The 2010 Clinical Practice Guidelines for Diagnosis and Management of Osteoporosis in Canada.

What does the BMD technologist need to know?

- Discuss the 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada and apply them in your daily practice to educate patients and other healthcare professionals.

Objectives for Lecture

- Explain the rationale and methodology for the development of the Clinical Practice Guidelines and the major changes from the 2002 Guidelines.
- Discuss the prevalence and impact of osteoporosis in Canada.
- Briefly discuss the clinical tools used to assess a patient for osteoporosis.
- Discuss the indications for baseline bone density measurement.
- Explain the role of BMD in fracture risk assessment.
- Discuss how fracture risk assessment guides treatment and reassessment strategies
- Discuss the various lifestyle modifications and treatments available for patients with osteoporosis

Explain the rationale and methodology for the development of the Clinical Practice Guidelines and the major changes from the 2002 Guidelines.

Evidence Based Medicine

- Evidence-based medicine (EBM) has become the foundation of clinical practice by physicians since it was formally identified in 1990 [1]. It is defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” [2] EBM seeks to apply valid research findings to achieve optimal patient care.

[1].Guyatt G, Rennie D, Meade M, Cook D. **JAMA evidence. Users' guide to the medical literature: a manual for evidence-based clinical practice**. 2nd ed.. New York, NY: McGraw-Hill; 2008;.

[2]. ***[2]***Sackett D, Rosenberg W, Gray J, Haynes R, Richardson W. **Evidence based medicine: what it is and what it isn't**. **BMJ**. 1996;**312**:71–72. **MEDLINE**

- In recognizing that sound evidence is only one component of making an informed decision, evidence-based practice (EBP) identifies a more holistic approach to patient care. EBP incorporates use of current best evidence, but also takes into account the clinical expertise/experience of the health professional and the patient's values and preferences when making a clinical decision.

From Evidence-based Practice for Medical Radiation Technologists, Cindy Murphy BHSc, RTR, ACR and Roberta Sharp BSc, MA, RTR, ACR Journal of medical Imaging and Radiation Sciences vol 40 Issue 4 Dec 2009 pg 148

Development of the Guidelines

- Key stakeholders were surveyed to identify priorities
- Systematic literature reviews were conducted in two key areas
  - Fracture risk assessment
  - Therapies for osteoporosis
- Graded recommendations were developed based on these reviews

Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].

Key Changes from 2002[1] to 2010[2]

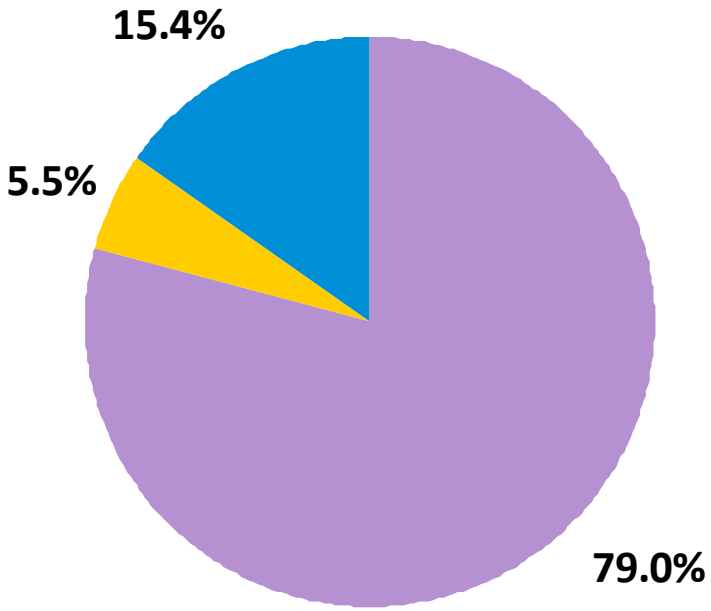
- Increased focus on the clinical impact of fragility fractures
- Increased focus on the care gap that exists in the identification and treatment of high-risk individuals

1. Brown JP, Josse RG. *CMAJ* 2002; 167(10 Suppl):S1-34.
2. Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

Undertreatment of Osteoporosis Post Fracture in Women[1]



- No diagnosis or treatment for osteoporosis
- Diagnosis of osteoporosis only
- Prescribed treatment for osteoporosis

This care gap is even wider in men and those who reside in long-term care[2,3]

A fracture is to osteoporosis what a heart attack is to cardiovascular disease. BUT...The treatment gap is far wider post fracture than post MI.[1,4]

1. Bessette L, et al. *Osteoporos Int* 2008; 19:79-86.
2. Papaioannou A, et al. *Osteoporos Int* 2008; 19(4):581-587.
3. Giangregorio L, *Osteoporos Int* 2009; 20(9):1471-8.
4. Austin PC, et al. *CMAJ* 2008; 179(9):901-908.

Key Changes from 2002[1] to 2010[2]: Fracture Risk Assessment

- 10-year fracture risk prediction tools incorporate clinical risk factors beyond BMD for improved clinical decision making:
  - CAROC: Joint initiative of the Canadian Association of Radiologists and Osteoporosis Canada[3] **OR**
  - FRAX: Fracture Risk Assessment Tool developed by the World Health Organization[4]

1. Brown JP, Josse RG. *CMAJ* 2002; 167(10 Suppl):S1-34.
2. Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print]..
3. Leslie WD, Berger C, Langsetmo L, et al. *Osteoporos Int*. In press.
4. Leslie WD, Lix LM, Langsetmo L, et al. *Osteoporos Int*. In press.

