ISCD
The International Society For Clinical Densitometry

International Osteoporosis Foundation

2010 Official Positions on FRAX®

Interpretation and Use of FRAX® in Clinical Practice

from the International Society for Clinical Densitometry and International Osteoporosis Foundation

The International Society for Clinical Densitometry (ISCD) and the International Osteoporosis Foundation (IOF) convened the FRAX® Position Development Conference (PDC) in Bucharest, Romania, on November 14, 2010, following a two-day joint meeting of the ISCD and IOF on the "Interpretation and Use of FRAX® in Clinical Practice". These three days of critical discussion and debate, led by a panel of international experts from ISCD, IOF and by dedicated task forces, have clarified a number of important issues pertaining to the interpretation and implementation of FRAX® in clinical practice. The Official Positions resulting from the PDC are intended to enhance quality and clinical utility of fracture risk assessment worldwide. Since the field of skeletal assessment is new and evolving rapidly, some clinically important issues addressed at the PDCs are not associated with robust medical evidence. Accordingly, some Official Positions are based largely on expert opinion. Despite limitations inherent in any process such as this, ISCD and IOF believe it is important to provide clinicians and technologists with the best distillation of current knowledge in the discipline of bone densitometry and provide guidance to the scientific community on where further research is needed to resolve areas of ambiguity and/or ongoing controversy.

ISCD is an international nonprofit professional society linking multiple disciplines with an interest in bone mass measurement and assessment of skeletal integrity. The ISCD's mission is to advance excellence in the assessment of skeletal health by: promoting education and a broader understanding of the clinical applications of bone mass measurement and other skeletal health assessment technologies; assuring proficiency and quality in the assessment of skeletal health through certification and accreditation; supporting clinical and scientific advances in the diagnosis and treatment of osteoporosis; and promoting appropriate patient access to bone mass measurement and other skeletal health assessment technologies.

IOF is a nonprofit, nongovernmental umbrella organization dedicated to the worldwide fight against osteoporosis, the disease known as "the silent epidemic". The IOF's members – committees of scientific researchers, patients, medical and research societies and industry representatives from around the world – share a common vision of a world without osteoporotic fractures. The IOF now represents 195 societies in 93 locations.

The ISCD and IOF wish to acknowledge the extraordinary efforts of the PDC Task Force Chairpersons and members, who represented a distinguished group of international experts. The dedication of these individuals for the past two years is exemplary.

All ISCD IOF Official Positions are for worldwide application. These official Positions may be downloaded from the ISCD and IOF websites at www.iscd.org and www.iofbonehealth.org

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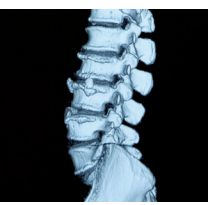

ISCD

INTRODUCTORY STATEMENT

1 FRAX is a computer-based algorithm which uses easily obtained clinical risk factors to estimate an individual's 10-year fracture probability. It may be utilized by clinicians to assist in the identification of patients at high risk for fractures.

FRAX CLINICAL STATEMENTS

2 Impaired functional status in patients with rheumatoid arthritis may be a risk factor for clinical fractures. FRAX may underestimate fracture probability in such patients.

3 There is no consistent evidence that non-glucocorticoid medications for rheumatoid arthritis alter fracture risk.

4 While there is evidence that duration and dose of tobacco smoking may impact on fracture risk, quantification of this risk is not possible.

5 Falls are a risk factor for fractures but are not accommodated as an entry variable in the current FRAX model. Fracture probability may be underestimated in individuals with a history of frequent falls, but quantification of this risk is not currently possible.

6 There is a relationship between number of prior fractures and subsequent fracture risk. FRAX underestimates fracture probability in persons with a history of multiple fractures.

7 There is a relationship between severity of prior vertebral fractures and subsequent fracture risk. FRAX may underestimate fracture probability in individuals with prevalent severe vertebral fractures.

