

Canadian Task Force on Preventive Health Care

Recommendations on screening for primary prevention of fragility fractures

Putting Prevention into Practice

Use of slide deck

- These slides are **public** after guideline release to help with dissemination, uptake and implementation into primary care practice
- Some or all of the slides may be used in educational contexts
- The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada





Fragility fractures working group

Task Force members

- Guylene Theriault (chair)
- Roland Grad (vice chair)
- Scott Klarenbach
- Donna Reynolds
- John Riva
- Brett Thombs

Task Force spokespersons

- Guylene Theriault (French and English)
- Roland Grad

External Support

Public Health Agency of Canada

- Heather Limburg
- Laure Tessier

Evidence Review and Synthesis Centre

University of Alberta

Content experts

- Bill Leslie
- Greg Kline



Overview of webinar

- Presentation
 - Methods
 - Background
 - Evidence
 - Recommendations
 - Implementation
 - Knowledge translation tools
 - Conclusions
- Questions and answers





Highlights

- Screening to prevent fragility fractures: who, why, when and how
- What is risk assessment-first screening?
- Fragility Fracture Decision Aid for shared decision-making
- Role of shared decision-making







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Methods

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 Independent panel of clinicians and methodologists

Mandate:

- Develop evidence-based clinical practice guidelines to support primary care providers deliver preventive healthcare
- Ensure dissemination, uptake and implementation of guidelines





Task Force Guideline Development Process



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Evidence Review and Synthesis Centres (ERSC)

- Independent systematic review (SR) of the literature based on the working group's analytical framework
- Present evidence with GRADE tables to inform Task Force guidelines
- Participate in working group and Task Force meetings (non-voting)





GRADE – rating evidence and grading recommendations





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Strong recommandation – low certainty evidence

- When there is low-certainty evidence of benefit and high certainty of harms or important resource implications.
- The task force is mindful of the resource constraints faced by our primary health care system and the resource burden of engaging in activities that consume scarce financial resources or limit access to primary care providers.
- Thus, when resource implications are certain to be important and benefits have not been demonstrated the task force will make a strong recommendation against



Guideline review process

- Internal review process involving:
 - ✓ Guideline working group and other Task Force members
 - ✓ Content experts who support the working group
- External stakeholder review undertaken at key stages:

✓ Protocol, systematic review(s) and guideline

- External stakeholder reviewer groups:
 ✓ Generalist and disease-specific stakeholders
 ✓ Academic peer reviewers
- **CMAJ** undertakes an independent peer review process to review guidelines before accepting for publication



Patient engagement

- Recruited via public ads on websites and outreach
- 2 phases of online focus groups conducted by St. Michael's Hospital, Toronto





Patient engagement

Phase 1: Prespecified Focus Group

- 4 males, 21 females (Selected to include some at elevated risk of fracture)
- Rated importance of outcomes in deciding whether to be screened and indicated willingness to screen

Phase 2: Task Force Patient Advisory Network (TF-PAN)

- 3 males, 3 females from general population
- Educational session
- Provided feedback on key messages and a decision aid example





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Background

What is a fragility fracture?

- A broken bone from a minor impact that should not cause a fracture
- Due to underlying weakened bone, low bone mass and mineral density, often called osteoporosis
- Hip, spine, humerus and wrist fractures are most common
 - Also called major osteoporotic fractures (MOFs)





Risk factors

- Prior fracture
- Parental hip fracture
- Low bone density
- Female sex (at birth)
- Older age/post-menopausal
- Endocrine disorders, diabetes, rheumatoid arthritis, end-stage renal disease
- Medications (e.g., chronic glucocorticoids)
- Lower body weight
- Smoking, alcohol use disorder
- Falls





Burden of fragility fractures

Hip fracture rate (Incidence in 2016)

- 168 per 100 000 65-79 years
- 1 045 per 100 000 80+ years



Estimated cost (2010/11): \$4.6 billion



Burden of fragility fractures

Fragility fractures can have significant negative impacts

- Disability, chronic pain
- Hospitalization
- Long-term care institutionalization
- Reduced quality of life
- Earlier death





What is screening?