Key Changes from 2002[1] to 2010[2] (cont'd)

- Higher daily vitamin D supplementation (D3)[3]
  - 400 – 1000 IU for individuals < 50 years
  - 800 – 2000 IU for individuals > 50 years
- Lower daily calcium intake (from all sources): 1200 mg
- Updated evidence-based approach to therapies

1. Brown JP, Josse RG. *CMAJ* 2002; 167(10 Suppl):S1-34.
2. Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].
3. Hanley DA, et al. *CMAJ* 2010; 182: E610-E618.

Discuss the prevalence and impact of osteoporosis in Canada.

Osteoporosis

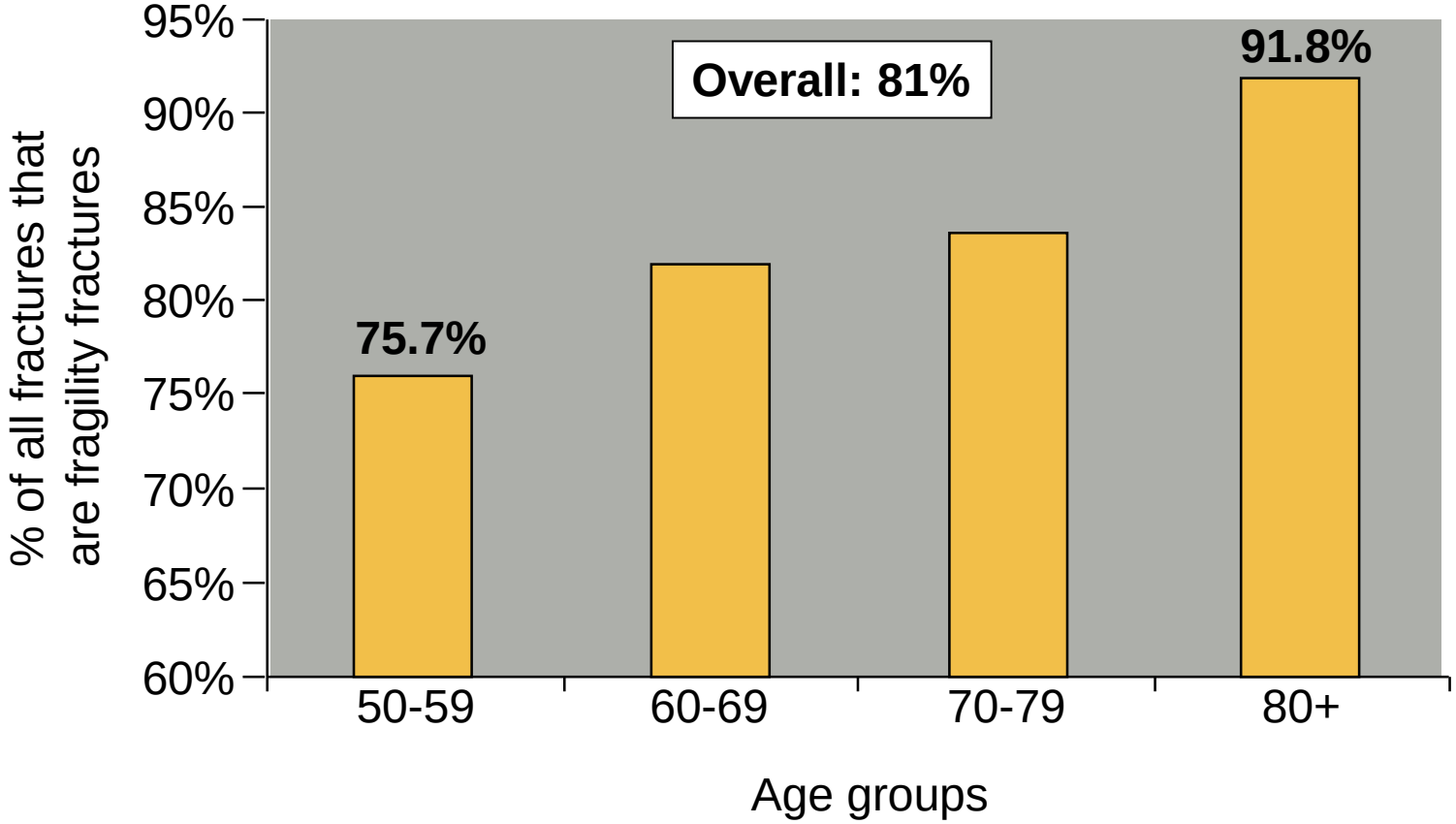
- Osteoporosis is a disease characterized by low bone mass and deterioration of bone tissue. This leads to increased bone fragility and risk of fracture (broken bones), particularly of the hip, spine and wrist. Osteoporosis is often known as "the silent thief" because bone loss occurs without symptoms. (Osteoporosis Canada)
- As many as 2 million Canadians suffer from osteoporosis.
- One in four women over the age of 50 has osteoporosis. At least one in eight men over 50 also has the disease. However, the disease can strike at any age.

