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### Beyond the T-score: New Thinking in Osteoporosis 2

In 2008, there was more to the assessment and management of osteoporosis than T-scores and DEXA scans. In fact, there are more absolute numbers of fractures in osteopenic patients than in osteoporotic patients. How do we approach this dilemma. Welcome to the clinician's roundtable on ReachMD XM 157, the channel for medical professionals. I am your host, Lee Freedman, and joining me today is Dr. Sanford Baim from the Colorado Center for Bone Research at the University of Colorado Health Sciences Center in Denver. He is also coauthor of the Clinician's Guide to the Prevention and Treatment of Osteoporosis, a publication from the National Osteoporosis Foundation.

#### DR. LEE FREEDMAN:

Thank you so much for being with us Dr. Baim.

#### DR. SANFORD BAIM:

It's my pleasure, Lee.

#### DR. LEE FREEDMAN:

With this dilemma that we can't just rely on bone density, I know this new model for absolute risk called FRAX has been introduced. Could you give us a thumbnail of what this model takes into account and how we can use it?

#### DR. SANFORD BAIM:

The FRAX model was developed from a World Health Organization meta-analysis of over 60,000 patients that were studied in Europe, North America, Asia, and Australia, and then validated in an independent cohort of more than 230,000 patients. What this model does is to predict in a more sensitive and positive predictive way than using bone densitometry alone the 10-year probability of hip fracture and all major osteoporosis fractures, and what this is derived from are (01:30) not only bone mineral density, but also clinical risk factors with or without femoral neck BMDs. So actually this is a specific tool that could be used anywhere in the world, not just in the US. So if bone mineral density was not available in a certain country, you could still have a risk assessment, meaning an absolute risk assessment. Again, this is absolute risk or quantitation of risk, which would be more appropriate over 10 years instead of a model that we have used since 1994 which is the WHO diagnostic DEXA criteria looking at the T scores of minus 2.5 or lower being osteoporosis, above minus

2.5 and below minus 1 being osteopenia, and above minus 1 being normal bone mass; this would be relative risk using bone densitometry WHO diagnostic criteria, which does not take into consideration clinical risk factors or the independence of specific risk factors to BMD such as previous fractures and age and many of the other clinical risk factors that were identified by Dr. <\_\_\_\_> as part of the WHO model. For example, if we used the old criteria and we took a, say 45-year-old Caucasian female with a T-score of minus 2.4 with (03:00) no other clinical risk factors, according to the WHO diagnostic criteria, that woman should be treated because she has osteoporosis.

**DR. LEE FREEDMAN:**

She sounds high risk. It sounds like someone I would start on a bisphosphonate or some other therapy, but in actuality her real risk is not that high?

**DR. SANFORD BAIM:**

Well, her 10-year fracture is not high and compared to a 70-year-old Caucasian female with the same T-score, there is quite a bit difference in the absolute risk because bone density does not evaluate the microarchitecture of bone and many of the other bone strength variables that come into to play that cause the independence of age as it pertains to fracture risk. So, in fact, that 45-year-old Caucasian female without clinical risk factors by history, physical exam, or anything else that you do as part of your diagnostic evaluation, actually that's her peak bone mass. She might be small boned; it's genetics, etc., etc., imparting 80% of her bone density. So she never lost it, she never had it as part of her genetics and she is not at high risk as compared to the same individual at 70 years of age, which we must then take into consideration bone strength and other variables that are not measurable by bone densitometry. So FRAX actually takes that into (04:30) consideration when it predicts quantitation of risk over 10 years.

**DR. LEE FREEDMAN:**

Very interesting. So there might be that older women with a better T score, but you would still go ahead and treat that person.

**DR. SANFORD BAIM:**

That's exactly what has transpired and the treatment modalities in the way clinicians have treated individuals previously where they actually treated the young postmenopausal women who actually peaked out at that bone mass and who do not require treatment and may have no family history of osteoporosis versus the individual who may be 70-75 years of age with the bone density of minus 1.4 T-score who should be treated because she has very significant 10-year risk of fracture.

**DR. LEE FREEDMAN:**

Interesting. Does FRAX gives us a simple threshold which we should start treatment or how would do we make that decision?