8 While there is evidence that hip, vertebral, and humeral fractures appear to confer greater risk of subsequent fracture than fractures at other sites, quantification of this incremental risk in FRAX is not possible.

9 A parental history of non-hip fragility fracture may be a risk factor for fracture. FRAX may underestimate fracture probability in individuals with a parental history of non-hip fragility fracture.

10 Evidence that bone turnover markers predict fracture risk independent of Bone Mineral Density (BMD) is inconclusive. Therefore, bone turnover markers are not included as risk factors in FRAX.

11 There is a dose relationship between glucocorticoid use of greater than 3 months and fracture risk. The average dose exposure captured within FRAX is likely to be a prednisone dose of 2.5-7.5 mg/day or its equivalent. Fracture probability is under-estimated when prednisone dose is greater than 7.5 mg/day and is over-estimated when prednisone dose is less than 2.5 mg/day.

12 Frequent intermittent use of higher doses of glucocorticoids increases fracture risk. Because of variability in the dose and dosing schedule, quantification of this risk is not possible.

13 High dose inhaled glucocorticoids may be a risk factor for fracture. FRAX may underestimate fracture probability in users of high dose inhaled glucocorticoids.

14 Appropriate glucocorticoid replacement in individuals with adrenal insufficiency has not been shown to increase fracture risk. In such patients, use of glucocorticoids should not be included in FRAX calculations.

FRAX BMD STATEMENTS

15 Measurements other than BMD or T-score at the femoral neck by Dual-energy X-ray Absorptiometry (DXA) are not recommended for use in FRAX.

16 FRAX may underestimate or overestimate major osteoporotic fracture risk when lumbar spine T-score is much lower or higher (>1 Standard Deviation discrepancy) than femoral neck T-score.

17 A procedure based upon the difference (offset) between the Lumbar Spine and Femoral Neck T-scores can enhance fracture prediction in the current version of FRAX.

18 The ISCD 2007 PDC Statements on fracture risk prediction and application of heel Quantitative Ultrasounds (QUS) are supported by a higher level of evidence in men and women than was available in 2007.

19 Currently validated heel QUS devices, using criteria defined in the 2007 ISCD PDC, predict fracture risk similarly.

20 FRAX with BMD predicts fracture risk better than clinical risk factors or BMD alone. Use of FRAX without BMD is appropriate when BMD is not readily available or to identify individuals who may benefit from a BMD measurement.

21 It is not appropriate to use FRAX to monitor treatment response.

22 Evidence that rate of bone loss may be an independent risk factor for fracture is conflicting. Therefore, rate of bone loss is not included as a FRAX risk factor.

FRAX INTERNATIONAL STATEMENTS

23 Separate FRAX models are available for United States (US) Asians, Blacks and Hispanics because hip and major osteoporotic fracture rates are lower in these ethnic groups than in US Whites. Until additional data are available, the US Caucasian FRAX calculator should be used to assess fracture risk in US Native American women.

24 Changing fracture and mortality rates and improved quality of data are expected. Therefore, periodic review of country-specific fracture rates used in the FRAX model is recommended.

25 There is significant variability in hip fracture rates throughout the world. The minimum requirement for construction of a country-specific FRAX model is hip fracture incidence data that are of high quality and representative of that country.

26 The accuracy of FRAX models is improved by the inclusion of country-, age- and sex-specific rates of other major osteoporotic fractures (clinical vertebral, humerus, distal forearm).

27 In the absence of high quality, national hip fracture data, a country-specific FRAX model can be built using hip fracture incidence rates from a surrogate country, but with incorporation of country-specific mortality rates.

28 In the absence of any hip fracture data, development of FRAX models based on broad categories of fracture risk (e.g. low, medium, high), adjusted for country-specific mortality rates is recommended.

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The 2007 ISCD Official Statements are still fully valid and serve as a companion to the ISCD & IOF 2010 Official Positions on FRAX®.
Endorsements from allied societies are forthcoming and will be posted on our websites as received.

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