Fragility Fracture: Definition

- A fracture occurring spontaneously or following minor trauma such as a fall from standing height or less[1,2]
  - Excluding craniofacial, hand, ankle and foot fractures

1. Kanis JA, et al. *Osteoporos Int* 2001; 12(5):417-427.
2. Bessette L, et al. *Osteoporos Int* 2008; 19:79-86.

The Majority of Fractures in Canadian Women ≥ Age 50 Are Fragility Fractures



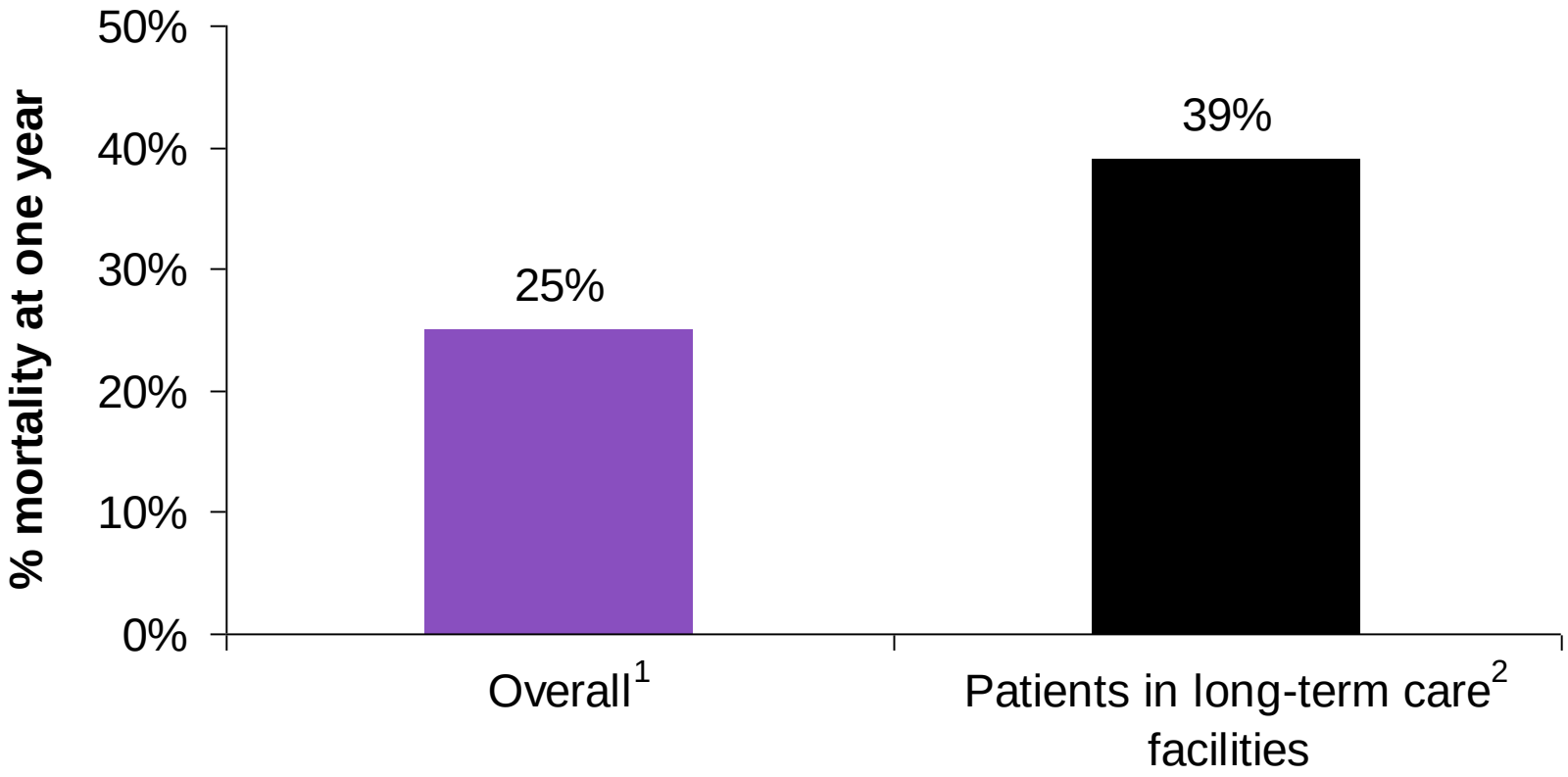
Bessette L, et al. *Osteoporos Int* 2008; 19:79-86.

Consequences of Fracture

- Increased risk of
  - Hospitalization/institutionalization[1,2]
  - Death[3-5]
  - Subsequent fracture [6-8]
- Decreased quality of life[9-12]
- Economic burden on healthcare system[2]

1. Papaioannou A, et al. *Osteoporos Int* 2001; 12(10):870-874.
2. Wiktorowicz ME, et al. *Osteoporos Int* 2001; 12(4):271-278.
3. Ioannidis G, et al. *CMAJ* 2009; 181(5):265-271.
4. Papaioannou A, et al. *J SOGC* 2000; 22(8):591-597.
5. Tosteson AN, et al. *Osteoporos Int* 2007; 18(11):1463-1472.
6. Papaioannou A, et al. *J SOGC* 2000; 22(8):591-597.
7. Colon-Emeric C, et al. *Osteoporos Int* 2003; 14:879-893.
8. Lindsay R, et al. *JAMA* 2001; 285:320-323.
9. Sawka AM, et al. *Osteoporos Int* 2005; 16:1836-1840.
10. Cranney A, et al. *J Rheumatol* 2005; 32(12):2393-2399.
11. Pasco JA, et al. *Osteoporos Int* 2005; 16(12):2046-2052.
12. Papaioannou A, et al. *Osteoporos Int* 2009; 20(5):703-715.

