Core principles for fracture prevention: North American Consensus from the National Osteoporosis Foundation, Osteoporosis Canada, and Academia Nacional de Medicina de Mexico E.M. Lewiecki, N. Binkley, P. Clark, S. Kim, W.D. Leslie & S.N. Morin



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#### CONSENSUS STATEMENT



# Core principles for fracture prevention: North American Consensus from the National Osteoporosis Foundation, Osteoporosis Canada, and Academia Nacional de Medicina de Mexico

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## Abstract

**Summary** Core principles for fracture prevention address fundamental concepts for the evaluation and management of patients at risk for fracture. These are intended to form the foundation of clinical practice guidelines and represent a first step toward guideline harmonization.

**Introduction** The large number of clinical practice guidelines for osteoporosis and discordance of recommendations has led to confusion among clinicians and patients, and likely contributes to the large osteoporosis treatment gap. We propose that stakeholder organizations reach agreement on fundamental principles in the management of osteoporosis and prevention of fracture as a first step toward a goal of guideline harmonization.

**Methods** The best available evidence, as interpreted by an ad hoc working group of expert representatives from major osteoporosis societies in North America, was considered in the development of core principles for skeletal healthcare. These principles were subsequently endorsed by the USA National Osteoporosis Foundation, Osteoporosis Canada, and Academia Nacional de Medicina de Mexico (National Academy of Medicine of Mexico).

**Results** Core principles are summarized here in bullet format. Categories include evaluation, lifestyle and nutrition, pharmacological therapy, and monitoring. A pathway forward to achieve guideline harmonization, at least in part, is proposed.

**Conclusion** Greater concordance of recommendations for the care of patients at risk for fracture are expected to lead to improved patient care across jurisdictions, with a narrowing of the osteoporosis treatment gap and reduced burden of fractures.

Keywords Best practice · Fracture · Guide · Harmonization · Osteoporosis

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# Background

Osteoporosis is a common disease and an important public health concern. The consequences of osteoporotic fractures include disability, loss of independence, death, and high healthcare costs. Despite the availability of many effective interventions to reduce fracture risk, most patients at risk of fractures are not being assessed or treated. The osteoporosis treatment gap (the difference between those who could benefit from treatment and those who receive it) has been recognized as a global crisis in the care of this disease [1]. There are many factors contributing to the treatment gap, one of which is the plethora of clinical practice guidelines generated by various professional organizations, national societies, foundations, and governmental agencies. A recent PubMed search (https://www.ncbi.nlm.nih.gov/pubmed) for "osteoporosis" and "guidelines" for the past 5 years generated over 900 matches. These guidelines are often created with different methodologies using diverse assumptions, addressing different patient populations, with variable strategies for updates as new data emerge. Recommendations for the management of osteoporosis have varied accordingly, sometimes confusing more than enlightening healthcare professionals who care for patients at risk for fracture. The idea of harmonizing clinical practice guidelines for the prevention of fractures and treatment of osteoporosis, and challenges in doing so, was presented over 20 years ago [2]. The concept of guideline harmonization is as timely now as it was then [3]. As a first step on the pathway toward harmonization, we propose that stakeholder organizations agree on core principles in skeletal healthcare for the prevention of fractures.

Here we present core principles for skeletal healthcare for postmenopausal women and men age 50 years and older. These have been reviewed and endorsed by national societies of USA, Canada, and Mexico: National Osteoporosis Foundation (NOF), Osteoporosis Canada (OC), and Academia Nacional de Medicina de Mexico, respectively, with the aim of establishing a foundation for the eventual harmonization of other aspects of fracture prevention care. We recognize it is unlikely that complete harmonization will be ever achieved because of regional differences in healthcare priorities, variability in resources, and availability of diagnostic tools and treatment options around the world. We are also very aware of the need for individualization of treatment decisions and limitations of all clinical practice guidelines.

## Methods

Adapting an approach used by international menopause societies [4], an ad hoc working group of representatives from major North American societies responsible for national clinical practice guidelines related to osteoporosis met in September 2019 to identify areas of broad agreement regarding principles of osteoporosis management. The aim was to produce a short document containing the points of consensus, acknowledging that these core principles do not replace more detailed and fully referenced clinical practice guidelines prepared by individual national and regional societies, such as the NOF [5] and OC [6].

#### **Core principles**

Based on the best available evidence and expert opinion, we recommend applying the following concepts to the care of adults at risk for fracture and those with osteoporosis.

**Evaluation** Following a fracture, individuals age 50 years and older should be evaluated for factors that contribute to skeletal fragility and falls, recognizing that the risk of another fracture is highest in the 1 to 2 years following a fracture ("imminent fracture risk"). A structured systematic strategy to identify,

evaluate, and treat patients who have fractured, such as fracture liaison service (FLS), has been associated with improved post-fracture outcomes [7] and is cost-effective [8, 9]. Bone density testing can be used to enhance fracture risk assessment before or after a fracture has occurred. Fracture risk algorithms can be used to estimate the 10-year probability of fracture [10, 11]. Laboratory tests and imaging studies are helpful in assessing fracture risk and guiding treatment decisions [7, 12].

