

## **The National Osteoporosis Foundation *Clinician's Guide to Prevention and Treatment of Osteoporosis*, 2008: A New Guidance to Establish a Standard of Care for Prevention of Osteoporosis-Related Fractures**

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In 1998, the National Osteoporosis Foundation (NOF) in the United States issued its first evidence-based clinical guidance for the prevention, diagnosis and management of osteoporosis (1). At that time and in a subsequent update in 2005, recommendations were given for bone mineral density (BMD) testing in postmenopausal white women and for prescribing pharmacological treatments in these women based on BMD T-scores with or without additional risk factors. NOF recommended that all women age 65 or older and postmenopausal women <65 with clinical risk factors for fracture undergo screening with DXA. NOF stated that women with osteoporosis, defined as a prior hip or vertebral fracture or a spine or hip T-score  $\leq -2.5$ , should be treated with medication to reduce fracture risk. The 1998 guidance also suggested that treatment be offered if the hip or spine T-score was  $-2.0$  or less, or  $-1.5$  or less if additional risk factors were present. While most clinician groups in the US agreed that it was correct to use prescription medication in postmenopausal women with osteoporosis, there was considerable disagreement about the appropriate management of women with osteopenia, using the World Health Organization (WHO) definition of a T-score between  $-1.0$  and  $-2.5$ .

Since that time, new data on many aspects of osteoporosis diagnosis, fracture risk assessment and management to reduce fractures have emerged that have created the opportunity to update the NOF *Clinician's Guide* once again. In particular, WHO recently launched its new tool for calculation of 10-year absolute fracture probability, FRAX™, to provide a universal

algorithm that can be applied in each country based upon country-specific fracture outcome and mortality data (2). In addition, a cost-effectiveness analysis in each country could be done to determine the level of risk at which treatment would be recommended.

The new NOF *Guide* was developed by an expert committee of scientists, including clinical investigators, an epidemiologist and a health economist, and their work was reviewed and commented upon by the member groups of the NOF Interspecialty Medical Council, consisting of the various medical professional societies to which most US physicians belong. The scientific underpinnings of the new *Guide's* recommendations are described in two publications in *Osteoporosis International* (3; 4). One is an analysis of the application of FRAX™ in both postmenopausal women and men over age 50 in the US and the other is a cost-effectiveness analysis that proposes treatment thresholds for US patients based upon 10-year fracture risk. From the health economics perspective it was determined that it is cost-effective in the US to treat if the 10-year absolute risk for hip fracture is  $\geq 3\%$ . Additional analyses by the *Guide* committee also led to a recommendation for treatment if the 10-year absolute risk of major osteoporosis-related fractures is  $\geq 20\%$ , since that risk calculation is also provided by FRAX™.

The 2008 NOF *Clinician's Guide* (5) is available without cost at [www.nof.org](http://www.nof.org). The *Guide* offers information about relevant aspects of bone biology; epidemiology and both clinical and economic consequences of fractures; and updated recommendations on calcium, vitamin D, exercise and lifestyle

issues such as alcohol and cigarette smoking. Considerations about secondary causes of osteoporosis and recommendations regarding patients receiving corticosteroids are also included in this new document. One section of the *Guide* describes the currently available medications approved by the US Food and Drug Administration for the prevention or treatment of osteoporosis, describing their indications, modes of administration and side effect profiles as described in their product labeling.

Additionally and very significantly, the *Guide* also provides for the first time evidence-based guidance on BMD testing and treatment in both women *and* men and in non-Caucasian ethnic groups. Specific recommendations include:

- Bone density testing, preferably at the spine and hip, in all women age 65 and older and in all men 70 and older.
- Bone density testing of postmenopausal women and men age 50-70 if there is concern about their risk factor profile.
- Bone density testing in women in the menopausal transition if there is a specific risk factor for bone loss; consideration of testing in postmenopausal women discontinuing estrogen.
- Testing is also recommended in: adults over age 50 who present with a fracture; adults with a medical condition or a medication associated with low bone mass or bone loss; anyone being considered for pharmacologic treatment for osteoporosis; anyone on treatment to monitor the response; or anyone not on therapy in whom evidence of bone loss would lead to treatment.

The *Guide* also recommends treatment intervention with an approved agent in postmenopausal women and men age 50 and older with the following:

- A hip fracture or a morphometric or clinical vertebral fracture.
- Other prior fractures and low bone mass (T score between -1.0 and -2.5 at the spine or hip).
- T score  $\leq$ -2.5 at the femoral neck, total hip or lumbar spine (after appropriate evaluation to eliminate secondary causes).
- Low bone mass as above and secondary causes associated with a high risk of fracture (e.g., use of glucocorticoid therapy).
- Low bone mass at the hip or spine and 10-year fracture probability – as determined by a gender- and ethnic-specific FRAX™ calculation as adapted for use in the US population – of hip fracture  $\geq$ 3% or of major osteoporosis-related fractures  $\geq$ 20%.

It is important to underscore that a primary purpose of the *Guide* is to provide patients and clinicians a better understanding of each individual's future probability of fracture in terms of absolute risk over a finite period of 10 years to assure that those at increased risk receive treatment. The *Guide* is not intended to restrict physicians in any way, and clinicians are encouraged to use clinical judgment when making treatment decisions based upon clinical information or additional risk factors known to them and on the personal attitudes and concerns of individual patients.

The information in the new NOF *Guide* will hopefully help us to achieve a standard of care to reduce the burden of osteoporosis-associated fractures. We have good diagnostic tools and excellent treatments, and we now are able to provide updated evidence-based advice for primary care clinicians about when and how to evaluate and counsel, when to test, and when to treat. The FRAX™ tool offers a much better way to assess fracture risk than BMD alone, eliminates the controversy about what to do for patients with "osteopenia", and gives

both clinicians and patients a better way to make treatment decisions.

## References

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3. Dawson-Hughes B, Tosteson AN, Melton LJ 3rd, Baim S, Favus MJ, Khosla S, Lindsay RL; National Osteoporosis Foundation Guide Committee. Implications of absolute fracture risk assessment for osteoporosis practice guidelines in the USA. *Osteoporos Int*. 2008 Apr;19(4):449-58.
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