One-year Mortality Risk after Hip Fracture



1. Ioannidis G, et al. *CMAJ* 2009; 181(5):265-271.
2. Papaioannou A, et al. *J SOGC* 2000; 22(8):591-597.

Impact on Function and Quality of Life

- Loss of confidence and fear of falling have been reported with all types of fractures
- < 40% of those who experience a hip fracture return to their prior walking abilities[1,2]
- Clinical fractures negatively affect self care and mobility, and are associated with chronic pain[3]

1. Cranney A, et al. *J Rheumatol* 2005; 32(12):2393-2399.
2. Pasco JA, et al. *Osteoporos Int* 2005; 16(12):2046-2052.
3. Papaioannou A, et al. *Osteoporos Int* 2009; 20(5):703-715.

Briefly discuss the clinical tools used to assess a patient for osteoporosis.

Recommendations for Clinical Assessment

Assessment	Recommended Elements of Clinical Assessment
History	Identify risk factors for low bone-mineral density (BMD), future fractures, and falls ❑ Prior fragility fractures ❑ Parental hip fracture ❑ Glucocorticoid use ❑ Current smoking ❑ High alcohol intake (≥ 3 units per day) ❑ Rheumatoid arthritis ❑ Inquire about falls in the previous 12 months ❑ Inquire about gait and balance

Recommendations for Clinical Assessment

Assessment	Recommended Elements of Clinical Assessment	
Physical examination	Measure weight (weight loss of ≥10% since age 25 is significant)	
	Measure height annually (prospective loss > 2cm) (historical height loss > 6 cm) Measure rib to pelvis distance ≤ 2 fingers' breadth Measure occiput-to-wall distance (for kyphosis) > 5cm	Diagnosis of vertebral fractures
	Assess fall risk by using Get-Up-and-Go Test (ability to get out of chair without using arms, walk several steps and return)	

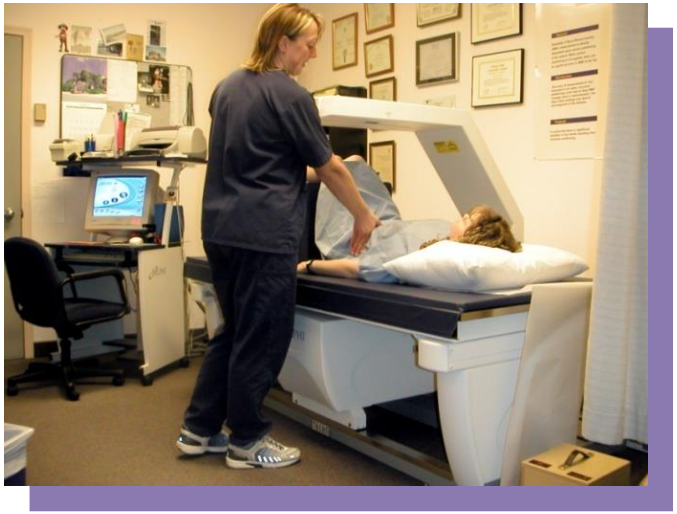
Discuss the indications for baseline bone density measurement.

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

Indications for BMD Testing in Older Adults (Age > 50 Years)

- All women and men age ≥ 65
- Postmenopausal women, and men aged 50 – 64 with clinical risk factors for fracture:
  - Fragility fracture after age 40
  - Prolonged glucocorticoid use†
  - Other high-risk medication use*
  - Parental hip fracture
  - Vertebral fracture or osteopenia identified on X-ray
  - Current smoking
  - High alcohol intake
  - Low body weight (< 60 kg) or major weight loss (>10% of weight at age 25)
  - Rheumatoid arthritis
  - Other disorders strongly associated with osteoporosis



† At least three months cumulative therapy in the previous year at a prednisone-equivalent dose ≥ 7.5 mg daily;
* e.g. aromatase inhibitors (Arimidex), androgen deprivation therapy.

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

Indications for BMD Testing for Individuals Under Age 50 Years

- Fragility fracture
- Prolonged use of glucocorticoids*
- Use of other high-risk medications†
- Hypogonadism or premature menopause
- Malabsorption syndrome
- Primary hyperparathyroidism
- Other disorders strongly associated with rapid bone loss and/or fracture

† At least three months cumulative therapy in the previous year at a prednisone-equivalent dose ≥ 7.5 mg daily;
* e.g. aromatase inhibitors, androgen deprivation therapy.

Explain the role of BMD in fracture risk assessment.

BMD Reporting Categories

Age	Category	Criteria*
< 50 years	Below expected range for age	Z-score ≤ -2.0
	Within expected range for age	Z-score > -2.0
≥ 50 years	Severe (established) osteoporosis	T-score ≤ -2.5 with fragility fracture
	Osteoporosis	T-score ≤ -2.5
	Low bone mass	T-score -1.0 to -2.5
	Normal	T-score ≥ -1.0

Absolute 10-year Fracture-Risk Tools

- Tools validated in Canada (choice based on personal preference and convenience)
  - CAROC: Joint initiative of the Canadian Association of Radiologists and Osteoporosis Canada[1]
  - FRAX: Fracture Risk Assessment Tool developed by the World Health Organization[2]
- There are large differences in fracture rates from country to country[3-5]
  - Assessment tools need to be country specific

1. Leslie WD, Berger C, et al. Osteoporosi Int; In press..
2. Leslie WD, Lix LM, et al. Osteoporosi Int; In press.
3. Kanis JA, et al. *J Bone Miner Res* 2002; 17(7):1237-1244.
4. Melton LJ, III. *Endocrinol Metab Clin North Am* 2003; 32(1):1-13.
5. Leslie WD, et al. *J Bone Miner Res* 2010; in press.

