

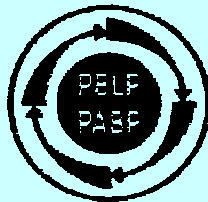
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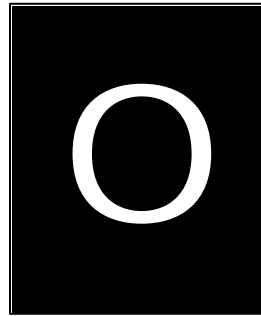
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**OSTEOPOROSIS
& FRAGILITY
FRACTURES**

Osteoporosis is a major but underdiagnosed health problem. Once seen as an inevitable consequence of aging that primarily affected women, osteoporosis is now known to affect roughly 13% of men (1 in 8), as well as 25% of women (1 in 4) in Canada. Effective methods exist to identify and treat osteoporosis before fractures occur, *and* to prevent recurrent fractures in those who first present with a fracture. Clinical screening and appropriate diagnostic tests can accurately identify patients who are at high risk.

Family physicians are uniquely positioned to play an important role in the prevention, early diagnosis, and effective management of osteoporosis. This module is intended to help:

- ? encourage patients to choose a lifestyle that can help prevent osteoporosis
- ? identify patients who may be at higher risk of developing or having osteoporosis
- ? select patients whose bone mineral density (BMD) should be determined
- ? recommend suitable interventions for patients with osteoporosis

CASES

Case 1: Margaret N., age 50, female

Margaret comes to your office for a well-patient examination, and to ask whether she should have a "test" for osteoporosis.

She is also wondering if she should start hormone replacement therapy (HRT). She has missed several periods over the past year. Her last period was 3 months ago, with no vaginal bleeding since. She reports having hot flashes, which she describes as "a nuisance but something I can live with."

Margaret is a non-smoker, drinks 3 cups of coffee

and 2 glasses of milk per day (500 ml), and takes no dietary supplements. She walks with a group of friends 4 to 5 days per week (2 miles each time). She has a positive family history for colon cancer: her father was diagnosed at age 67 and her paternal grandmother at age 72. Her family history for osteoporosis is negative. Her clinical examination is normal. She is 160 cm tall and weighs 70.5 kg.

How would you advise Margaret about her request for a “test” for osteoporosis?

How would you advise Margaret about HRT and about keeping her bones healthy?

Would your advice be different if Margaret’s mother had a history of hip fracture at age 68?

Case 2: Robert S., age 59, male

Robert is a semi-retired consultant who is new to your practice. He fell while curling and suffered an undisplaced fracture of his left wrist. He now presents for follow-up.

He is a trim and fit non-smoker with an active life style. He works out regularly at the local “Y,” golfs in the summer and downhill skis in the winter. His past history is unremarkable except for a tibial plateau fracture 2 years ago while skiing. Robert thought that the damage was more extensive than expected from what he thought was a relatively minor fall, but the orthopedic surgeon who carried out the open reduction on his knee reassured him that the bone seemed normal.

Robert’s family history is non-contributory, and he has no other complaints. He rarely drinks milk, but otherwise has a balanced diet.

Would you order a BMD test for Robert? If you did measure BMD, how would you proceed once you had the results?

Case 3: Julie K., age 66, female

Julie is a retiree who has come to see you today with a complaint of recurring pain in her calves from brisk walking.

Her medical history includes longstanding hypertension, infrequent attacks of stress-induced angina, mild Menière’s disease, and significant osteoarthritis. (These conditions are currently well-controlled with appropriate medications.) Recently, x-rays of Julie’s hip and back identified osteopenia.

Julie also has longstanding (40+ years) “irritable bowel syndrome.” She manages to keep the attacks infrequent by avoiding dairy products. She has been taking daily calcium (1000 mg elemental calcium) and vitamin D (400 I.U.) supplements, since age 60.

Julie is of average height and weight. She is generally fitness-conscious—walking 3 to 6 km (2 to 4 miles) on most days. She bowls every weekend. Until 6 years ago, she was a pack-a-day smoker. Her current consumption is about 3 cigarettes per day.

Would you raise the issue of possible osteoporosis today?

How would you manage Julie’s bone health?

Case 4: Alice B., age 60, female

Alice, a high school teacher, is nearing retirement. She presents to discuss HRT, after hearing news reports about increased risk of breast cancer and cardiovascular complications associated with HRT.

Her medical history includes: benign breast biopsy 3 years ago; hysterectomy 3 years ago for severe menorrhagia 10 years ago; normal mammograms. Alice’s mother died of bowel cancer at age 72, her father of a myocardial infarction at age 81.

When Alice started on estrogen 5 years ago, her T-score was –2.0. Four months ago, it was –1.5.

How would you respond to Alice’s concerns about HRT?

What would you recommend to Alice about her bone health, if she decides not to continue with HRT?

Would your approach differ if Alice had suffered a wrist fracture 5 years ago?

INFORMATION SECTION

DEFINITIONS, SCOPE & IMPACT

Definitions

1. **Osteoporosis** is characterized by systemic “low bone mass and micro-architectural deterioration of bone tissue”¹ and “compromised bone strength”² that predispose to an increased risk of fracture. In the context of bone mineral density (BMD) assessment, a T-score below –2.5 indicates osteoporosis (Table A).^{3,4}

2. **Fragility fractures** are described as **low-impact or low-trauma** fractures. According to the WHO, they are “caused by injury that would be insufficient to fracture normal bone: the result of reduced compressive and/or torsional strength of bone.”¹⁵ In practical terms, this corresponds to fractures that occur or result from minimal trauma (e.g., a fall from a standing height or less).⁶
3. Bone mineral density (**BMD**) is generally determined by central/axial dual-energy x-ray absorptiometry (DXA, DEXA). Test results are expressed as a “**T-score**” — the number of standard deviations (SDs) above or below the mean BMD of normal young adults (i.e., peak bone mass) of the same sex and race as the patient.⁶
4. In the context of BMD testing, osteopenia indicates a T-score that is subnormal but not low enough to qualify as osteoporosis (Table A).⁶

Table A: Bone density rating and T-scores^{3,4}

Bone density	T-score
Normal	+2.5 to -1.0
Osteopenia	-1.0 to -2.5
Osteoporosis	-2.5 and below
Severe (established) osteoporosis	-2.5 and below <u>plus</u> history of fragility fracture