 Use of an instrument with <u>all</u> patients in a specific setting to identify who might benefit from an intervention



Information on Screening

Key Points:

- Some health issues could be caught early in people without symptoms using screening tests.
- However, not all screening tests that detect diseases
 earlier improve health outcomes.
- Screening is only warranted if it improves health outcomes compared to other ways of finding disease.



The Task Force produces evidence-based guidelines for preventive health care. Guidelines provide recommendations on whether or not to offer screening to certain groups.

There can be some confusion around what is meant by screening. Below is some information to help clarify.



Screening:

- ✓ Uses a medical test or tool to identify people at risk of a specific disease or health problem. They may be at a higher risk based on factors like age or sex.
- ✓ Is for people who do not show symptoms of a disease or health problem. Test may occur during a primary care visit.
- ✓ Result can be positive, negative, or uncertain. Screening indicates a possible health problem when the result is positive.
- Positive result will lead to more testing to confirm the diagnosis. Additional testing could be more intensive and invasive.
- Example of screening test: Occult blood testing every 2 years for individuals 60-74 years old



Screening is <u>not</u>:

- × For people who are showing symptoms of a disease or health problem.
- Used to provide a definite diagnosis. Making a definitive diagnosis requires confirmatory tests, such as a biopsy.
- The only way to identify conditions. Often, conditions are identified once symptoms are apparent.
- For an individual presenting to their family doctor because of blood in their stools, occult blood testing is NOT an example of screening.

To access our guidelines, tools, and resources, visit our website at www.canadiantaskforce.ca @OS 2022 Canadian Task Force on Preventive Health Care



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Treatment

First-line treatment includes:

- Bisphosphates (alendronate, risedronate or zoledronic acid)
- If contraindications for bisphosphonates, denosumab may be used

Other interventions:

- Exercise
- Smoking cessation
- Fall prevention
- Calcium and vitamin D





Who is the guideline for?



Targeted to

- Primary care health professionals
- Patients



Target Population

 Community-dwelling adults aged 40+



It does not apply to people

Currently taking medications
 to prevent fragility fractures



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Benefits and harms of screening

Benefits

 Screening allows clinicians option to prescribe preventive medication to those at highest risk of fracture



Reduction in fractures and associated morbidity





- Screening and preventive therapy may lead to
 - Overdiagnosis
 - Labelling, stigma
 - Adverse effects from medications

Guideline scope

- Focus on <u>screening</u> for the primary prevention of fragility fractures
 - Screening to identify who may benefit from pharmacotherapy
- Treatment recommendations, vitamin D, calcium, falls prevention and exercise, is beyond the scope
- We will issue a guideline on falls prevention and consider other related topics in future





Current Canadian guidance

Osteoporosis Canada

 The upcoming 2023 Osteoporosis Canada guideline was unavailable for review. However, a 2020 analysis supporting the upcoming guideline suggested the following for males and females: "BMD testing is indicated at age 70 if no additional FRAX clinical risk factors are present, or at age 65 if one or more clinical risk factors exists"



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Current Canadian guidance

Choosing Wisely

- For women over 65 and men over 70, BMD scans are only appropriate for those with moderate risk of fracture or when the results will change the patient's care plan
- Younger women and men ages 50 to 69 should consider the test if they have risk factors for serious bone loss





Current Canadian guidance

Society of Obstetricians and Gynaecologists of Canada, 2022

- All adults ≥65 years should be screened by clinical evaluation and BMD
- In postmenopausal women <65 years, evaluate using clinical FRAX (without BMD)
 - If the FRAX score for MOF is >10%, BMD should also be considered.
- BMD should be considered for patients <65 at elevated risk





How can you screen to prevent fragility fractures?