10-year Risk Assessment: CAROC

- Semiquantitative method for estimating 10-year absolute risk of a major osteoporotic fracture* in postmenopausal women and men over age 50
  - Stratified into three zones (Low: < 10%, moderate, high: > 20%)
- Basal risk category is obtained from age, sex, and T-score at the femoral neck

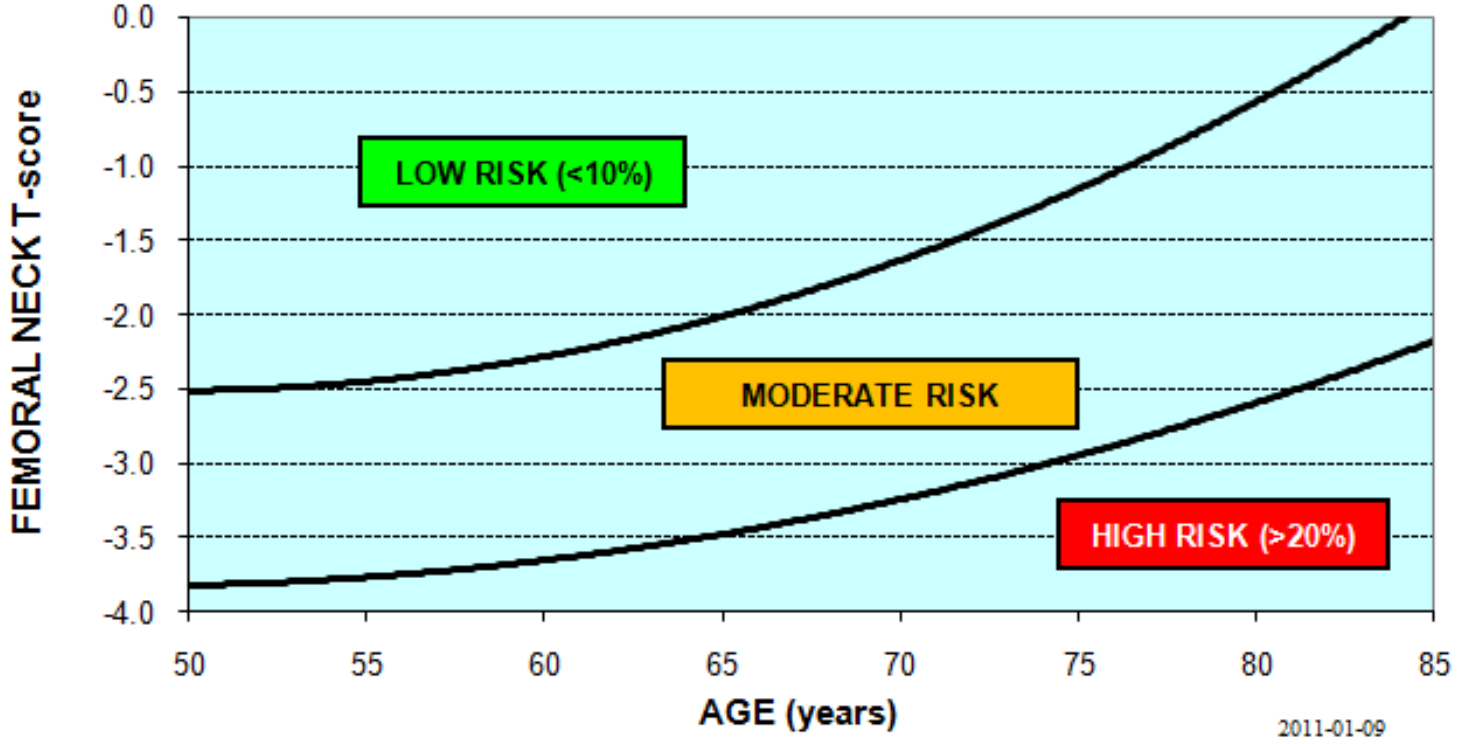
* Combined risk for fractures of the proximal femur, vertebra [clinical], forearm, and proximal humerus. Other fractures attributable to osteoporosis are not reflected; total osteoporotic fracture burden is underestimated

Siminoski K, et al. *Can Assoc Radiol J* 2005; 56(3):178-188.

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

10-year Risk Assessment for Women (CAROC Basal Risk)