Scope and impact

5. Osteoporosis plays a major role in hip and vertebral fractures. Its incidence is expected to rise sharply over the next few decades as our population ages.⁷ Already, 1 in 8 men and 1 in 4 women in Canada have osteoporosis.⁸ Total acute care costs resulting directly from osteoporosis were estimated to be over \$1.3 billion (Cdn) in Canada in 1993.⁹
6. Vertebral fractures (although often asymptomatic and undiagnosed) and hip fractures are associated with significantly increased mortality.^{10,11,12} In fact, women have a higher lifetime risk of fracturing a hip (1 in 6) and dying from it than of developing (1 in 9) and dying from breast cancer.^{6,13}
7. Men are as prone to fragility fractures as women,¹⁴ but their pattern of age-related bone loss is different. The lifetime risk of fragility fracture in men >50 years is about 1 in 8 (13%), and it is estimated that about 1 in 5 (19%) of males >50 years old have a T-score below -2.5.⁶

8. Ethnic differences in BMD and fracture risk are still being explored. For example, patients of Asian origin have a lower hip fracture rate, despite a lower BMD than Caucasians.^{6,14}

RISK ASSESSMENT

9. The **presence of one major clinical risk factor should trigger further assessment** (including BMD, if not already determined) **and discussion of intervention(s)** aimed at preventing fracture. Minor factors are also relevant in this context: the presence of *two or more minor factors* should prompt further investigation.⁶
10. Major risk factors (Table B) and low BMD have a cumulative effect on fracture risk.
 - a. A recent review investigated some 80 potential predictors of fragility fracture risk¹⁵ and identified **four key predictive factors for osteoporosis-related fractures** (1) prior fragility fracture; (2) age; (3) family history of osteoporosis; (4) BMD (the best quantifiable predictor).
 - b. The other commonly-cited factors are not consistent *independent* predictors, once adjustments are made for age and/or BMD.⁶

Table B: Clinical risk factors used to identify who should undergo BMD testing⁶

Major factors	Minor factors
<p>Key predictors</p> <ul style="list-style-type: none"> • age >65 years • fragility fracture after age 40 • family history of fragility fracture • systemic glucocorticoid therapy for >3 months <p>Other factors</p> <ul style="list-style-type: none"> • early menopause (age <45) • hypogonadism • osteopenia on x-ray • propensity to fall • malabsorption syndrome • primary hyperparathyroidism 	<ul style="list-style-type: none"> • rheumatoid arthritis • past history of clinical hyperthyroidism • chronic anti-convulsant therapy • low dietary calcium intake • smoking • excessive alcohol intake • excessive caffeine intake (e.g., >4 cups per day) • weight <57 kg • weight loss >10% of weight at age 25 • chronic heparin therapy

Presence of 1 major or 2 minor factors suggests need for BMD testing in post-menopausal women and men >50 years

11. For individuals who have not yet suffered a fragility fracture, low BMD is the most readily quantifiable predictor of risk. For each unit decrease of T-score, fracture risk approximately doubles.^{6,16}

Table C: Average 10-year probability (%) of an osteoporotic fracture* by sex, age and BMD expressed as T-score

Age (years)	Overall average probability	T-score				
		1	0	-1	-2	Below -2.5
Men						
50	3.3	1.8	2.7	4.2	6.3	9.2
55	3.9	1.9	3.0	4.6	7.0	10.4
60	4.9	2.5	3.6	5.4	7.9	11.6
65	5.9	3.0	4.3	6.2	8.8	13.0
70	7.6	3.4	5.1	7.4	10.9	16.2
75	10.4	4.1	6.3	9.6	14.4	21.5
80	13.1	5.3	7.7	11.1	15.8	23.2
85	13.1	5.3	7.5	10.4	14.3	21.4
Women						
50	6.0	2.4	3.8	5.9	9.2	13.9
55	7.8	2.6	4.1	6.7	10.7	16.8
60	10.6	3.2	5.1	8.2	13.0	20.5
65	14.3	4.0	6.3	10.0	15.6	24.9
70	18.9	4.3	7.1	11.5	18.3	29.8
75	22.9	4.2	7.0	11.8	19.4	32.6
80	26.5	4.6	7.7	12.7	20.5	34.4
85	27.0	4.5	7.4	12.0	19.1	33.1

Adapted from Kanis JA, Johnell O, Oden A, Dawson A, De Laet C, Jonsson B. Ten year probabilities of osteoporotic fractures according to BMD and diagnostic thresholds. *Osteoporos Int*2001;12:989-95, with permission.

Major clinical risk factors

Age

12. Age is a major risk factor. The 10-year probability of suffering a fracture of a forearm, humerus, spine, or hip increases markedly, as much as 5-fold for men and 8-fold for women between age 45 and 85.⁶

Prior fragility fracture

13. A prior fragility fracture is associated with a 1.5 to 9.5-fold increase in the risk of further fractures — depending on patient’s age, fracture site(s), and number of fractures. Overall, the risk of a subsequent fracture in patients with a prior fracture at any site is 2.2 times that of those with no prior fracture.¹⁷

14. Patients who have suffered a fragility fracture are considered to have osteoporosis — even if their BMD does not meet the usual criteria for

osteoporosis.⁶

Family history of fragility fracture

15. Genetic influence on osteoporosis risk is multifactorial, and likely accounts for 50 to 80% of BMD variability. Given that it is now clear that osteoporosis is common in men, exploration of a family history of fragility fracture should include both male and female 1st- and 2nd-degree relatives.⁶

Others

16. Systemic glucocorticoid use for more than a few months is a major risk factor for bone loss and fracture — especially for men >50 years and for postmenopausal women — even at doses as low as 2.5 mg prednisone or equivalent per day.¹⁸ Patients who have taken between 2.5 and 7.5 mg/day for >3 months should undergo BMD testing and review of other risk factors. Those who are receiving or will receive >7.5 mg/day for >3 months should undergo baseline BMD testing and be offered bone-sparing therapy.⁶

17. Although falls can cause fractures in the absence of osteoporosis, a history of falls or the presence of factors that increase the likelihood of falling should be queried. Risk factors for falling include general frailty and muscle weakness, impaired gait or balance, low body mass, and reduced visual acuity.⁶

18. Early (age <40) or relatively early menopause (age <45), hypogonadism, malabsorption syndrome, and primary hyperparathyroidism increase the risk of osteoporosis, as does the finding of osteopenia on x-ray.⁶

