

# Clinicians' FORUM

From time to time, the editors of *Menopause Management* field interesting clinical questions and dilemmas. In this forum, our Editorial Advisory Board members, and guest commentator,\* experts in a range of fields related to midlife women's health, tell readers how they handle these situations.

The viewpoints expressed in "Clinicians' Forum" are those of the contributors, and not necessarily those of *Menopause Management* or The North American Menopause Society (NAMS).

**Question:** Do you utilize fracture risk assessment tools, such as FRAX, in your clinical practice? If you do, please explain why, as well as how they are utilized and whether time or access is a problem. If you don't use them, why not?

## Answers:

Using the World Health Organization (WHO) Fracture Risk Assessment Tool (FRAX) has made it essential for clinicians who are "baby boomers" and "generation Xers" to catch up with the technologic advances that the savvy "generation Y" individuals consider "standard of care." I've found that in order to fully utilize FRAX and easily incorporate it into clinical practice, use of a computer in the exam room or consultation room is key. With a computer available, the ability to calculate the FRAX fracture risk is simple and does not add significant time to the office visit.

When I first considered this new tool, I immediately started to fret about where I would be able to find the additional consultation time required to utilize it. To use FRAX one needs to

know the patient's age, height, smoking status, use of alcohol, use of glucocorticoids, personal and parental fracture history and femoral neck bone mineral density (BMD) to record and consider each individual data point to calculate fracture risk. I was concerned that this would take a lot more time than what I had been doing, which was deciding treatment based mainly on *T*-scores.

However, since the calculation is computer-driven, as per the easily accessible program on the FRAX-WHO site ([www.shef.ac.uk/FRAX](http://www.shef.ac.uk/FRAX)), my concerns did not materialize. Other Web sites, such as the National Osteoporosis Foundation ([www.nog.org/professionals/clinicians\\_guide\\_landing\\_pg.htm](http://www.nog.org/professionals/clinicians_guide_landing_pg.htm)), also have easily accessible information to assist clinicians in educating their patients about fracture risk and accessing each patient's individual risk of future fracture. Therefore, when I'm counseling patients I find that calculating their fracture risk with the computer program is quite fast and is a great educational tool.

However, with the computer-driven assessment, it is easier to fail to ask other key questions about bone health that do not come up on the screen, such as secondary causes of osteoporosis. Another concern is that at patient visits—

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either between dual-energy X-ray absorptiometry (DEXA) tests or before DEXA is due, when a formal FRAX is therefore not done—it is still important to address bone health issues. With-



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out the FRAX tickler, asking about changes in bone health in the patient and her family, inquiring about regular muscle-strengthening and weight-bearing exercise, and counseling about the need for adequate calcium (1,200 mg/day) and vitamin D (800–1,000 IU/day) may be put off until the patient's next visit, when

her FRAX assessment is due. Another problem with FRAX is that I may not have all the information I need to make the full assessment of fracture risk at the time the patient is in my office. Many of my at-risk patients who are in my office for their routine examinations have not yet had their DEXA; therefore, calculation of risk cannot be done at that visit. Having the most recent DEXA available at the patient's routine visit, or at a visit every 2 years, is the prerequisite for optimal use of FRAX.

—Gloria Bachmann, MD

FRAX is a work in progress that deserves more study, as it is a promising method of calculating a statistical estimate of fracture risk. But it must be used carefully so that it doesn't result in the underestimation of fracture risk. In my opinion, at this time it probably works best for the elderly patient over age 70 and not for younger women.

To give some background, in terms of population analyses, fracture risk is inversely related to BMD; however, the same relationship does not hold true in osteoporosis treatment studies. Over time it became clear that treatment reduced fracture risk with minimal change in BMD, and led to the concept that an important effect of treatment was to improve bone quality. It was already known that certain risk factors contributed to fracture risk and had minimal effect on BMD. This led to a new definition of osteoporosis in

2001, which stated that decreased bone strength caused by decreased bone quality and low BMD were the major contributors to fracture risk.

