NOFSA Guideline for the Diagnosis and Management of Osteoporosis

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Objective
This document is an update of the clinical guideline published by the National Osteoporosis Foundation of South Africa (NOFSA) in 2000, which aims to improve the overall efficacy of the diagnosis and management of patients with, or at risk for, osteoporosis. The guideline is not limited to any particular patient group and targets all health care workers. This is a detailed summary, which is cross-referenced to the full guideline and is available on the NOFSA (www.osteoporosis.org.za) and JEMDSA (www.jemdsa.co.za) websites.

Outcomes
The prevention of osteoporotic fractures and reduction in morbidity and mortality were the major considerations in the development of this guideline. Although no formal economic analysis was undertaken, the cost-efficacy of diagnostic and therapeutic interventions was considered in all recommendations.

Evidence
Systematic reviews and the highest level of evidence (randomised controlled trials (RCTs) and meta-analyses) were used as far as possible, and isolated descriptive studies and expert opinions were largely ignored. The Grading of Recommendation, Assessment, Development and Evaluation (GRADE) criteria were used to describe the quality of evidence and the strength of recommendations. A draft guideline was developed, revised by the NOFSA Council during a two-day workshop, and finalised at a consensus meeting attended by relevant stakeholders.

Key recommendations
It is important to emphasise that this document should serve as a guide for clinical decision making and that it is not intended to represent rigid, prescriptive rules on patient management. The main recommendations are:

1. Greater awareness about osteoporosis, its complications, prevention and treatment is necessary, as is broader access to health care for all patients suffering from this disease.

2. Local research on the incidence of, risk factors for and normal reference data on osteoporosis is required. This will enable the formulation of a health economic strategy for the management of osteoporosis in this country.

3. A diagnosis of osteoporosis is presently based on low bone mineral density (BMD) (a so-called BMD T-score ≤ -2.5) or evidence of a fragility fracture.

4. A BMD measurement should be performed in any patient if the indication, largely based on the patient’s clinical risk factor (CRF) profile, is valid.

5. BMD testing is indicated routinely in women over 65 years of age and in men aged 70 years and older.

6. Central (axial) dual energy X-ray absorptiometry (DXA) should be used to measure BMD and to diagnose osteoporosis. Use the NHANES III young female reference data to determine T-scores in postmenopausal women and men over the age of 50 years of all races. Use BMD Z-scores in younger individuals. A diagnosis of osteoporosis in children should be based on a low BMD (Z-score ≤ -2.0 corrected for body size, gender, ethnicity and pubertal status) plus a significant fracture history. Other techniques, including quantitative ultrasound (QUS), cannot be used to diagnose osteoporosis, but this does not preclude their use to assess fracture risk, particularly if axial (spine or hip) DXA is not available.

7. The differences between diagnostic criteria and...
interventional thresholds are emphasised. The need to treat should not depend on a BMD value alone, but should also be determined by the patient's age (advanced age is the most important risk factor for osteoporosis, other than a low BMD), general health, willingness to consider treatment, the presence of prior fractures, CRFs and causes of ongoing bone loss, as well as the cost-efficacy and side-effects of available treatment.

8. A thorough clinical assessment, BMD measurement employing DXA, search for evidence of vertebral fracture (using standard X-rays or DXA-based vertebral fracture assessment, DXA-VFA) and appropriate laboratory evaluation (to ensure that osteoporosis is the cause of the low BMD and not primary hyperparathyroidism or osteomalacia, and to exclude causes of secondary osteoporosis) are necessary before embarking on treatment with bone-active drugs.

9. Initiate treatment in those with a T-score ≤ -2.5 at the hip or lumbar spine.

10. Initiate treatment in those with a typical osteoporotic fracture.

11. Initiate treatment in postmenopausal women and in men with low bone mass or osteopenia (T-score between -1.0 and -2.5) in whom a clinical risk profile suggests above average risk of fracture. This might be assessed using the World Health Organization (WHO) FRAX® tool but, since little epidemiologic fracture data are available in this country, a simple algorithm (Figure 4) may be used in the interim.

12. Non-pharmacological measures to improve bone strength and prevent falls are emphasised. Ensure an adequate intake of calcium (1,200mg per day) and vitamin D (800-1,000 IU per day; up to 2,000 IU per day during pregnancy and lactation); walk for 30-40 minutes, three times per week; employ simple clinical tools to assess and address the risk of falling; stop smoking; limit alcohol consumption to less than three drinks per day; and avoid bone-toxic drugs as far as possible.

13. Osteoporosis is a heterogeneous syndrome and no single ideal drug can be recommended for treatment of all patients. The choice of drug should be individualized and is largely determined by (i) the severity and nature of the disease (e.g. nonpharmacological measures, calcium/vitamin D, and regular follow-up should suffice in those with very mild osteopenia and no fractures; consider hormone therapy (HT) or strontium ranelate for those with more significant osteopenia; a bisphosphonate or strontium ranelate for subjects with DXA-proven osteoporosis; and anabolic agents for those with advanced fracturing disease, an ultra-low BMD, or failed treatment with antiresorptive agents, ARAs); (ii) the patient profile (e.g. a bisphosphonate or strontium ranelate for otherwise healthy individuals with osteoporosis; HT for 50- to 60-year-old women with menopausal symptoms in whom HT is not contraindicated; a selective estrogen receptor modulator (SERM) for postmenopausal women with predominantly vertebral osteoporosis at risk of breast cancer); and (iii) available resources and personal preferences.

14. Regular clinical, densitometric and morphometric (X-rays or VFA) monitoring is important. The clinician should be aware of the many pitfalls that exist in assessing the densitometric follow-up of patients, particularly those treated with ARAs.

15. The acute painful vertebral syndrome should be treated with conventional analgesics, a short-term corset or brace, physiotherapy, hydrotherapy and gradual mobilisation.

16. Given our current knowledge, the use of specific bone-active drugs (e.g. calcitonin) or vertebroplasty cannot, at present, be recommended for the treatment of the acute painful vertebral syndrome. Under certain circumstances, the use of balloon kyphoplasty may, however, be considered.

17. Extensive dissemination of this guideline, including its electronic distribution, is necessary if key recommendations are to be implemented.

18. The electronic version of the guideline, including its publication on the NOFSA (www.osteoporosis.org.za) and JEMDSA (www.jemdsa.co.za) websites, will allow for regular update.