Minor clinical risk factors

19. Several other medications and clinical conditions (listed in Table B) represent minor risk factors that should be considered, along with the more usual “top-of-mind” factors, when osteoporosis risk is determined.⁶

DIAGNOSIS

20. Osteoporosis is often diagnosed late in the course of disease, after the patient suffers a fragility fracture.

Clinical evaluation of risk is recommended for all post-menopausal women and all men over age

50, followed by targeted BMD testing. This outperforms any single method of risk assessment, and allows timely intervention that may help avoid progression to fracture.⁶

Radiological clues

21. A patient's history of fragility fracture is the only clinically applicable index of bone quality. N.B.: Osteopenia identified on skeletal x-rays is *not* a good predictor of BMD.⁶

22. "Incidental" fracture deformities seen on spinal radiographs may establish osteoporosis when x-rays are taken to investigate patients with other problems (e.g., back pain). Since 2/3 of spinal fractures are asymptomatic, they are unlikely to be diagnosed promptly.⁶ Significant loss of height (4 cm by history or 2 cm by prospective measurement) or kyphosis should trigger an x-ray of the spine (Consensus recommendation).⁶

23. Non-traumatic vertebral height reduction of 20 to 25% constitutes a vertebral fracture. The presence of a prominent non-traumatic spinal fracture is associated with a risk of further fractures comparable to that arising from a T-score of -1.⁶

Bone testing

24. Diagnosis of osteoporosis is commonly based on low BMD, because no direct measures of "bone quality" are available. Two approaches to measuring bone density are used.

- a. Measurement of the central/axial skeleton (e.g., hip, spine, proximal femur, whole skeleton) typically involves dual-energy x-ray absorptiometry (DXA). Central DXA measurement is the most effective way to estimate fracture risk in post-menopausal Caucasian women.¹⁶
- b. Measurement of part of the peripheral skeleton (e.g., heel, wrist) commonly involves either DXA or quantitative ultrasound (QUS). QUS effectively estimates the risk of fracture in post-menopausal women >65 (Level 1 evidence), but its use in younger women and men is limited. Attempts to use QUS as a surrogate for direct measurement of the lumbar spine, femoral neck, or total hip have not proved useful.⁶

25. There appears to be some misunderstanding about when to order BMD testing (Appendix 4). Although more BMD tests are being ordered, they are often

for patients at low risk for osteoporotic fractures rather than for those at high risk.¹⁹

The decision to measure BMD should be based on:

- age-related risk
 - the presence of clinical risk factors
 - consultation with the patient
- a. BMD testing of all patients >65 years old has been recommended.
 - b. Testing is recommended for men 50 to 65 years old and for post-menopausal women <65 years old **only** when one or more major factors **or** at least two minor factors are present (Table B, Appendix 1).
 - c. **BMD should only be measured if the results will affect management decisions.**⁶

26. DXA is the preferred technique for measuring BMD. It provides the best estimate of fracture risk at the spine and hip, which are the most clinically important sites for fragility fracture (Level 1 evidence). Unfortunately, DXA equipment for measuring axial BMD is not readily available in some areas. Although single photon absorptiometry (SPA) may be used for diagnosis if DXA is unavailable, SPA is not useful for follow-up because of its lower sensitivity.⁶

27. *Serial BMD monitoring* can help determine the rate of bone loss. It can thus differentiate "slow losers" from "fast losers," and confirm response to therapy. However, it is important to remember that changes in BMD usually are relatively small over 1-2 years.

- a. Because of difficulties in calibrating different machines (even from the same manufacturer), the same machine should be used for baseline and subsequent tests. Human and instrument factors introduce further variability in serial measurements.⁶
- b. Once anti-resorptive therapy for osteoporosis has been started, patients should have a follow-up hip and spine DXA in 1-2 years (Grade A recommendation).⁶ Note that changes in BMD for these patients do not strongly correlate to changes in fracture risk, since small increases in BMD resulting from therapy account for only part of the reduction in risk of fracture.
- c. No studies have sufficiently evaluated the optimal timing of repeated *screening*, but every 2 years has been suggested.²⁰

Exclusion of secondary causes

28. Secondary causes of bone loss (such as hypoparathyroidism, hypogonadism, and renal disease) need to be considered when a diagnosis of osteoporosis is being assessed, but there are no evidence-based guidelines to indicate what investigations to perform.²¹ The 1996 OSC guidelines recommend that patients diagnosed with osteoporosis should have CBC, serum calcium, total alkaline phosphatase, serum creatinine, and protein electrophoresis. Other investigations would depend on clinical suspicion⁶ (Expert opinion). The UK guidelines add TSH and protein electrophoresis only if there is a suspicion of multiple myeloma.²²

PREVENTION & MANAGEMENT

29. **Preventing and treating osteoporosis can help prevent fragility fractures.** The ability of medications to prevent fractures has only been confirmed in populations with an average age >65 years — primarily because fragility fractures most commonly occur in men and women in this age group. Nonetheless, most approved therapies prevent or reverse bone loss when initiated at or soon after age 50. It is thus prudent to begin identifying high-risk patients from age 50 onwards — if they are willing to consider intervention — so that appropriate intervention(s) to be started as early as possible.⁶

Pharmacologic interventions (Appendix 2)*Bisphosphonates*

30. Bisphosphonates have been shown to consistently be the most effective means of preventing both vertebral and non-vertebral fractures. The available evidence that supports their use was recently reviewed.²³

- They inhibit bone resorption.
- They are considered to be *first-line therapy* for the prevention and treatment of osteoporosis (Level 1-2 evidence).
- All are poorly absorbed (1 to 5% of oral doses), and so should be taken on an empty stomach, with only water.
- They are excreted by the kidneys and should not be prescribed if patients have renal failure.

31. Available bisphosphonates have short plasma half-lives, rapid clearance, and different pharmacological profiles (e.g., potency, efficacy,

toxicity).⁶

a. **Etidronate** (Didrocal®) was the first bisphosphonate shown to be beneficial in treating osteoporosis. It is generally well tolerated. Diarrhea is the most common complaint. Extended, continuous use can lead to impaired bone mineralization. Hence, it is given cyclically (e.g., 400 mg/day for 2 weeks every 3 months). Cyclical use significantly increases lumbar spine BMD and seems to reduce the vertebral fracture rate.

b. **Alendronate** (Fosamax®) is generally well tolerated, but rare cases of esophagitis have been reported. It has been shown to reduce vertebral fractures in men >50. In postmenopausal women, it can reduce hip, vertebral and non-vertebral fractures. It increases BMD at all measured sites.