Lifestyle, physical activity, and nutrition Healthy lifestyle and good nutrition are recommended for all patients. Regular weight-bearing and muscle-strengthening physical activity as tolerated should be strongly encouraged. Specific types of physical activity should be customized as needed according to the preferences and limitation of each patient. Attention should be devoted to activities that promote good balance and reduce the risk of falls, especially in older patients and those with prior fracture. For patients at risk for falls, interventions such as gait and balance training and physiotherapy should be considered. Smoking and excess alcohol intake should be avoided. When taking a medication known to have adverse bone, muscle, or balance effects, the balance of benefits and risks should be considered, with efforts to minimize or avoid exposure when possible. Adequate calcium intake is best obtained from dietary sources, using supplements only when the diet is deficient and cannot be corrected. If vitamin D is inadequate, supplements should be taken, with dosing to consider the desired target range and individual variation in absorption and metabolism.

**Pharmacological therapy** Before starting pharmacological therapy, patients should be evaluated for factors contributing to skeletal fragility and falls risk. Non-pharmacological interventions to reduce fracture risk should be initiated. Patients should also be assessed for factors that could influence treatment choice and aid in determining the balance of benefits and risks with a particular type of treatment.

The selection of initial therapy should consider all available information, including patient preference, comorbidities, availability, affordability, and the balance of benefits and risks individualized for each patient. Duration of therapy and consideration for sequential therapy should be individualized based on clinical factors such as treatment response, fracture history, and reassessment of benefits and risks.

**Monitoring** Depending on clinical circumstances, it may be appropriate to monitor untreated adults to determine whether treatment should be initiated. Treated patients should be monitored to assure adherence and appropriate response to therapy. In clinical practice, measurement of bone mineral density (BMD) by dual-energy X-ray absorptiometry is a widely used tool for monitoring skeletal health.

## **Pathway forward**

It would be helpful to have a better understanding of how well, or how poorly, healthcare professionals are implementing clinical practice guidelines that are currently available, and which groups of professionals are using which guidelines. This information might be obtained by means of a comprehensive online survey. More data are needed on the effects of guideline discordance on patient outcomes. The potential benefits and limitations of guideline harmonization should be explored in greater detail.

If stakeholder organizations are willing to agree upon fundamental principles for best practice care, such as those presented here, efforts to develop agreement on other more controversial aspects of osteoporosis care should be pursued. Examples of this include the dose or dose range for calcium intake, the preferred type of vitamin D assay and the optimal target range for vitamin D levels, and strategies for selecting and changing therapy.

# Conclusion

Agreement on core principles for the care for patients at risk for fracture is the first step toward a goal of guideline harmonization. While total harmonization of guidelines is almost certainly unachievable, healthcare providers and their patients are likely to benefit from greater concordance of recommendations in the care of patients with osteoporosis. More data are needed to fully evaluate and understand the consequences of guidelines dissonance on patient-level outcomes.

# Summary of core principles

- Osteoporosis is a common disease that increases risk of fractures with consequences including loss of independence, death, and high healthcare costs.
- Bone density measurement using DXA can be used to enhance fracture risk assessment before or after a fracture has occurred.
- Fracture risk algorithms (e.g., FRAX) that include consideration of clinical risk factors should be used to guide pharmacologic treatment recommendations.
- Non-pharmacological interventions (e.g., activities to increase strength and balance and optimize nutrition) are essential components of care to reduce fracture risk.
- Pharmacological therapy
- For patients at high fracture risk, antiresorptive agents are usually first line therapy.
- Anabolic agents may be considered for patients at very high fracture risk.

- Treatment decisions should be individualized according to all available clinical information, including patient preferences.
- Treated patients should be monitored to assure adherence and response to therapy.

### **Compliance with ethical standards**

**Conflict of interest** EML has received no direct income from potentially conflicting entities. His employer, New Mexico Clinical Research & Osteoporosis Center, has received research grants from Radius, Amgen, Mereo, Bindex; income for service on scientific advisory boards or consulting for Amgen, Radius, Alexion, Sandoz, Samsung Bioepis, Sanifit; service on speakers' bureaus for Radius, Alexion; project development for University of New Mexico; and royalties from UpToDate for sections on DXA, fracture risk assessment, and prevention of osteoporosis. He is a board member of the National Osteoporosis Foundation, International Society for Clinical Densitometry, and Osteoporosis Foundation of New Mexico.

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SK has no financial or industry related conflicts of interest; she is chair of the Scientific Advisory Council for Osteoporosis Canada, co-chair of the pharmacotherapy working group for the Osteoporosis Canada Clinical Practice Guidelines Update, and serves on the Osteoporosis Canada Board of Directors.

WDL has no financial or industry-related conflicts of interest; he is chair of the steering committee for the Osteoporosis Canada Clinical Practice Guidelines Update.

SNM is a member of the steering committee for the Osteoporosis Canada Clinical Practice Guidelines Update; she has received a research grant from Amgen (paid to research institution).

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