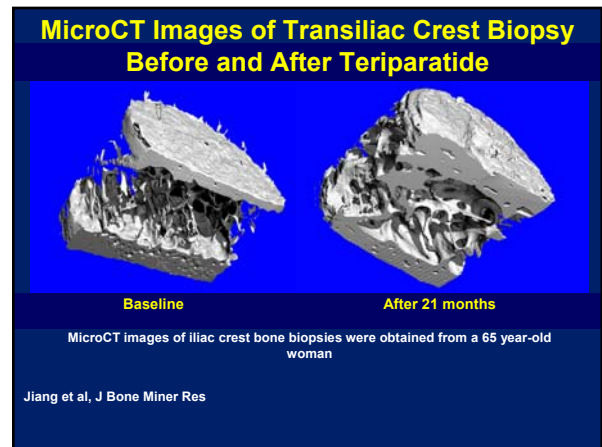
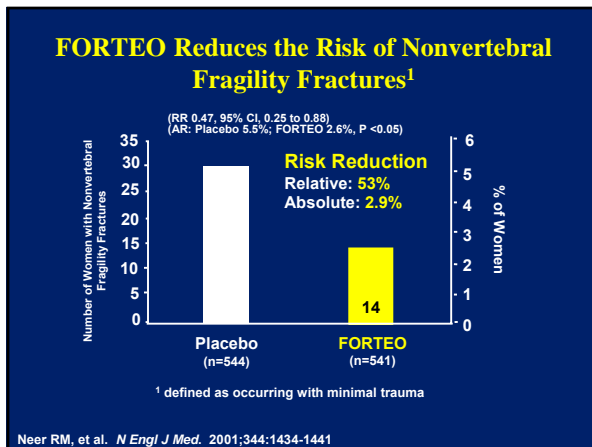
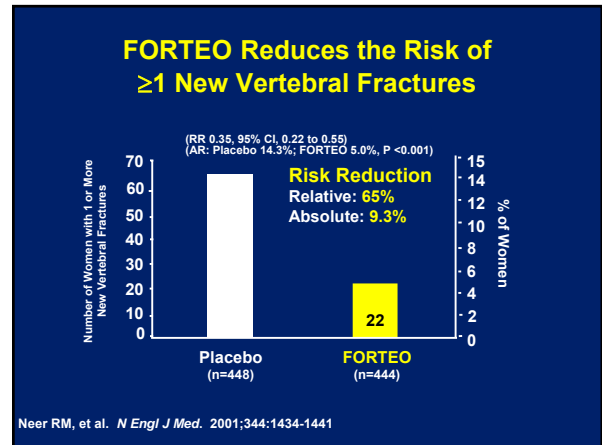
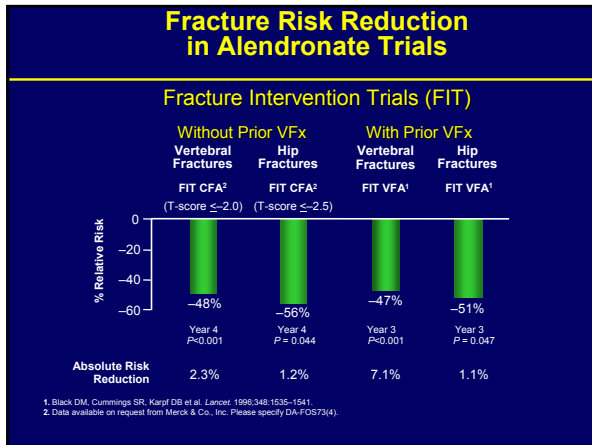
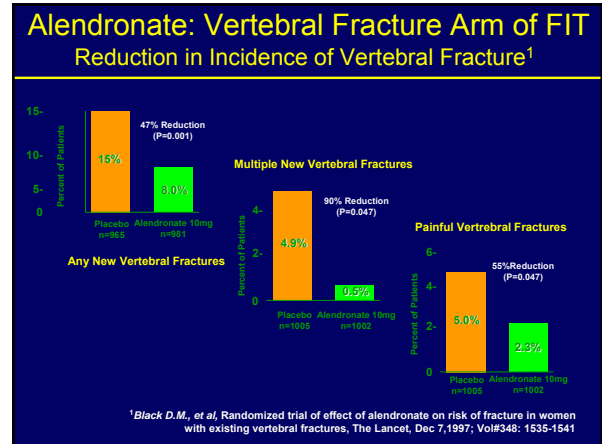
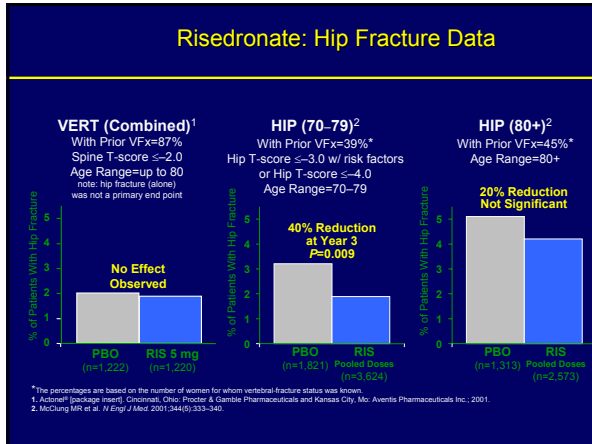


