

National Osteoporosis Foundation (NOF)/International Society for Clinical Densitometry (ISCD) Recommendations to DXA Manufacturers for FRAX® Implementation*

NOF and ISCD Recommend:

- 1. DXA software provides a "default" FRAX® output only when the patient meets NOF criteria for using FRAX® to assist with treatment decision, i.e.,
 - a) an untreated postmenopausal woman or a man age 50 or older
 - **b)** with low bone mass (T-score between -1.0 and -2.5)
 - c) with no prior hip or vertebral fracture (clinical or morphometric)
 - **d)** and an evaluable hip for DXA study
- 2. Other software options exist to have FRAX® always calculated (always on), or never calculated (always off), regardless of its utility according to the NOF *Clinician's Guide*, but the default will be as indicated above.
- 3. When FRAX[®] results are reported, the software includes a disclaimer along the lines of "This 10-year fracture risk estimate was calculated using a "yes" response for the following FRAX[®] risk factors in this individual: maternal/paternal history of hip fracture, tobacco use, etc."

Additional Notes:

- 1. Examples of "untreated" patients include:
 - a) No ET/HT or estrogen agonist/antagonist (SERM) for the past one year
 - **b)** No calcitonin for the past one year
 - c) No PTH for the past one year
 - **d)** No denosumab for the past one year
 - e) No bisphosphonate for the past two years (unless it is an oral taken for <2 months)

Note: calcium and vitamin D do NOT constitute "treatment" in this context.

- 2. The software includes "Important Information" to assist the DXA Technologist in collection of risk factor information as follows:
 - a) The "fracture" option should be checked "yes" if the patient sustained a broken bone after age 50 excluding fractures of the skull, facial bones, hands and feet.
 - **b)** Glucocorticoid usage option should be checked "yes" if the patient has received prednisone 5mg daily or equivalent for 3 or more months.
 - c) Rheumatoid arthritis (RA) should be checked "yes" only if the patient relates having been diagnosed with the disease by a physician, (i.e., not a self-diagnosis of RA).
 - **d)** Whenever there is uncertainty by the patient as to an answer, mark it as "no"

Note: The above could be provided as a hot link or drop down box that is easily retrievable by clicking on the risk factor before entering a "yes" or "no" response.

- 3. In association with the FRAX output, the software will include the following:
 - a) "All treatment decisions require clinical judgment and consideration of individual patient factors, including patient preferences, comorbidities, previous drug use, risk factors not captured in the FRAX model (e.g., frailty, falls, vitamin D deficiency, increased bone turnover, interval significant decline in bone density) and possible under- or over-estimation of fracture risk by FRAX[®]."
 - **b)** "In addition, NOF's *Clinician's Guide* recommends that FDA-approved medical therapies be considered in postmenopausal women and men age 50 years and older with a:
 - a. Hip or vertebral (clinical or morphometric) fracture
 - b. T-score \leq -2.5 at the spine or hip
 - c. Ten-year fracture probability by FRAX[®] \geq 3% for hip fracture or \geq 20% for major osteoporotic fracture."

^{*}These recommendations apply only to the US