BMD

- Uses dual-energy X-ray absorptiometry (DXA) of the femoral neck (hip)
- Provides a T-score (based on standard reference values) used for risk assessment

Risk assessment tools:

- Fracture Risk Assessment Tool (FRAX) (with or without BMD)
- Canadian Association of Radiologists/Osteoporosis Canada (CAROC) tool (requires BMD)





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Evidence

Available Evidence

We conducted 4 systematic reviews (SRs) and 1 rapid overview of reviews

1. Harms and benefits of screening (SR)

4 RCTs and 1 clinical controlled trial (i.e., quasi-randomized)

2. Risk prediction tool calibration (SR)

- 32 validation cohort studies
- 3. Treatment benefits (SR)
 - 27 RCTs
- 4. Patient acceptability (SR)
 - 1 study of values and preferences of screening and 11 studies on acceptability of initiating treatment

5. Treatment harms (overview of reviews)

10 systematic reviews





Applicability of available evidence

- In 3 RCTs, participants were "self-selected" based on willingness to complete a risk assessment independently (a subgroup which may differ from the general population)
- All studies recruited via mailed invitations which differs from the typically opportunistic screening setting in Canada
- Participants in the RCTs had higher education levels than the average population
- The evidence was down-rated in GRADE due to issues of applicability



Benefits of screening (hip fractures)

Outcome	Study approach; Population	Included studies; Sample size; Follow-up	Absolute difference (95% CI)1. Control event rate (study data)2. General Canadian population risk	Certainty
Hip fractures	Offer-to-screen in "self-selected" population; Risk assessment-first (e.g., FRAX +/- BMD) Females ≥65 years	3 RCTs + 1 CCT; n=43,736; Follow-up: 3-5 years	 6.2 fewer per 1000 (9.0 fewer to 2.8 fewer) 4.0 fewer per 1000 (5.8 fewer to 1.8 fewer) 	Moderate to High
	"All eligible" / offer-to- screen; BMD-first screening Females 45-54 years	1 RCT; n=2,797; Follow-up: 9 years	 0.1 fewer in 1000 (1.6 fewer to 7.4 more) 0.4 fewer in 1000 (6.5 fewer to 29.7 more) 	Very low
	Acceptors of screening; BMD-first screening Females 45-54 years	1 RCT; n=2,604; Follow-up: 9 years	 1.3 fewer per 1000 (1.9 fewer to 5.0 more) 5.0 fewer per 1000 (7.7 fewer to 20.2 more) 	Very low
	Offer-to-screen in "self-selected" population; BMD-first screening Males ≥65 years	1 CCT; n=1,380; Follow-up: 4.9 years	 9.6 fewer per 1000 (20.4 fewer to 12.9 more) 5.1 fewer per 1000 (10.9 fewer to 6.9 more) 	Very low to low

Benefits of screening (all clinical fragility fractures)

Outcome	Study approach; Population	Included studies; Sample size; Follow-up	Absolute difference (95% CI) 1. Control event rate (study data) 2. General Canadian population risk	Certainty
All clinical fragility fractures	Offer-to-screen in "self-selected" population; Risk assessment- first (e.g., FRAX +/- BMD) Females ≥65 years	3 RCTs (1–3); n=42,009; Follow-up: 3-5 years	 5.9 fewer per 1000 (10.9 fewer to 0.8 fewer) 11.8 fewer per 1000 (21.8 fewer to 1.7 fewer) 	Moderate
	"All eligible" / offer-to- screen; BMD-first screening Females 45-54 years	1 RCT; n=2,797; Follow-up: 9 years	 0.3 more per 1,000 (10.9 fewer to 17.0 more) 0.7 more per 1,000 (21.4 fewer to 33.5 more) 	Very low
	Acceptors of screening; BMD-first screening Females 45-54 years	1 RCT; n=2,604; Follow-up: 9 years	 9.2 fewer per 1,000 (18.4 fewer to 4.8 more) 18.1 fewer per 1,000 (36.2 fewer to 9.4 more) 	Very low



Potential benefits and harms of screening

Screened women	RCT	Based on Canadian fracture risk
Hip fractures	4 6 less /1000	4 less /1000
Clinical fractures	🖡 6 less /1000	📕 <mark>12 less /1000</mark>
Treated individuals	Data on bisphospho	onates
Gastrointestinal issues (e.g., GERD)	1 6 more /100	0
Atypical fractures	1 0.06-1.1 more	e /1000
Osteonecrosis of the jaw	10.22 more /10	000
Overdiagnosis	120-200/1000 <mark>sc</mark>	<mark>reened women</mark>