The usual dose is 5 mg/day or 35 mg/week (as a single dose) for prevention, or 10 mg/day or 70 mg/week (as a single dose) for treatment. The weekly regimen has been shown in short-term studies to be equivalent to the conventional daily treatment regimen and is better tolerated by most patients.^{6,24}

The usual dose is 5 mg daily or 35 mg once a week.^{6,25}

c. **Risedronate** (Actonel®) is generally well tolerated. Occasional reports of headache and diarrhea are the primary side-effects. It increases BMD and prevents hip fracture in patients with low femoral neck BMD, including those with prior vertebral fracture. It did not significantly reduce hip fracture risk among elderly women selected primarily because of risk factors other than low BMD. It reduces the risk of vertebral fractures within the first year of therapy.

32. Etidronate maintains BMD in patients taking glucocorticoids. Alendronate and risedronate prevent and treat glucocorticoid-induced osteoporosis and reduce vertebral fracture risk.⁶

Calcitonin

33. This naturally occurring polypeptide acts as an anti-resorptive agent at pharmacologic doses. Recombinant salmon calcitonin (delivered in a nasal spray) has been shown to:⁶

- maintain or minimally increase hip and spinal BMD
- prevent vertebral fractures (but not non-vertebral fractures) in post-menopausal women with severe osteoporosis

- slow bone loss at all sites, and prevent loss at some, in patients recently started on glucocorticoids²⁶
- maintain or increase BMD in patients with existing glucocorticoid-induced osteoporosis
- reduce bone pain due to acute vertebral fractures

Hormone therapy

34. Ovarian hormone therapy, more commonly referred to as hormone replacement therapy (HRT), has been used for over 60 years to treat the vasomotor symptoms (hot flushes and night sweats) of menopause and to halt the accelerated bone loss that follows menopause.⁶

- a. HRT is classified as a 1st-line preventive therapy in post-menopausal women with low BMD and a 2nd-line treatment for osteoporosis, based on efficacy. The risk-benefit ratio of HRT may, however, be unfavourable when HRT is used exclusively for the management of low bone density.⁶
- b. A large trial, the Women's Health Initiative, recently ended prematurely because of safety concerns. Estrogen-progesterone therapy for more than 5 years was associated with a significant increase in the risk of invasive breast cancer (26%), coronary artery disease (29%), stroke (41%), and venous thromboembolism. The corresponding absolute risk was small, but nonetheless significant.²⁷

35. Administration of testosterone to men with low levels could theoretically have a beneficial effect on bone density. Such use of testosterone has not, however, been systematically studied. In view of the recently-identified problems with HRT in women, a cautious approach is indicated.

Selective estrogen receptor modulators (SERMs)

36. These nonhormonal agents have an affinity comparable to estradiol at estrogen receptors and act as agonists or antagonists (depending upon the tissue and the chemical structure of the SERM).

Raloxifene (Evista®) is the only SERM currently approved for the prevention and treatment of osteoporosis.⁶

- It is taken in a single regimen of 1 tablet (60mg) each day.
- It has estrogen agonistic effects on bone and lipid metabolism, and antagonistic effects on

breast and uterine tissue.⁶

- It may increase the incidence of vasomotor symptoms of menopause.^{28,29} It may also cause venous thromboembolism, at a relative risk comparable to that of HRT or tamoxifen.⁶

Alternative or adjunct therapies

37. Vitamin K, ipriflavone (a synthetic phytoestrogen with weak estrogen-like activity), and fluoride are the only alternative approaches for which there are sufficient data to warrant comment.⁶

- a. On the basis of current evidence, **vitamin K** is not currently recommended for prevention or treatment of osteoporosis in either men or women.
- b. **Ipriflavone** is not recommended for treating postmenopausal osteoporosis, but may be considered as a 2nd-line preventive therapy in postmenopausal women. It is not recommended for use in men or premenopausal women.
- c. **Fluoride** is a potent stimulator of bone formation. Although it may increase BMD, fluoride has not been shown to reduce osteoporotic fractures and has dose-related toxicity. Its use to prevent or manage osteoporosis is thus not recommended.

Parathyroid hormone (PTH)

38. Teriparatide (rhPTH(1-34)) is a synthetic derivative of parathyroid hormone (PTH). It increases spinal BMD in men, and BMD at all skeletal sites except the radius, in postmenopausal women with severe osteoporosis. Teriparatide is expected to become a 1st-line treatment for postmenopausal women with severe osteoporosis (Level 1 evidence), once it receives marketing approval in Canada and the USA.⁶

Non-pharmacologic interventions (Appendix 3)

Nutrition

39. Bone is a complex tissue whose synthesis and maintenance require all essential nutrients. Studies on nutritional components have focused on calcium and vitamin D, macronutrients (e.g., protein, fatty acids, fibre), and micronutrients (i.e., minerals).⁶

40. Adequate calcium and vitamin D (from the diet or supplements) are essential adjuncts to both preventative therapy and osteoporosis treatment.⁶

- a. Recommended **calcium** intake varies with age. For adults and seniors, it is:
- **1000 mg/day for adults under age 50**
 - **1500 mg/day for those over age 50**
- b. Sun exposure in Canada seems to be *inadequate* to substitute for ingested **vitamin D**. Recommended intake for adults is 400 IU (10 mcg/day) up to age 50 (Level 4 evidence), and 800 IU (20 mcg/day) thereafter (Level 1 evidence).⁶ Cholecalciferol (vitamin D3) is more potent and thus preferable to ergocalciferol (vitamin D2). One cup (250 ml) of milk contains approximately 100 IU of vitamin D3.