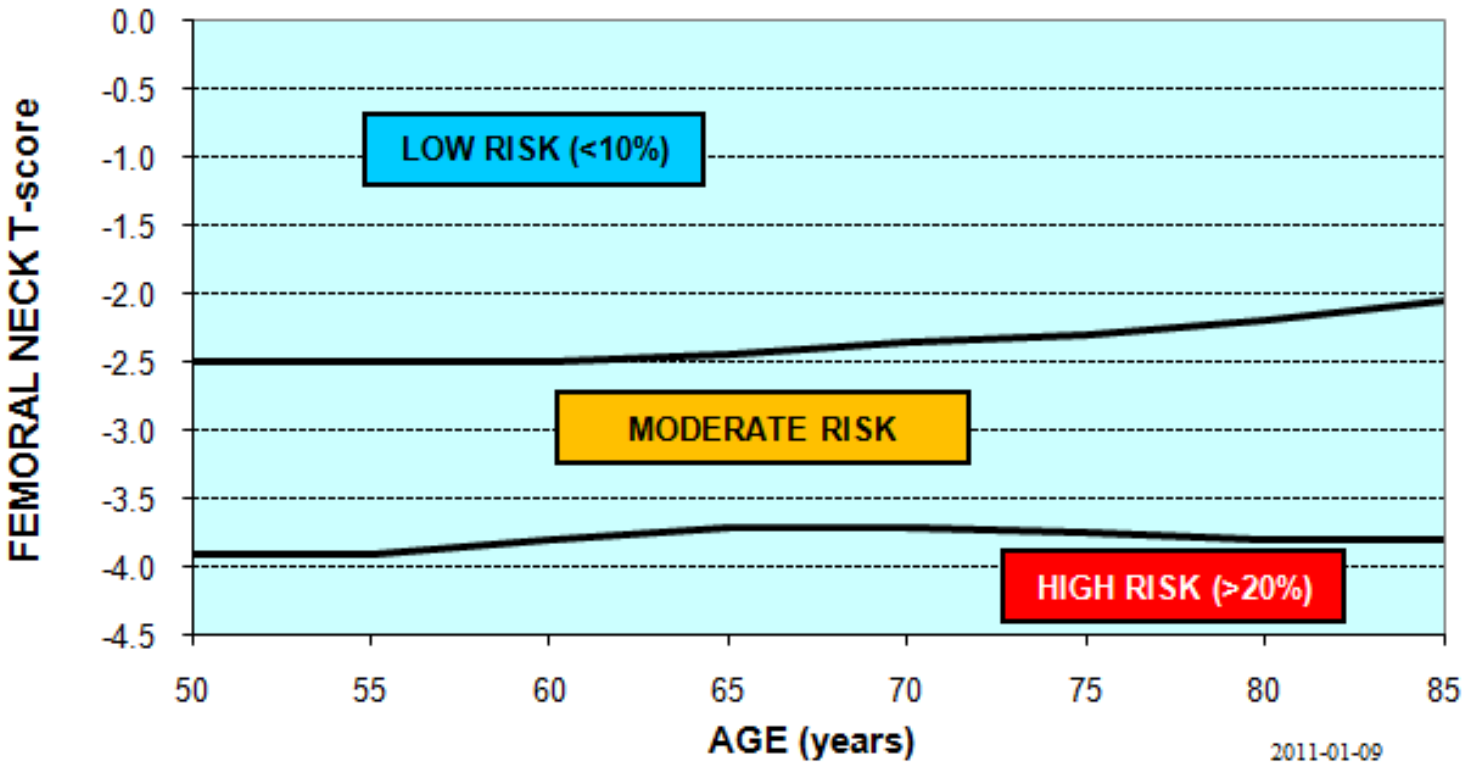


Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

10-year Risk Assessment for Men (CAROC Basal Risk)



Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].

Risk Assessment with CAROC: Important Additional Risk Factors

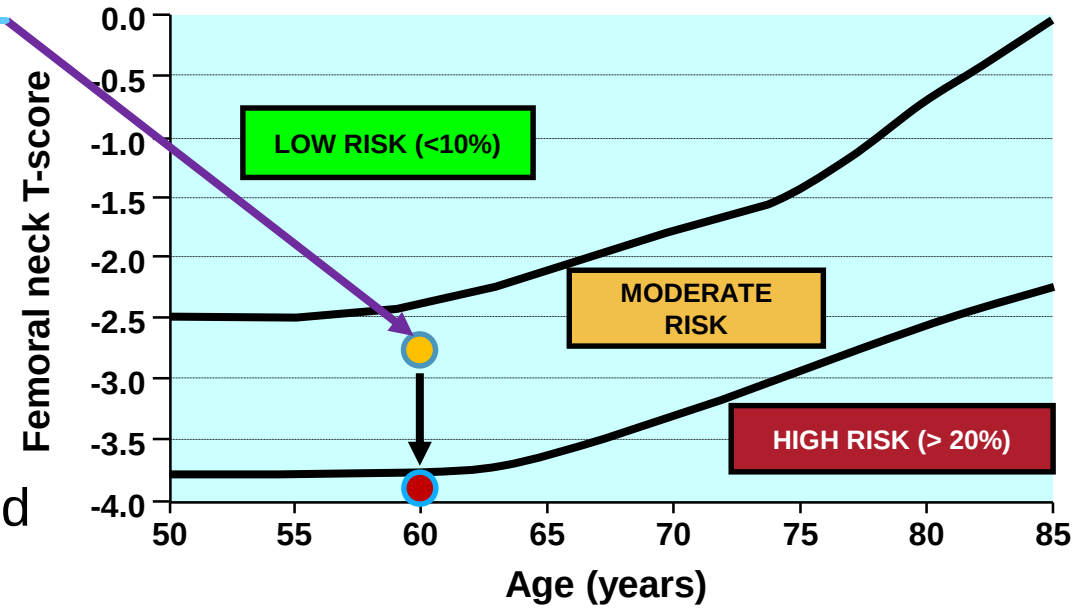
- Factors that increase CAROC basal risk by one category (i.e., from low to moderate or moderate to high)
  - Fragility fracture after age 40*[1,2]
  - Recent prolonged systemic glucocorticoid use**[2]

* Hip fracture, vertebral fracture, or multiple fracture events should be considered high risk
** >3 months use in the prior year at a prednisone-equivalent dose ≥ 7.5 mg daily

1. Siminoski K, et al. *Can Assoc Radiol J* 2005; 56(3):178-188.
2. Kanis JA, et al. *J Bone Miner Res* 2004; 19(6):893-899.