Harms of screening (Overdiagnosis)

- Overdiagnosis occurs when individuals are correctly classified or labelled as at high risk of fracture but would never have known this nor experienced a fracture and may therefore undergo further assessments or preventive pharmacotherapy without possible benefit
- Among females ≥65 years who were screened,
 11.8-19.3% would be overdiagnosed as high-risk. (low-certainty evidence)


Accuracy of risk assessment tools

	Outcome	Studies; Sample size	Findings Calibration = Observed/Expected	Certainty
Canadian clinical FRAX	10-year <mark>hip fractures</mark>	3 cohort; 67,611	Acceptable calibration (pooled O:E 1.13, 95% CI 0.74-1.72).	Low
(without BMD)	10-year <mark>clinical</mark> fragility fractures	3 cohort; 67,611	Acceptable calibration (pooled <mark>O:E 1.10</mark> , 95% CI 1.01-1.20)	Moderate
Canadian FRAX with BMD	10-year <mark>hip fractures</mark>	3 cohort; 61,156	Underestimation of the observed risk (pooled O:E 1.31, 95% CI 0.91-2.13)	Low
	10-year <mark>clinical</mark> fragility fractures	3 cohort; 61,156	Acceptable calibration (pooled <mark>O:E 1.16</mark> , 95% CI 1.12- 1.20)	Moderate 37

Patient values and preferences

 In surveys and focus groups, people with low BMD or prior fragility fractures stated they were more willing to screen



However

 Females 50-65 years were interested in screening BUT had low acceptability of treatment (systematic review)







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Recommendations

Recommendation



We recommend **"risk assessment-first"** screening for females 65+

(*Conditional recommendation; low-certainty evidence*)



We recommend **against screening females 40-64 and males of any age**

(Strong recommendation; very low certainty evidence)



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Guideline recommendations

Screening is not recommended for

- Females <65 years
- Males of any age



Strong recommendation, very low-certainty evidence



Rationale

- For younger females and males there was no direct evidence establishing a benefit of screening and low- to moderate-certainty evidence of potential harms (e.g., overdiagnosis and adverse events of medications)
- The task force places a high value on not expending systemwide resources on interventions with no established benefit



Strong recommendation, very low-certainty evidence



Recommendation



We recommend **"risk assessment-first"** screening for females 65+

(*Conditional recommendation; low-certainty evidence*)



We recommend **against screening females 40-64 and males of any age**

(Strong recommendation; very low certainty evidence)



Guideline recommendations

Females 65+

The Task Force recommends **risk assessment-first screening as follows:**

- 1. FRAX:
 - Use the Canadian clinical FRAX fracture risk assessment tool (without BMD)
 - Engage in shared-decision making on the benefits and harms of treatment (based on your individual risk)

2. BMD + FRAX:

 After this discussion, if preventive pharmacotherapy is considered, request BMD and add the T-score into FRAX



Conditional recommendation, low-certainty evidence

Risk assessment-first vs BMD-first screening

"Risk assessment-first" screening	"BMD test-first" screening
 Starts with fracture risk estimation (e.g., FRAX <u>without</u> BMD) After SDM if patient is interested in Rx, order BMD 	 Starts with BMD Usually followed by risk assessment (e.g., FRAX with BMD or CAROC)
 Risk is then re- estimated by adding the BMD T-score to the FRAX calculation 	
Consider Tools Fores	



Rationale

 For females aged 65+, the reduction in hip and clinical fragility fractures outweighs potential risks of overdiagnosis and adverse events



Conditional recommendation, low-certainty evidence





Fragility fractures can severely affect quality of life for older adults. For women over age 65, there is good evidence that screening can make a difference. Surprisingly, screening occurs in younger women and men, although there is no evidence of benefit."