41. An increase in dietary **protein** intake reduces the risk of hip fracture in men and women with inadequate intake. There is no good quality evidence to determine the effect of essential fatty acids or dietary fiber on fracture risk.⁶

42. There is a significant association between heavy **caffeine** intake (>4 cups coffee/day) and hip fractures in both men and women. In studies in which **sodium** intake is measured properly, daily intake exceeding 2100 mg (90 mmol) has a significant negative effect for both men and women. High caffeine and sodium intake should thus be avoided (Level 2-3 evidence).⁶

43. There is no good-quality evidence to support dietary supplementation of minerals (e.g., boron, copper, iron, magnesium, manganese, phosphorus, silica, strontium, zinc) in adults with normal digestion and nutrition. High iron intake (>30 mg/day) may actually be associated with increased hip fracture risk in women >39 years.⁶

Physical activity

44. Physical activity improves skeletal structure and strength. It affects parts of the skeleton differently, according to the pattern of stress produced. Aerobic and impact exercise and sports that include them (e.g., brisk walking, gymnastics, field and racquet sports, jogging) are more beneficial than strength, endurance and non-weight-bearing activities (e.g., body building, cycling, static exercise machines, swimming, weightlifting).⁶

45. Physical activity (especially impact type) is associated with greater BMD in men, and it can prevent bone loss in the lumbar spine in premenopausal women and reduce the rate of

bone loss in menopausal women.⁶

- a. Higher activity levels in middle life are associated with reduced hip fracture risk in older age.
- b. Individually tailored exercise programs that include progressive muscle strengthening, balance retraining, and walking reduce the risk of both falls and resulting injuries in older persons.^{30,31} In contrast, general group-delivered programs do not seem to be as effective in reducing the risk of falls.⁶
- c. Excessive activity (e.g., long-distance running) may actually be detrimental to the skeleton, perhaps because of effects on hormonal status (especially in premenopausal women) and associated undernutrition.⁶

46. Immobilization is detrimental, and bone loss is faster in persons who are most inactive.⁶

Other interventions

47. Home hazard assessment and modification, under the guidance of an occupational therapist, can reduce the risk of falling (both inside the home and elsewhere) for older adults with a history of falling,³² whereas home visits with an educational preventive focus seem to be ineffective.³³

48. A multifaceted intervention program can reduce the number of falls in community-dwelling elderly:³⁴

- screening for risk factors involving health and physical environment
- assessment and modification of physical activity
- assessment and modification of home hazards
- withdrawal of psychotropic medications (which can be effective by itself)

PUTTING IT ALL TOGETHER

49. Several evidence-based guidelines for the prevention and treatment of osteoporosis are currently available: Osteoporosis Society of Canada,⁶ the US Preventive Services Task Force,²⁰ the NZ Guideline Group,³⁵ UK Bone & Tooth Society.²² For most cases, there is high agreement among the guidelines.

50. The OSC's new clinical practice guidelines are the most comprehensive — 78 summary statements and 45 recommendations.⁶

The accompanying appendices are based primarily on these guidelines and are intended to summarize items that pertain to bone loss in men

of age >50 and in postmenopausal women.

Note: Interventions that are not recommended were *excluded* from these appendices.

51. Helpful and varied information for patients is available at the websites of the Osteoporosis Society of Canada (www.osteoporosis.ca), the National Osteoporosis Foundation (www.nof.org), and the National Library of Medicine (<http://www.nlm.nih.gov/medlineplus/osteoporosis>).

THE BOTTOM LINE

To help reduce the burden of fragility fractures associated with osteoporosis:

- Encourage appropriate lifestyle choices to help maximize healthy bones — from childhood onwards (e.g., suitable exercise; adequate calcium/vitamin D intake; no smoking)
- Investigate patients with fragility fractures
- Routinely assess postmenopausal women and men >50 for clinical risk factors, and recommend BMD testing* for those at high risk of fragility fractures
- Recommend BMD testing* for all patients >65 years of age
- Recommend bone-sparing therapy for patients confirmed to be osteoporotic

* if results will affect management decisions

CASE COMMENTARIES

Case 1: Margaret N., age 50, female

How would you advise Margaret about her request for a “test” for osteoporosis?

Margaret’s history raises several issues frequently encountered in the clinical management of menopause, with particular reference to its relationship to osteoporosis.

Margaret’s request for BMD testing demonstrates her awareness of increased risk for osteoporosis now that she has entered menopause. However, recent evidence-based guidelines recommend BMD testing at the onset of menopause only if at least one major or two minor risk factors are present. Margaret has no clinical risk factors, although her dietary intake of calcium may be low. Accordingly, BMD testing for Margaret can be deferred until she is 65, unless she develops other risk factors in the interim (Info point

25, Table B).

If Margaret was at increased risk, BMD testing would be advised (Appendix 4). If her results were normal, although there is limited evidence to guide the timing of further screening BMDs, a repeat test after 2 years would seem appropriate (Info point 27).

How would you advise Margaret about HRT and about keeping her bones healthy?

The issue of HRT is somewhat more complex and problematic. The perspective on HRT changed considerably with the publication of Women’s Health Initiative results (Info point 34b). A decided shift toward reducing the routine long-term use of HRT and restricting its use to short-term therapy of menopausal symptoms has occurred.

In the WHI, the observed increases in the absolute risk of coronary heart disease, stroke, phlebitis and breast cancer were clear but quite small—in contrast to the relative risk increases, which were quite large. For selected patients, it can be argued that the increased risks related to HRT could be at least partially offset by potential reductions in mortality from hip fractures and colorectal carcinoma.

Given Margaret’s hot flashes and family history of colon cancer, hormone therapy in the short term might have benefit for her (Info point 34). However, patients’ and physicians’ innate fear of breast cancer seems to be the dominant factor in the decision-making process. Also, there are alternative means of controlling mortality from colon cancer through screening with fecal occult blood testing and/or colonoscopy.

Except for her inadequate intake of both calcium and vitamin D, Margaret’s life-style and health habits are for the most part consistent with current recommendations for optimal bone health care.

Thus, appropriate recommendations would include:

- increase vitamin D and calcium intake (through diet and/or the use of supplements) (Info point 40),
- continue to participate regularly in weight-bearing exercise (Info points 44, 45), and
- avoid excessive caffeine and salt intake (Info point 42).

Would your advice be different if Margaret’s mother had a history of hip fracture at age 68?

The occurrence of a hip fracture in her mother would constitute a major risk factor for Margaret (Info point

15, Table B). This would be a clear indication for Margaret to undergo BMD testing now.

Case 2: Robert S., age 59, male

Would you order a BMD test for Robert?

Although it may be uncertain whether these fractures fit the definition of “fragility fractures” precisely (Info point 2), two fractures in a span of 2 years provide a “red flag” for possible osteoporosis — particularly in someone leading a very active lifestyle who has never sustained fractures before.

It is clear that osteoporosis is much more prevalent in men than was formerly thought (Info points 5,7), and more attention is needed to identify risk factors (especially major risk factors) for osteoporosis (Info point 10a, Table B). Robert’s history of probable fragility fracture and low calcium intake make him a candidate for BMD testing.