Example of Adjusting Basal Risk: Based on Additional Risk Factors

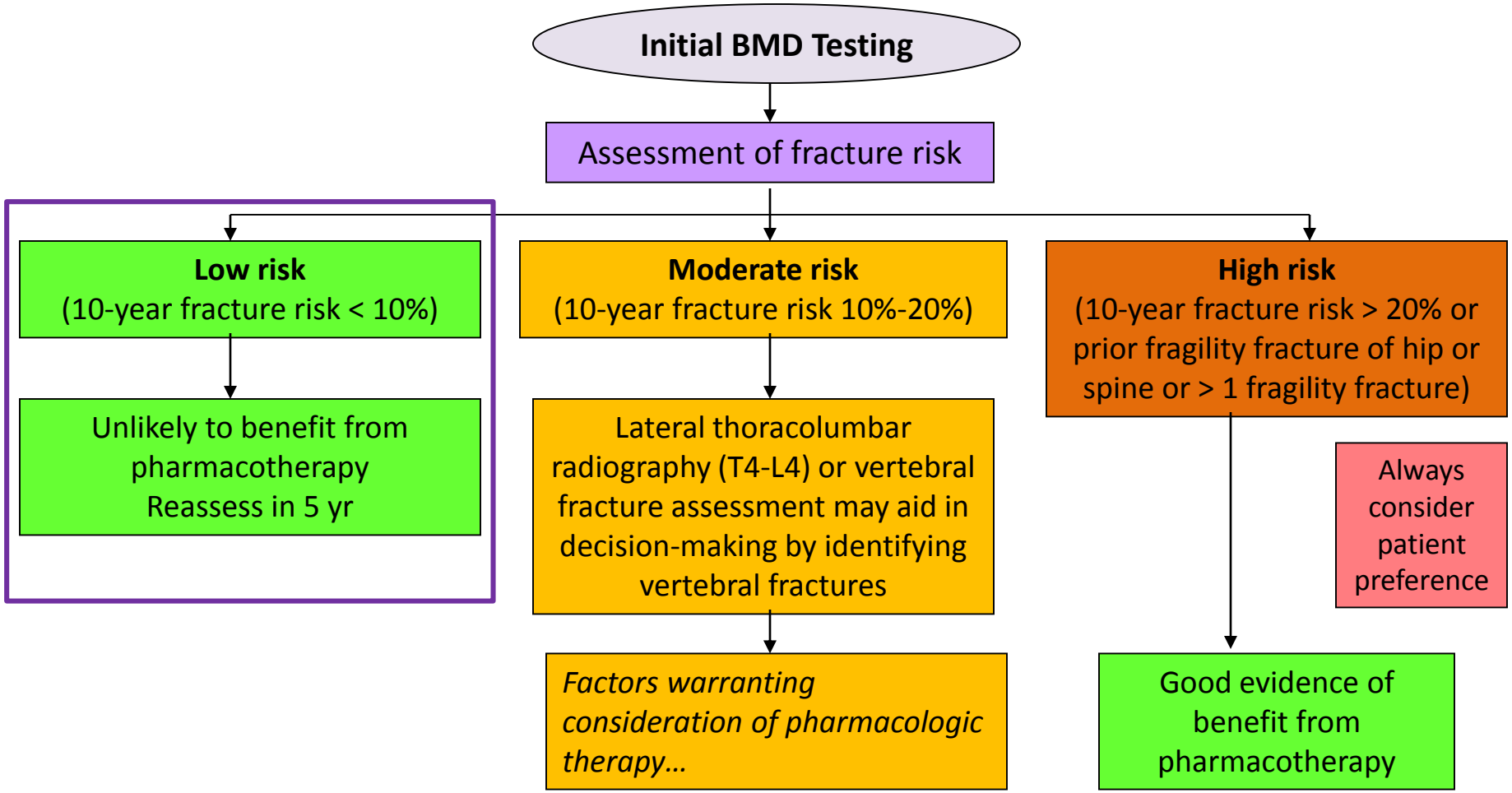
- 60-year-old woman
- Femoral neck T-score = -2.8
- Based on age and T-score alone = moderate risk
- History of fragility fracture or prolonged systemic glucocorticoid use would shift her to high risk



Papaioannou A, et al. *CMAJ* 2010 Oct 12. [Epub ahead of print].

Discuss how fracture risk assessment guides treatment and reassessment strategies

Integrated Approach, Continued



Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

Integrated Approach, Continued

Moderate risk

(10-year fracture risk 10%-20%)

Lateral thoracolumbar radiography (T4-L4) or vertebral fracture assessment may aid in decision-making by identifying vertebral fractures

Factors warranting consideration of pharmacologic therapy:

- Additional vertebral fracture(s) (by vertebral fracture assessment or lateral spine radiograph)
- Previous wrist fracture in individuals aged > 65 or those with T-score ≤ -2.5
- Lumbar spine T-score much lower than femoral neck T-score
- Rapid bone loss
- Men undergoing androgen-deprivation therapy for prostate cancer
- Women undergoing aromatase inhibitor therapy for breast cancer
- Long-term or repeated use of systemic glucocorticoids (oral or parenteral) not meeting conventional criteria for recent prolonged use
- Recurrent falls (≥ 2 in the past 12 mo)
- Other disorders strongly associated with osteoporosis, rapid bone loss or fractures

