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Defining Bone Health and Fracture Risk in West Virginia: The World Health Organization FRAX® Assessment Tool

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Abstract

This article highlights the expanding burden of osteoporosis in West Virginia. WV ranks second nationally in the percentage of its population that is ≥ 65 years of age.[1,2] Our older population increases the risk of osteoporosis and fracture; the most recent data indicates that 77% of our women age 50 and older have osteoporosis or low bone mass.[3] The lifetime risk of osteoporotic related fracture is alarming and occurs in 50% of females and 25% of males age 50 and older.[3,4] The risk of osteoporosis related hip fracture in women is equal to the combined risk of breast, uterine or ovarian cancer with the annual risk of osteoporotic fracture greater than the combined risk of breast cancer, stroke and heart attack.[3,5,6] Detecting individuals at risk for fracture has been aided by an internationally validated fracture prediction tool from the World Health Organization -- FRAX®. The FRAX® tool can be incorporated into protocols to help minimize barriers to effective osteoporosis screening and treatment in WV.

Introduction

Health promotion and disease prevention for the expanding elderly population is a major challenge facing our state and the nation.[1,2,7] In 2004, the United States Surgeon General published *Bone Health and Osteoporosis: A Report of the Surgeon General* and the WV Department of Health and Human Resources published *The Burden of Osteoporosis in West Virginia*.[3,8] Both reports highlight the burden of bone disease as a major public health and economic problem with total national costs estimated to be $140 billion by 2040.[3,9,10] The estimated economic toll of osteoporosis related fragility fractures in West Virginia was reported in this *Journal* with current screening and treatment protocols providing minimal cost savings for our state.[11] However, improved screening and treatment protocols aimed at identifying individuals at greatest risk of fracture have been developed and validated thereby reducing the fracture incidence and the fiscal burden associated with fracture care.[12-19] These bone health assessment tools can be easily incorporated into existing practices and will help minimize the significant barriers to evidence-based health promotion programs and health care services in WV.[20,21] Before discussing the use of fracture prediction algorithms, an understanding of the evolving definition of osteoporosis is needed.

Osteoporosis is a skeletal disorder characterized by low bone strength and increased risk of fracture.[22] This definition has evolved from the 1994 World Health Organization (WHO) definition of osteoporosis which was based solely on bone mineral density (BMD) testing and T-score generation.[13] A T-score is the number of standard deviations a patient's bone density varies from a healthy, thirty-year-old reference value. Osteopenia is defined as a T-score that is between 1 and 2.5 standard deviations below this reference value (T-score -1.0 to -2.5 = osteopenia) while osteoporosis is a T-score at or below -2.5 (**Figure 1**). The critical problem with the original WHO definition is that the majority of fragility fractures occur in the osteopenic range and not in the -2.5 T-score cut off value for osteoporosis.[17,23,24] Therefore, generation of a T-score following BMD testing will not allow one to effectively predict fracture risk. For example, identical T-scores of -2.5 in two women (a 50-year-old and 80-year-old), would not produce the same fracture risk. The 80-year-old has a fivefold higher probability of hip fracture with age being a major independent determinant of fracture risk (**Figure 2**).[25,26] The improved screening tools used to predict an individual's absolute risk of fracture take into account both modifiable and non-modifiable variables.

Based solely on the non-modifiable risk factors of age, race and gender, the state of West Virginia is at high risk for low bone mass and osteoporosis. Older, Caucasian women are at the highest risk of developing osteoporosis and fracture; West Virginia is predominantly Caucasian (94.4%) and female (51.1%).[1-3] WV is second nationally in the percent of population ≥ 65 years of age (15.7%) with 77% of our women age 50 and older having osteoporosis or low bone mass.[2,3] Modifiable risk factors like smoking, physical activity and alcohol consumption also contribute to our state's prevalence of low bone mass and osteoporosis. The state's smoking prevalence (28.2%) and level of physical inactivity (31.7%) are both higher than the national averages of 19.7% and 24.0%, respectively.[21] Heavy alcohol use, defined as at least five alcoholic drinks for men or at least four drinks

for women on a single occasion in the past month, occurs in 11.1% of West Virginia residents.[21] At present, the National Osteoporosis Foundation estimates that there are 369,900 women and men in West Virginia with either osteoporosis or low bone mass. This number is predicted to climb to nearly 466,300 by 2020.[3,4] Increased prevalence of low bone mass and osteoporosis make fracture more likely.