If you did measure BMD, how would you proceed once you had the results?

As it turned out, Robert’s T-score was -2.0 , suggesting the possibility of secondary causes for his impaired bony structure (Info point 4, Table A). Given Robert’s recent history of a probable fragility fracture, an osteoporosis assessment would be indicated even with a result in the “osteopenia” range.

In hindsight, a detailed assessment of osteoporosis risk after the fractured tibia may have led to BMD measurement and a preventive course of action.

If no secondary causes are identified, at a minimum, counselling about calcium and vitamin D intake is recommended (Info point 40). Since skiing is a relatively high-risk sport for fractures, Robert might also want to reconsider his recreational activities.

Careful *consideration* of antiresorptive therapy with a bisphosphonate following a fragility fracture is also recommended — even in the face of a BMD that is not in the osteoporotic range (Info points 13, 14). Alendronate or risedronate would be considered the most appropriate choices in men (Info point 31). Repeat BMD testing in 1 to 2 years would be appropriate (Info point 27, Appendix 1).

Case 3: Julie K., age 66, female

Would you raise the issue of possible osteoporosis today?

Patients with multiple systems problems always pose a challenge in family medicine. Important problems that are not the primary reason for a particular visit are easy to overlook — especially when the patient is suffering from conditions that are more readily identified with life-threatening events. For Julie, further investigation and treatment of her claudication would be the focus for this visit. However, the need to explore her risk for osteoporosis would be hopefully identified for prompt attention at a follow-up visit.

Julie’s age (over 65) is in itself an indication for BMD testing. Her risk for osteoporosis is further increased by: a lifetime of avoiding dairy products with suboptimal intake of calcium and vitamin D (Info point 40, Appendix 3); a long history of smoking (Table B); a finding of “osteopenia” noted on spinal x-rays (Table C). This risk may be tempered slightly by the fact that Julie is generally fitness-conscious, walks daily, and is not underweight (Info points 44, 45 and Table B). Note that osteoarthritis is not an additional risk factor, whereas rheumatoid arthritis would be.

In view of her Menière’s disease and medications, Julie’s risk of a falling is also significant. It would be important to ask if she experiences any dizziness or postural hypotension related to her antihypertensive or anti-anginal therapy when she is bowling. Her increased risk of both osteoporosis and falling would act in concert to raise her risk of a fragility fracture.

How would you manage Julie’s bone health?

If her BMD results confirm osteoporosis (T-score below -2.5), antiresorptive therapy would be indicated. First-line therapy would be alendronate (10 mg OD or 70 mg weekly) or risedronate (5 mg OD or 35 mg weekly) or raloxifene 60 mg/day (all Grade A recommendation). Etidronate is an alternative treatment (Grade B recommendation) (Info point 31).

Prescription of a bisphosphonate would unfortunately add to her medication regimen, and increase the potential for side effects, non compliance, and drug interactions. However, this may be a very important therapy in the long term. Compliance may be enhanced by using a once-a-week regimen (Info point 31). This regimen is more convenient for both alendronate and risedronate, as patients are advised to take these medications first thing in the morning, with a full glass

of water only, on an empty stomach, approximately 1/2 hour before breakfast, and not to lie down for at least 30 minutes after taking the medication. If patients do not follow these directions, adverse GI effects are more common.

Regardless of her T-score, an increase in calcium/vitamin D intake (to 1500 mg and 800 IU respectively) is indicated by her age. Although Julie has already reduced her cigarette use, cessation of smoking would be recommended. A falls assessment might also be advisable (Info point 48).

Follow-up BMD by spine and hip DXA in 1-2 years is recommended (Info point 27, Appendix 1).

Case 4: Alice B., age 57, female

How would you respond to Alice's concerns about HRT?

Alice will need an explanation of the implications of the Women's Health Initiative study findings (Info point 34), to guide her decision about whether or not to stay on estrogen, as the estrogen-only arm of the study is continuing. Given her level of demineralization (osteopenia), she will likely be — in a relatively short time — at higher risk for an osteoporotic fracture if left untreated. Her most recent T-score indicates that hormone therapy has been effective in preserving her BMD.

If she chooses to remain on estrogen, a BMD every 2 years could monitor her progress and allow for a regular review and discussion of the pros and cons of continuing hormone treatment (Appendix 2). Appropriate breast screening will also be important.

What would you recommend to Alice about her bone health, if she decides not to continue with HRT?

If Alice chooses to discontinue estrogen, an alternative approach to dealing with her osteopenia will be needed. Current guidelines suggest consideration of a bisphosphonate or raloxifene (Info points 31, 36, Appendix 2).

Calcium and vitamin D intake should also be reviewed, along with physical activity (Info points 40, 45).

Continued BMD monitoring is indicated, to ensure that treatment is effective, regardless of the medication used.

Would your approach differ if Alice had suffered a wrist fracture 5 years ago?

If history suggests that this was a fragility fracture (Info point 2), treatment with a bisphosphonate or SERM would be recommended (Info point 31), even if Alice's T-score was above the range normally associated with osteoporosis (Info points 13, 14, Appendix 2).

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We encourage you to direct your questions and comments to the clinical discussion board on our website: www.fmpe.org

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Criteria used in this module to assign levels of evidence and grades of recommendation⁶

Part A: Levels of evidence	
Level	Criteria
<i>Studies of diagnosis</i>	
1	<ul style="list-style-type: none"> i. Independent interpretation of test results ii. Independent interpretation of the diagnostic standard iii. Selection of people suspected, but not known, to have the disorder iv. Reproducible description of the test and diagnostic standard v. At least 50 people with and 50 people without the disorder
2	Meets 4 of the Level 1 criteria
3	Meets 3 of the Level 1 criteria
4	Meets 1 or 2 of the Level 1 criteria
<i>Studies of treatment and intervention</i>	
1+	Systematic overview or meta-analysis of randomized controlled trials
1	One randomized controlled trial with adequate power
2+	Systematic overview or meta-analysis of Level 2 randomized controlled trials
2	Randomized controlled trial that does not meet Level 1 criteria
3	Non-randomized clinical trial or cohort study
4	Before–after study, cohort study with noncontemporaneous controls, case–control study
5	Case series without controls
6	Case report or case series of <10 patients
<i>Studies of prognosis</i>	
1	<ul style="list-style-type: none"> i. Inception cohort of patients with the condition of interest, but free of the outcome of interest ii. Reproducible inclusion and exclusion criteria iii. Follow-up of at least 80% of participants iv. Statistical adjustment for confounders v. Reproducible description of the outcome measures
2	Meets criterion i and three other Level 1 criteria
3	Meets criterion i and two other Level 1 criteria
4	Meets criterion i and one other Level 1 criteria
Part B: Grades of recommendation	
Grade	Criteria
A	Need supportive level 1 or 1+ evidence plus consensus*
B	Need supportive level 2 or 2+ evidence plus consensus*
C	Need supportive level 3 evidence plus consensus
D	Any lower level of evidence supported by consensus
* An appropriate level of evidence was necessary, but not sufficient to assign a grade in recommendation; consensus was required in addition.	