The use of risk factors associated with reduced bone quality and the BMD measurement is the cornerstone of the FRAX model published in 2008. This is a model that predicts a risk of fracture over 10 years. It is suggested that treatment be given to a patient *if the 10-year risk of an osteoporotic fracture is 20% or more or hip fracture risk is 3% or higher.*

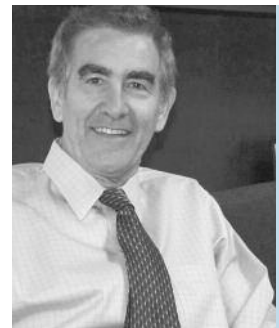
The following risk factors are used in the FRAX model: low body mass index, previous history of fracture, family history of hip fracture, smoking, corticosteroid use, alcohol use >3 units/day, rheumatoid arthritis and secondary osteoporosis. The BMD value used in the model is that for the femoral neck, rather than the spine, which is often affected by arthritic changes with aging, causing an artefactual increase in density.

It is difficult to know the relative contributions of different risk factors in the FRAX model since detailed analyses are not provided. It is likely that the most important risk factors are age and history of a previous fracture, and so it may not be necessary to have a model. However, if it is built into the software of a BMD measurement device, it becomes no trouble to use it.

There are issues with FRAX; for example, in patients between ages 55 and 65 who show low BMD only in the spine (not uncommon in rapid postmenopausal bone loss) the FRAX model will completely underestimate the risk. Here is an example:

- 65-year-old woman with no other risk factors
- *T*-scores: femoral neck –1.8, spine –3.5
- 10-year risk: 13% chance of developing an osteoporotic fracture; 1.3% chance of a hip fracture

According to treatment guidelines, treatment is not indicated even though she has severe spinal osteoporosis. Actually, this patient would



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not meet the recommended treatment figure until she is 73 years old, at which time her spine BMD would be much lower. This represents a problem with using femoral neck as a surrogate for spine BMD. In addition, if one waits until age 73, by that time the patient has developed a marked decrease in bone structure, which makes treatment response more difficult. Even in trials in which active treatment was given, patients continued to fracture, a finding probably accounted for by the loss of structure.

Another issue is that there are other risk factors associated with increased fractures that were not included in the database used to develop the FRAX model, and it is likely that other risk factors will emerge (such as the level of serum 25-hydroxyvitamin D), so the model is probably incomplete.

The FRAX model is driven by pharmacoeconomics. It represents differences between practitioners of preventive medicine who have resources, and practitioners who have economic constraints commonly seen in socialized medical systems. More proof of the value of FRAX needs to be confirmed in future long-term longitudinal studies, and validation should be performed by an independent statistical group.

—J.C. Gallagher, MD

As gynecologists, women's health advocates and menopause clinicians, the challenge of osteoporosis prevention is our concern. We are all well aware of the public health problem that osteoporosis creates for women as they age. As clinicians who are both the stewards of health-care resources and practitioners who are responsible for the health of our individual patients, we have to decide whom to screen and whom to treat for this condition. Ironically, as public awareness of this condition has increased, one of our familiar, effective therapeutic options—estrogen, with what was previously thought to be many benefits—is no longer generally acceptable for prevention of osteoporosis. The FRAX tool can inform us in this role. FRAX is easy to use and requires clinicians and their patients to be systematic in going beyond bone

density in thinking about fracture risk and appropriate interventions.

Concerns from our patients about osteoporosis often fall into two categories. First are the women who, for whatever reason, are worried about their bones. When they have a BMD test showing osteopenia, we must counsel them about pharmacologic treatment. Then, there are our patients who have bone loss and are reluctant to embark on drug therapy, either because of general reluctance to take medications or because of specific side effects they have heard about. And the fact remains that no one in their 80s was taking bisphosphonates, the current primary agents, when they were 50 or 60. The use of medication to prevent osteoporosis in younger menopausal woman is still mostly a theoretical endeavor.