Estimates of the number of osteoporotic fractures in West Virginia, including the associated morbidity and mortality, are disturbing. Over 179,000 osteoporotic related fractures are predicted in WV women during the 20 year period from 1995-2015.[3] These estimates include 100,000 vertebral fractures, 41,000 hip fractures and 38,500 wrist fractures. Twenty-four percent of women aged 50 and above die within one year of a hip fracture.[3,6]

Twenty percent of previously ambulatory persons will require permanent long-term care after a hip fracture.[6] It is important to note that a woman's combined risk of breast, uterine and ovarian cancer is equal to her risk of sustaining a hip fracture; the combined incidence of breast cancer, stroke and heart attack are not equal to the annual risk of osteoporotic fracture (**Table 1**).[3,6,27] Healthcare costs associated with fragility fractures also surpass the costs of treating breast cancer, stroke and heart disease.[10,27]

Barriers to Improved Bone Health in West Virginia

Early recognition of osteoporosis can be difficult as bone loss is considered a "silent disease," often asymptomatic until structural failure and fracture occur. In patients without fracture, central dual-energy X-ray absorptiometry

Table 1*: Osteoporotic Fractures Compared to Other Diseases.**

	Annual Incidence
Osteoporotic Fractures	2,000,000
Heart Attack	513,000
Stroke	228,000
Breast Cancer	184,300

(DXA) is the preferred modality for the measurement of bone mineral density.[28] Access to existing bone health management resources is critically linked to the success of any treatment program.[29] However, DXA is not available in all 55 counties in WV. In 2004, according to the West Virginia Osteoporosis Prevention Program, only 24 counties had access to DXA scans.[3] Persons who must travel between 10 and 24 miles are 20% less likely to receive DXA screening than those who travel less

Figure 1. Most Fractures Do Not Occur in Patients with Osteoporosis.
Fracture rate (y-axis; wider bars) increases as the T-score moves further below the young adult mean (x-axis). However, an increased number of fractures (z-axis; narrow bars) occur in patients with osteopenia (the T-score range of 1 to 2.5 standard deviations below the mean; rectangle area). Source: International Osteoporosis Foundation FRAX® teaching slide kit at www.iofbonehealth.org/health-professionals/educational-tools-and-slide-kits.html

Osteoporotic fractures and bone mineral density (BMD)

Adapted from Siris et al., Arch Intern Med. 2004
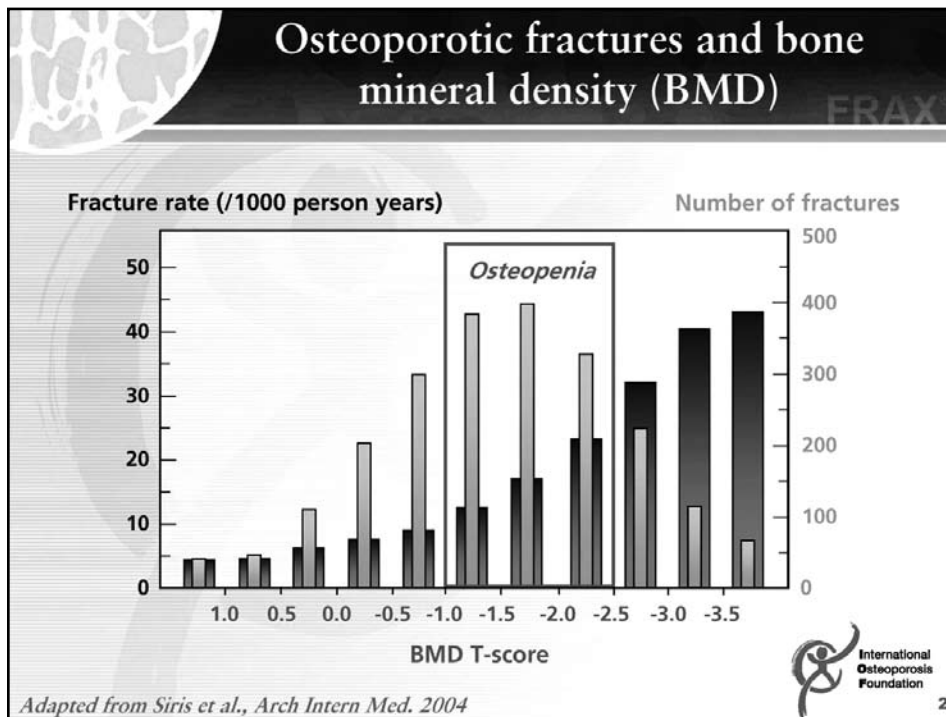
than five miles.[30] The rural nature of our state adds to the difficulty of managing the osteoporosis epidemic.