RESOURCES

Online resources for health care professionals and patients

International Osteoporosis Foundation
www.OsteoFound.org

National Osteoporosis Foundation (USA)
www.NOF.org

Osteoporosis Québec (Canadian; bilingual)
www.Osteoporose.qc.ca

Osteoporosis Society of Canada (Canadian; bilingual)
www.Osteoporosis.ca

Online resources for health care professionals

2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada.
www.cmaj.ca/content/vol167/10_suppl/index.shtml

International Bone and Mineral Society
www.IBMSonline.org

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* Websites accessed March 2003

Appendix 1: Key approaches to screening for and diagnosing osteoporosis⁶

	Recom. level ^①	Evidence level ^①	OSC Ref ^②
Patients who should undergo central (hip and spine) BMD testing by DXA are:			
• all men and women ≥65 years of age	A*	3	R-05
• post-menopausal women with at least one major or two minor clinical risk factors (Table B)	A†	N/S	R-05
• men over age 50 with at least one major or two minor clinical risk factors (Table B)	A	N/S	R-05
• those receiving ≥2.5 mg prednisone/day for more than 3 months	B	N/S	R-03
• those receiving ≥7.5 mg prednisone/day for more than 3 months	A	N/S	R-02
• those who have been received antiresorptive treatment for 1 to 2 years	A	N/S	R-07
Patients considered to be at increased risk and requiring further assessment (i.e., BMD testing) are those:			
• with one or more major risk factors (Table B) — especially age >65, personal history of fragility fracture, or family history of fragility fracture	A	1	R-01
• with two or more minor risk factors (Table B)	consensus opinion	3	R-04
• receiving ≥2.5 mg prednisone/day for more than 3 months	B	2	R-03
Patients considered to be at high risk and candidates for pharmacologic intervention are those:			
• receiving ≥7.5 mg prednisone/day for >3 months	A	1	R-02
Patients considered to have osteoporosis and be candidates for pharmacologic intervention are:			
• ≥65 years old with a T-score below -2.5	A	1	R-01
• patients with low BMD by DXA (i.e., T-score below -2.5)	N/S	N/S	F-02
• postmenopausal women with vertebral or other fragility fracture and T-score below -1.5	A	1	R-01 S-02
• men of age >50 with vertebral or other fragility fracture and T-score below -1.5	A	1	R-01 S-02

① See Levels of Evidence.

② See corresponding summary statements (S), recommendations (R), or figures (F) in Osteoporosis Society of Canada (OSC) practice guidelines.⁶

* USPSTF gives B recommendation for all post-menopausal women ≥65 years, but does not consider men in guideline.

† USPSTF gives B recommendation for all women at increased risk for osteoporotic fractures starting at age 60.

Source:

Brown JP, Josse RG (for the Scientific Advisory Council of the Osteoporosis Society of Canada). 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ* 2002;167(10 Suppl):S1-34. PMID: 12427685



Appendix 2: Key approaches to pharmacologic management of osteoporosis^{6,22}

	Recom. level ^①	Evidence level ^①	OSC Ref ^②
Candidates for bisphosphonates (Info points 30-32) are:			
• men with osteoporosis (1 st -line treatment)	A-B	1-2	R-15
• postmenopausal women with osteoporosis (1 st -line treatment)	A-B	1-2	R-12
• postmenopausal women or men at risk with low bone density ^③ (1 st -line prevention)	A	1	R-11 R-15
• patients requiring prolonged glucocorticoid therapy (1 st -line prevention or treatment)	A-B	1-2	R-13 R-14
Candidates for calcitonin (Info point 33) are:			
• patients with pain associated with acute vertebral fractures (1 st -line treatment)	A	1	R-20
• postmenopausal women with osteoporosis (2 nd -line treatment)	B	2	R-17
• men with osteoporosis (in whom calcitonin “may be considered”)	D	N/S	R-19
• nonpregnant premenopausal women with osteoporosis (in whom calcitonin “may be considered”)	D	N/S	R-18
Candidates for ovarian hormone therapy (Info points 34, 35) are:			
• postmenopausal women with low bone density (1 st -line preventive therapy)	A*	1	R-21
• postmenopausal women with osteoporosis (2 nd -line treatment)	B*	N/S	R-23
• women who experience menopause at age <45 (1 st -line preventive therapy)	D	N/S	R-22
Candidates for SERM therapy (Info point 36) are:			
• postmenopausal women with osteoporosis (1 st -line treatment)	A	1	R-25
• postmenopausal women with low bone density (1 st -line preventive therapy)	A	1	R-24
Candidates for ipriflavone (Info point 37b) are:			
• postmenopausal women with low bone density (2 nd -line preventive therapy)	B	2	R-26
Candidates for rhPTH(1-34) (once available) (Info point 38) are:			
• postmenopausal women with severe osteoporosis (1 st -line treatment)	A	1	R-35
• men with severe osteoporosis and patients with severe osteoporosis who are receiving prolonged glucocorticoid therapy (recommended treatment)	D	N/S	R-36

① See Levels of Evidence.