Repeat BMD in 1-3 yr and reassess risk

Good evidence of benefit from pharmaco-therapy

Recommendations for Frequency of BMD Testing

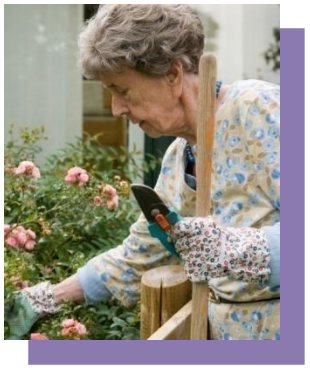
- Usually repeated every 1 – 3 years, with a decrease in testing once therapy is shown to be effective
- In those at low risk without additional risk factors for rapid BMD loss, a longer testing interval (5 – 10 years) may be sufficient

Return to main presentation

- Discuss the various lifestyle modifications and treatments available for patients with osteoporosis

Modalities Used to Prevent Fracture

- Lifestyle modifications
  - Vitamin D
  - Calcium
  - Exercise
  - Falls prevention



- Pharmacologic therapy
  - Bisphosphonates
  - Other anti-resorptives
    - Calcitonin
    - Denosumab
    - Hormone therapy
    - Raloxifene
  - Parathyroid hormone
  - Combination therapy

Recommended Vitamin D Supplementation

Group	Recommended Vitamin D Intake (D3)
Adults <50 without osteoporosis or conditions affecting vitamin D absorption	400 – 1000 IU daily (10 mcg to 25 mcg daily)
Adults > 50 or high risk for adverse outcomes from vitamin D insufficiency (e.g., recurrent fractures or osteoporosis and comorbid conditions that affect vitamin D absorption)	800 – 2000 IU daily (20 mcg to 50 mcg daily)

Hanley DA, et al. *CMAJ* 2010; 182:E610-E618.

Recommended Calcium Intake

- From diet and supplements combined: **1200 mg daily**
  - Several different types of calcium supplements are available
- Evidence shows a benefit of calcium on reduction of fracture risk[1]
- Concerns about serious adverse effects with high-dose supplementation[2-4]

1. Tang BM, et al. *Lancet* 2007; 370(9588):657-666.
2. Bolland MJ, et al. *J Clin Endocrinol Metab* 2010; 95(3):1174-1181.
3. Bolland MJ, et al. *BMJ* 2008; 336(7638):262-266.
4 Reid IR, et al. *Osteoporos Int* 2008; 19(8):1119-1123.

Benefits of Exercise: Fractures and Bone Health

- Programs > 1 year including aerobic exercises and strength training have demonstrated positive effects on BMD and thoracic kyphosis but have limited evidence for fracture reduction[1]

- Moderate to vigorous exercise has demonstrated an ability to reduce hip fracture risk[2]

Return to main presentation

1. De Kam D, et al. *Osteoporos Int* 2009; 20(12):2111-25.
2. Moayyeri A. *Ann Epidemiol* 2008; 18:827-835.

Oral Bisphosphonates: Summary

Drug (Brand name)	Dosing Schedules
Alendronate (Fosamax®, Fosavance®)	10 mg daily 70 mg weekly
Risedronate (Actonel®)	5 mg daily 35 mg weekly 150 mg monthly
Etidronate (Didrocal®)	Cyclical therapy of daily 200 mg for 14 days followed by calcium supplements for 10 weeks

See notes page for information on patient instructions, precautions and adverse events

Return to main presentation

IV Bisphosphonate: Summary

Drug (Brand name)	Dosing Schedule
Zoledronic Acid (Aclasta®)	5 mg intravenously once yearly

See notes page for information on patient instructions, precautions and adverse events

Return to main presentation

Other Medications: Summary

Drug (Brand name)	Dosing Schedule
Calcitonin (Miacalcin®)	200 IU intranasally daily
Calcium (many formulations)	Many dosing schedules
Denosumab (Prolia®)	60 mg subcutaneous injection every six months
Hormone therapy (many formulations)	Many dosing schedules
Raloxifene (Evista®)	60 mg daily
Teriparatide (Forteo®)	20 µg subcutaneously daily

See notes page for information on patient instructions, precautions and adverse events

Return to main presentation

Osteoporosis Canada
Ostéoporose Canada

2010 Guidelines

First Line Therapies with Evidence for Fracture Prevention in Postmenopausal Women*

Type of Fracture	Antiresorptive therapy						Bone formation therapy
	Bisphosphonates			Denosumab	Raloxifene	Hormone therapy (Estrogen)**	Teriparatide
	Alendronate	Risedronate	Zoledronic acid				
Vertebral	✓	✓	✓	✓	✓	✓	✓
Hip	✓	✓	✓	✓	-	✓	-
Non-vertebral+	✓	✓	✓	✓	-	✓	✓

* For postmenopausal women, ✓ indicates first line therapies and Grade A recommendation. For men requiring treatment, alendronate, risedronate, and zoledronic acid can be used as first line therapies for prevention of fractures [Grade D].
+ In clinical trials, non-vertebral fractures are a composite endpoint including hip, femur, pelvis, tibia, humerus, radius, and clavicle.
** Hormone therapy (estrogen) can be used as first line therapy in women with menopausal symptoms.

Summary

- The guidelines are here to assist healthcare professionals and policy makers with decision making and patient/public education using evidence based medicine.
- I hope this will help you in your job day to day in your interactions with patients and other healthcare professionals

- Thank you to Osteoporosis Canada for allowing me to use their slides.

  www.osteoporosis.ca

Any Questions?