Chesnut CH III et al. J Bone Miner Res. 2004;19:1241-1249.

Risedronate: Cumulative New Vertebral Fracture Incidence



Harris, et al. JAMA. 1999



Tertiary Prevention: Following a Fracture

- ◆ Block or slow the progression of disability
- ◆ It is important to prevent falls
- ◆ Physicians fail to diagnose and treat osteoporosis
 - ◆ Bone density testing not performed
 - ◆ Calcium and vitamin D supplements not given
 - ◆ Effective medications not prescribed
 - ◆ Therapy prescribed often does not conform

Following a Fracture

- ◆ Calcium supplements reduce bone loss and fracture
- ◆ Vitamin D supplements reduce fractures and falls
- ◆ Physical activity preserves bone mass, builds muscle mass, reduces falls, delays loss of independence
 - ◆ Bed rest reduces bone mass
- ◆ Medications reduce risk of future fractures

Fall Prevention

- ◆ One third people over age 65 fall each year; half fall more than once
- ◆ 1 in 10 falls results in serious injury
- ◆ 90% of hip fractures are the result of a fall
- ◆ Activities often decrease after a fall even if not hurt
 - ◆ More deconditioned and more likely to fall again

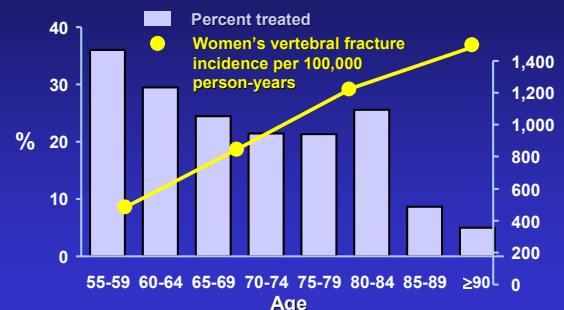
Risk for Falls

- ◆ There are identifiable risk factors for falls
- ◆ Changes with aging
 - ◆ Balance, coordination, strength, sensory, vision, blood pressure, circulation, cognition
- ◆ Use of medications
- ◆ Environmental factors

Fall Prevention

- ◆ Targeted interventions: multiple risk factors
- ◆ Muscle strengthening/balance retraining
- ◆ Professional home hazard assessment and modification
- ◆ Stopping or reducing psychotropic medications

Osteoporosis Treatment Rate After Fracture Decreases with Age as Fracture Incidence Rises



Melton LJ III et al. *Osteoporos Int*;10:214, 1999.
Freedman KG et al. *J Bone Joint Surg*;82A:1063, 2000.

Steps to Healthy Bones

- ♦ Optimal nutrition
- ♦ Healthy body weight
- ♦ Yearly height checks
- ♦ Regular exercise
- ♦ Tobacco cessation
- ♦ Moderation of alcohol intake
- ♦ Fall prevention
- ♦ Medication when indicated



Surgeon General's Report

“Federal, State, and local governments (including State and local health departments) to join forces with the private sector and community organizations in a coordinated, collaborative effort to promote bone health.”