The FRAX tool has been on my computers in my “favorites” since it came out. (Full disclosure requires me to admit that there are computers for our electronic medical record in all our exam rooms.) My other favorite is the Women's Health Initiative Web site ([www.whi.org](http://www.whi.org)) to aid in reviewing the risks of estrogen. FRAX is especially helpful in the discussion with women



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who have osteopenia, as this “diagnosis” generates considerable anxiety. The FRAX numbers reinforce the concept that fracture risk is low for women who are newly menopausal and osteopenic. Postponing pharmacologic treatment can be supported by individualized data. By the same token, the FRAX tool can lend credence to an argument for medication. Many patients find

information that is personalized and specific more compelling than a general recommendation.

It is important to remember that the FRAX tool is a work in progress. In the past months experts have been sorting out the implications of the fact that different databases are used as norms for *T*-score calculation in different DEXA machines. The current determination of the treatment threshold (3% risk for hip fracture and 20% risk for major osteoporotic fracture) is based partly on cost-effectiveness—and this may not be right for all patients. Finally, we will have to wait to see whether prospective data confirm the theoretical assumptions that have been codified with the FRAX tool.

Nevertheless, I find FRAX useful to focus a discussion of bone health on fracture risk and get away from relying entirely on bone density results. It would be wonderful if a printable version with a patient-oriented explanation could be added to the site.

—*Martha K. Richardson, MD*

#### Resources

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Osteoporosis is a major health threat, especially in postmenopausal women. It is estimated that there are more than 1.5 million osteoporosis-related fractures in the US per year.<sup>1</sup> Because of this, I am convinced of the importance and value of utilizing fracture risk assessment techniques such as the FRAX.<sup>2</sup> I use these tools with my private menopausal patients and we also use them extensively in our menopause clinic.<sup>3</sup> There are several reasons I find them to be valuable:

- They are useful as educational tools for patients as well as medical students, residents and extended-care providers. The significance of low bone mass (formerly referred to as osteopenia) is often a source of confusion and uncertainty for patients and those in training. Since there is great temptation to treat all women with low bone mass, fracture risk assessment is one way to bring better

menopause-related education to our students and residents.<sup>3,4</sup>

- There are many times when I see women with low bone mass who actually have a low risk of fracture, but are put on bisphosphonates or other treatments for osteoporosis. Data from the National Osteoporosis Risk Assessment study<sup>5</sup> demonstrate that, while women with osteoporosis have the greatest risk of fracturing, it is actually women with low bone mass who sustain the greatest number of fractures. Clearly, not all of these women have an indication for pharmacologic treatment. The fracture risk assessment tools help delineate which of these women have an indication, and help to put the risk of fracture into better perspective for our patients and trainees. They also give providers an objective assessment for making decisions.
- This type of risk assessment has been utilized for years in the treatment of cardiovascular disease, employing the National Cholesterol Education Program's risk assessment tool.<sup>6</sup> In this tool, a patient's age, gender, cholesterol levels, smoking status, blood pressure and hypertension therapy status (receiving or not receiving treatment) are used to calculate the 10-year risk of a myocardial infarction or coronary death. This tool, like the FRAX, is able to educate patients and trainees while guiding management and monitoring of risk factors.

Prior to the FRAX, I utilized data from Black et al<sup>7</sup> to calculate the 5-year risk of a fracture. Currently, I utilize the FRAX system. In our menopause clinic we have an intake form that includes queries about menopause symptomatology, cardiovascular risk factors, age-appropriate screening information and fracture risk factors. From this, along with our history and physical examination, we can utilize a fracture risk assessment tool, like the FRAX, to determine the 10-year risk of an osteoporosis-related fracture.



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Time and access are not major barriers. Prior to the FRAX tool, we kept paper copies of the scoring key and assessment charts available. Now, with FRAX, the calculator is available online.<sup>2</sup> Calculating the assessment provides an opportunity to educate patients and trainees on the appropriateness of pharmacologic treatment along with the need and timing for follow-up testing. It also gives us an opportunity to discuss the possibility of using hormone therapy alone for managing both the symptoms of menopause as well as providing bone protection during the menopausal transition, when bone loss is at a peak. I look forward to the continued refinement of FRAX and the possibility of having the results automatically reported with bone density screening.

—Peter F. Schnatz, DO, FACOG

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## Breast Cancer Risk Reduction: SERMs, Surgery and Beyond

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