Dr. Guylene Theriault, chair,
 Fragility Fractures Working Group







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Patient values and preferences

 A decision aid to support shared decision-making may help align screening and treatment with patient preferences





Decision Aid

Fragility Fracture Decision Aid for shared decision-making



https://frax.canadiantaskforce.ca/





Feasibility and acceptability

- Risk-assessment first screening may be acceptable to patients and clinicians given the increased emphasis on shared decision-making
- Knowledge translation should emphasize the lack of evidence of benefit in males and younger females and the potential harms
- A transition to risk assessment first screening may be acceptable to physicians as it will save time and reduce unnecessary BMD tests





Screening over 25 years



* No evidence this prevents more fractures





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Implementation

 Transition to riskassessment first screening for females ≥65





Canadian Task Force on Preventive Health Care Decrease in screening females
 <65 and males



What does this mean for clinicians?

 Clinicians can stop ordering BMD testing in women under 65 years and men of any age



 Clinicians should screen females aged ≥ 65 years using a risk assessment-first approach and engage in shared decisionmaking about the possible benefits and harms of preventive pharmacotherapy prior to ordering BMD



- It is unknown how often rescreening with FRAX +/-BMD should occur
- Rescreening with a BMD test before 8 years in eligible women does not appear to be necessary

The Task Force hopes the guideline will help avoid unnecessary BMD tests



- Data underpinning the Canadian FRAX algorithm is limited for some racial and ethnic groups
- Country-specific versions of FRAX and FRAX for Black, Hispanic and Asian populations in the US are available but also have limitations





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- These recommendations emphasize good clinical practice where clinicians are alert to changes in physical health and well-being
- Awareness of secondary prevention and management after fracture is important







"

We hope a risk assessmentfirst approach will help reduce unnecessary BMD tests both for patients and the health care system. It doesn't make sense to order tests that will not lead to treatment decisions."

Dr. Donna Reynolds, Fragility
 Fractures Working Group



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Knowledge translation (KT) tools



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Knowledge Translation Tools

- Decision aid to help clinicians and patients understand a patient's fracture risk: <u>https://frax.canadiantaskforce.ca/</u>
- Clinician infographic
- At publication, tools will be freely available for download in both French and English at:

http://canadiantaskforce.ca





Screening to prevent fragility fractures How much time does it take?

APZ

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We recommend risk assessment-first (FRAX):

 Bone mineral density (BMD) only for women 65+ who know their fracture risk and show interest in preventive treatment



Reduces unnecessary testing



Shared decision-making

We do not recommend BMD
testing-first for women or men

🗸 Takes less time

Assume:

- A practice of 1200 patients followed over 25 years
- 600 aged 50+ and 300 aged 65+
- ¹/₂ are women and ¹/₂ are men
- Screening is estimated to age 85 years
- Rescreening occurs every 2-5 years for BMD-first; every 8 years for risk assessment-first

Context:

- No trials show benefit of screening men of any age or women ≤65
- Rescreening women within 8 years does not appear useful



* No evidence this prevents more fractures

Your time as a clinician is valuable: do better for your patients in less time

How was this calculated?

The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada. Find guidelines, tools and resoures at <u>www.canadiantaskforce.ca</u> ©**OS** 2023 Canadian Task Force on Preventive Health Care

Clinician infographic



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Tools







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Systematic reviews

Published in Systematic Reviews

 All reviews available on the Task Force website: <u>https://canadiantaskfor</u> <u>ce.ca/guidelines/systematic-</u> <u>reviews-and-protocols/</u>





Communications



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Conclusions

Task Force recommends

• Shared decisionmaking with patients





Use Fragility Fracture Decision Aid for shared decision-making



Knowledge gaps

- High quality trials needed on:
 - Benefits and harms of screening males, younger females
 - How often to screen and age to stop screening
 - Potential harms after stopping pharmacotherapy
 - Diverse populations

More research is needed



More information

For the guideline, related clinician and patient tools, visit:

• <u>http://canadiantaskforce.ca</u>





Questions and answers







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The GRADE system

The "GRADE" system: Grading of Recommendations Assessment Development & Evaluation





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GRADE process - define and collect