**DR. SANFORD BAIM:**

Well, this goes back to the National Osteoporosis Foundation's Clinician's Guide. So FRAX doesn't tell anyone when to intervene. It provides us with a 10-year absolute risk based on each country's data that was entered into the model. So, for example, one country

would have a fracture incidence of X and other fracture incidents of Y and their mortality rates would be quite different. This does not specifically state who should be treated though, so the FRAX model just provides us with quantitation of risk. It is left (06:00) to the individual country to then consider what would be cost effective to intervene depending upon a specific fracture threshold, meaning the 10-year fracture risk, and that's where the clinician's guide and actually the technical papers that were published this year in Osteoporosis International come into play where the technical papers that were published actually reviewed the US specific mortality rates, incidence of fracture rates, and then looked at the quality of life issues and cost of fracture and then came up with a specific threshold that is actually cost effective to intervene. For example, for hip fractures, the cost-effecting threshold in the United States looking at the US specific data, as I mentioned, is 3%. So that if an individual has a 10-year fracture risk of 3% for hip fractures, it would be cost effective to treat that patient looking at the data inserts in the model at the time that it was actually derived. For all major fractures, it's 20% 10-year all major fracture risk. So, if you look at 10-year all major fracture risk on the FRAX model, it would be 20%. Those are absolutes as it pertains to a number, but in clinical medicine (07:30) would you not treat a person with a 10-year hip fracture risk of 2.97%, you know, I mean everything is relative and we have to think about the FRAX model as it pertains to the dosing or the variables that were actually inserted in the model so that if a patient has been started on high-dose glucocorticoids that is quite different than low dose or minimal dose glucocorticoids for a long or short period of time, and this also depends upon whether that patient meets ACR rheumatology guidelines for intervention. The FRAX model does not include the variability in dosing whether it's alcohol dosing, glucocorticoid dose, the number of previous fractures, the severity of those fractures are not included in the FRAX model. This is all part of the art of medicine and so we have to consider that just because the FRAX model spits out a number for us, we also have to use our clinical judgment in the ascertainment of the degree of data insertions into the model. Example: A patient has 3 vertebral fractures, one hip fracture; this changes everything in regard to what I would consider as an intervention even if the patient had a very low 10-year fracture risk because it didn't include anything else and the patient may not have had any other clinical risk factors (09:00) and did not have osteoporosis by BMD determination. So, in other words, we have to really use our clinical judgment in the ascertainment of true fracture risk and intervention in that specific patient.

### DR. LEE FREEDMAN:

If you have just tuned in, you are listening to **ReachMD XM 157, the channel for medical professionals. This is the clinician's roundtable and I am your host, Dr. Lee Freedman. I am taking about the approach to osteoporosis with Dr. Sanford Baim from the Colorado Center for Bone Research in Denver.**

So we can assess our patients 10-year absolute risk for a fracture by using the FRAX model, but you get that absolute risk and then that should be interpreted within the context of what is considered cost effective for your particular country in the United States that is by the National Osteoporosis Foundation's clinical guide, but has been deemed to be cost effective is if the 10-year risk for a hip fracture is 3% or greater or if the risk for any osteoporotic fracture is 20% or greater, but then you would still have to be a doctor, you still have to take into account the person's individual profile, the strength of the risk factors that went into that FRAX model, and you still have to make a decision for your individual patient. Now, Dr. Baim assuming that we go ahead and decide to treat these patients, how quickly do our treatments work and how should we monitor our patients once they are on treatment?

### DR. SANFORD BAIM:

I think that again this is an important issue in regard to the total patient and when we consider a total patient as it pertains to treatment, we look at all risk factors (10:30) for that specific patient. So, again prior to treatment with a pharmacologic FDA-approved medication, we have to assess that patient for secondary etiologies, vitamin D insufficiency, as well as other disease states including hyperparathyroidism are known to effect bone density and certainly can cause low bone mass independent of age related and postmenopausal osteoporosis. So, again according to the National Osteoporosis Foundation Clinician's Guide which reviews all of this, it is really important to exclude secondary etiologies for the development of osteoporosis, meaning postmenopausal and age-related osteoporosis because if we use the characteristic pharmacologic interventions, they will not work, they will not prevent progression of osteoporosis by bone densitometry or fractures. Thus, it is really important that we assess our patients prior to institution of treatment to exclude these other entities. Another example would be many of the patients that are referred to us at the Colorado Center for Bone Research. They have calcium malabsorption, vitamin D insufficiency, and they are found over a period of time not to respond to these

pharmacologic agents and so you have to have adequacy of vitamin D and calcium incorporation for these medications to actually be fully effective.

**DR. LEE FREEDMAN:**

All the (12:00) bisphosphonates or calcitonin, the world is not going to do the trick if there are other elements contributing to the bone loss such as you have stated.

**DR. SANFORD BAIM:**

Correct, and then all modifiable risk factors should be addressed. So if that patient or the clinician is smoking; is drinking three or more units of alcoholic drinks a day, you would want to correct that. If the patient is on high-dose glucocorticoids, you would work on the possibility of reducing the dose of glucocorticoids or trying alternative medications that do not effect bone re-modelling rates that would be certainly an added factor in a positive way to prevent bone loss.

**DR. LEE FREEDMAN:**

I want to thank Dr. Sanford Baim from the Colorado Center for Bone Research for discussing with us the newer thinking and newer approaches to the assessment of risk in the process of osteoporosis.

This has been the clinician's roundtable on ReachMD XM 157, the channel for medical professionals. Thank you for listening.