② See corresponding recommendations (R) in OSC practice guidelines.⁶

③ Low bone density arbitrarily defined as T-score below -1.5 (see Figure 02 in OSC practice guidelines).⁶

* Although there is strong evidence (Level 1-2) for the benefit of ovarian hormone therapy, the risks may outweigh the benefits unless women cannot tolerate other effective treatment.^{6,35}

Note: Patients should be monitored by central DXA (total hip and spine) 1 to 2 years after initiating therapy (see Recommendation 07 [Info point 27] in OSC practice guidelines).⁶

Sources: Brown JP, Josse RG (for the Scientific Advisory Council of the Osteoporosis Society of Canada). 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ* 2002;167(10 Suppl):S1-34. PMID: 12427685

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Appendix 3: Key non-pharmacologic approaches to preventing osteoporosis and/or fragility fractures⁶

	Recom. level ^①	Evidence level ^①	OSC Ref ^②
Recommended calcium intake (Info point 40a) (food plus supplements, PRN) is:			
• 1000 mg daily for women aged 19 to 50 years	A	1	S-54 R-37
• 1500 mg daily for women >50 years of age	A	1	
• 1000 mg daily for men aged 19 to 50 years	C	3	
• 1500 mg daily for men >50 years of age	C	1	
Recommended vitamin D (Info point 40b) (preferably as vitamin D3/cholecalciferol) intake (food plus supplements PRN) is:			
• 400 IU (10 mcg) daily for men and women aged 19 to 50 years	D	4	S-57 R-38
• 800 IU (20 mcg) daily for men and women >50 years of age	A	1	
Increasing protein intake (Info point 41) is recommended for:			
• patients with inadequate dietary protein	C	3	S-58 R-39
Intake of caffeine and sodium (Info point 42) should be restricted to:			
• 4 cups of coffee or less per day	B	2	S-60 R-40
• 2100 mg (90 mmol) sodium or less per day	C	3,5	S-61 R-41
Participation in appropriate exercise (Info points 44, 45) (especially weight-bearing with impact component) is recommended for:			
• pre/post-menopausal women	B	2+/1	S-73 S-74 R-44
• men	C	4	S-72 R-44
Participation in tailored exercise (Info point 45b) to improve strength and balance is recommended for:			
• older men and women who have fallen/are at risk of falling	A	2+/1+	S-77 R-45

① See Levels of Evidence.

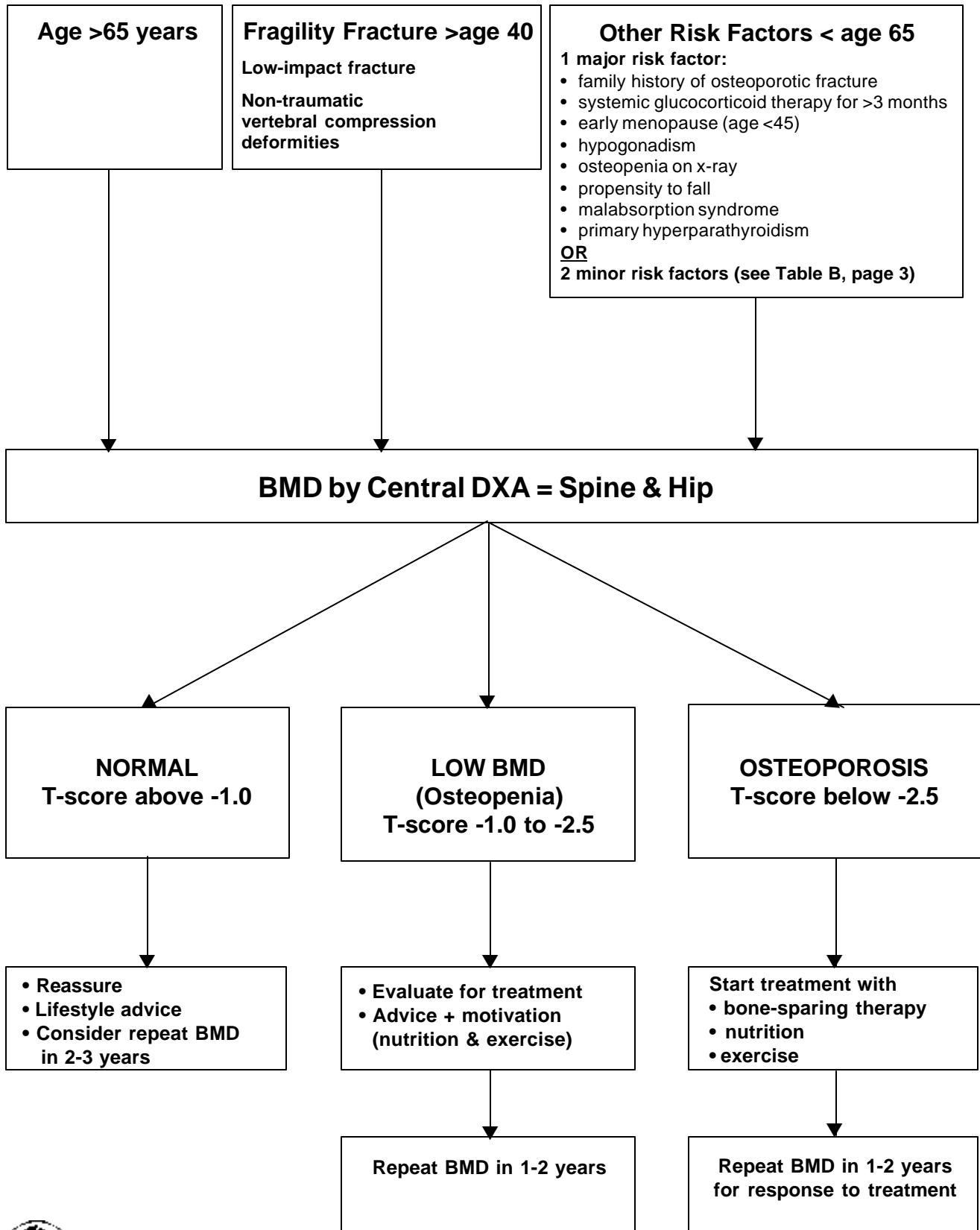
② See corresponding summary statements (S) or recommendations (R) in OSC practice guidelines.⁶

Source:

Brown JP, Josse RG (for the Scientific Advisory Council of the Osteoporosis Society of Canada). 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ* 2002;167(10 Suppl):S1-34. PMID: 12427685



Appendix 4. Whom to test for osteoporosis with BMD



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Adapted from Brown JP, Josse RG (for the Scientific Advisory Council of the Osteoporosis Society of Canada). 2002 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada. *CMAJ* 2002;167(10 Suppl):S1-34. PMID: 12427685 and Royal College of Physicians and Bone and Tooth Society of Great Britain. Osteoporosis: Clinical guidelines for prevention and treatment. Update of pharmacological interventions and an algorithm for management. London: RCP; 2000.