- **Define** questions re: populations, alternative management strategies and patient-important outcomes
- Characterise outcomes as critical or important to developing recommendations
- Systematic **search** for relevant studies
- Estimate effect of intervention on each outcome based on pre-defined criteria for eligible studies
- Assess certainty of evidence associated
 with effect estimate





GRADE – rating certainty of evidence

GRADE Approach:

- Hierarchy of evidence certainty: RCTs > Observational studies
- Rating of certainty by outcome is reduced based on:
 - Study limitations (Risk of Bias)
 - Imprecision
 - Inconsistency of results
 - Indirectness of evidence
 - Publication bias likely





Direct vs. indirect evidence

- Direct evidence –studies examining the effects of screening vs.
 no screening or usual care
- When direct evidence is **unavailable**, the Task Force may also examine indirect evidence
- **Indirect evidence** is less certain:
 - Iinked to the outcome of interest (e.g. depression symptoms are dependent on the effectiveness of treatment) or
 - ✓ **related** to the screening intervention of interest





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Other screening recommendations

Osteoporosis Canada, 2023*

•BMD testing is indicated at age 70 if no additional FRAX clinical risk factors are present, or at age 65 if one or more clinical risk factors exists

*The upcoming 2023 Osteoporosis Canada guideline was unavailable for review. However, a 2020 analysis supporting the upcoming guideline was used for the above recommendation.

Society of Obstetricians and Gynaegologists of Canada, 2022

•All adults ≥65 years should be screened by clinical evaluation and BMD.

•In postmenopausal women <65 years, evaluate using clinical FRAX (without BMD). If the FRAX score for MOF is >10%, BMD should also be considered.

•BMD should be considered for patients <65 years if at elevated risk

National Osteoporosis Guideline Group UK, 2022

•A FRAX assessment should be performed in any postmenopausal woman, or man aged ≥50 years, with a clinical risk factor for fragility fracture, to guide BMD measurement and prompt timely referral and/or drug treatment, where indicated









The Bone Health and Osteoporosis Foundation (formerly the National Osteoporosis Foundation) (USA), 2022

- Perform BMD testing in the following:
 - Women aged \geq 65 years and men \geq 70 years.
 - Postmenopausal women and men 50–69 years, based on risk profile.
 - Postmenopausal women and men ≥ 50 years with history of adultage fracture.

The American College of Obstetricians and Gynecologists, 2021

Recommend screening for osteoporosis in postmenopausal patients 65 years and older with BMD testing
Recommend screening with BMD in postmenopausal patients <65 years who are at increased risk, as determined by a formal clinical risk assessment tool

Scottish Intercollegiate Guidelines Network, 2021

 A FRAX assessment should be performed in any postmenopausal woman, or men aged ≥50 years, with a clinical risk factor for fragility fracture, to guide BMD measurement and prompt timely referral and/or drug treatment, where indicated









American Association of Clinical Endocrinologists and American College of Endocrinology, 2020

- Postmenopausal women ≥50: A detailed history, physical exam, and clinical fracture risk assessment with FRAX® or other fracture risk assessment tool
- BMD testing for women ≥65 and younger postmenopausal women at increased risk for bone loss and fracture, based on analysis of fracture risk.

UK National Screening Committee, 2019

•Does not recommend screening for osteoporosis in postmenopausal women.

US Preventive Services Task Force, 2018

•Recommend screening for osteoporosis with BMD to prevent osteoporotic fractures in women 65 years and older.

Recommend screening for osteoporosis with BMD to prevent osteoporotic fractures in postmenopausal women <65 years at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool.
The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men. (I statement)









National Institute for Health and Care Excellence (England), 2017

- In women ≥65 years and men ≥75 years and in women <65 years and men
 <75 years with risk factors:
 - Use either FRAX (without BMD) or QFracture to estimate 10-year predicted absolute fracture risk when assessing risk of fracture.
 - Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD in people whose fracture risk is in the region of an intervention threshold for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

American College of Radiology, 2016

- Perform BMD screening for the following groups:
 - All women ≥65 years and men ≥70 years
 - Women <65 years or men <70 years who have additional risk factors.





National Institute for Health and Care Excellence