West Virginia is the second most rural state in the country with 64% of the population living in communities of less than 2,500 people.[31] Rural residents rely more on the availability of DXA from free-standing, non-facility providers.[30] Legislative and regulatory changes have affected the level of reimbursement for DXA scanning with significant reductions in the RVUs assigned to central DXA (CPT 77080). In 2006, Medicare DXA reimbursement was approximately $139. In 2007, DXA payment in free-standing facilities was cut by about 40%. Additional cuts in 2010 have decreased reimbursement to $56. This legislative response to a critical component for effective osteoporosis evaluation and management is disconcerting. Current health care reform addresses

DXA reimbursement in the Senate bill but not in House legislation. The ultimate effect is pending with the anticipated closing of free-standing DXA facilities, comprising two-thirds of all facilities in the state. If access to the preferred testing modality is limited, is there still a way to predict fracture risk in patients?

Fracture Risk Assessment

The evolving definition of osteoporosis has expanded to include fracture risk instead of just BMD. Risk assessment and intervention protocols only offering treatment to people with T-scores in the osteoporosis range will not address the majority of fractures which occur in patients with osteopenia (T-score -1 to -2.5) (**Figure 1**). One of the most recent advances in identifying individuals at risk of sustaining fragility fracture is the internationally validated WHO

fracture risk algorithm (FRAX® tool, available online at www.shef.ac.uk/FRAX).[27] FRAX® provides a tool to predict the 10-year absolute risk, rather than relative risk, of sustaining a future hip or major osteoporotic fracture (wrist, proximal humerus, hip or clinical vertebral fracture). The FRAX® tool determines the absolute risk through the integration of independent risk factors present in the patient. Risk factors incorporated into the FRAX® algorithm consist of country of origin, age, gender, BMI, previous fracture, parental history of hip fracture, current smoking, use of glucocorticoids, rheumatoid arthritis, secondary osteoporosis, alcohol consumption and, *when available*, BMD at the femoral neck (g/cm²) obtained by DXA (**Figure 3**). The algorithm corrects for the different contributions of each independent risk factor to yield the ten year probability of sustaining either a hip fracture or other major osteoporotic fracture.[27] When the absolute risk of sustaining a hip fracture within the next ten years is 3% or above, or the risk of major orthopaedic fracture is 20% or above, treatment is considered cost effective and has been shown to decrease the rate of subsequent fractures.[12-19] Current National Osteoporosis Foundation recommendations for treatment include incorporation of FRAX® for T-scores between -1 and -2.5 in addition to treatment recommendations for (1) patients with a history of hip or vertebral fracture and (2) patients with a femoral neck or spine T-score -2.5 or lower.

One of the major benefits of FRAX® is that BMD measurement by DXA scan is not required to calculate fracture risk. This functionality provides a significant advantage to the 31 counties in West Virginia that do not have access to DXA. When the tool is used without BMD testing data, the algorithm will take into account secondary osteoporosis risk factors (**Table 2**). Of note, the predictive value of FRAX® without BMD data is greater than or equal to

Figure 2. Age and Bone Mineral Density are Major Independent Determinants of Fracture Risk. *At the same BMD (T-score -2.5), an 80-year-old female has over a fivefold greater risk of fracture than a 50-year-old. Source: International Osteoporosis Foundation FRAX® teaching slide kit at www.iofbonehealth.org/health-professionals/educational-tools-and-slide-kits.html*
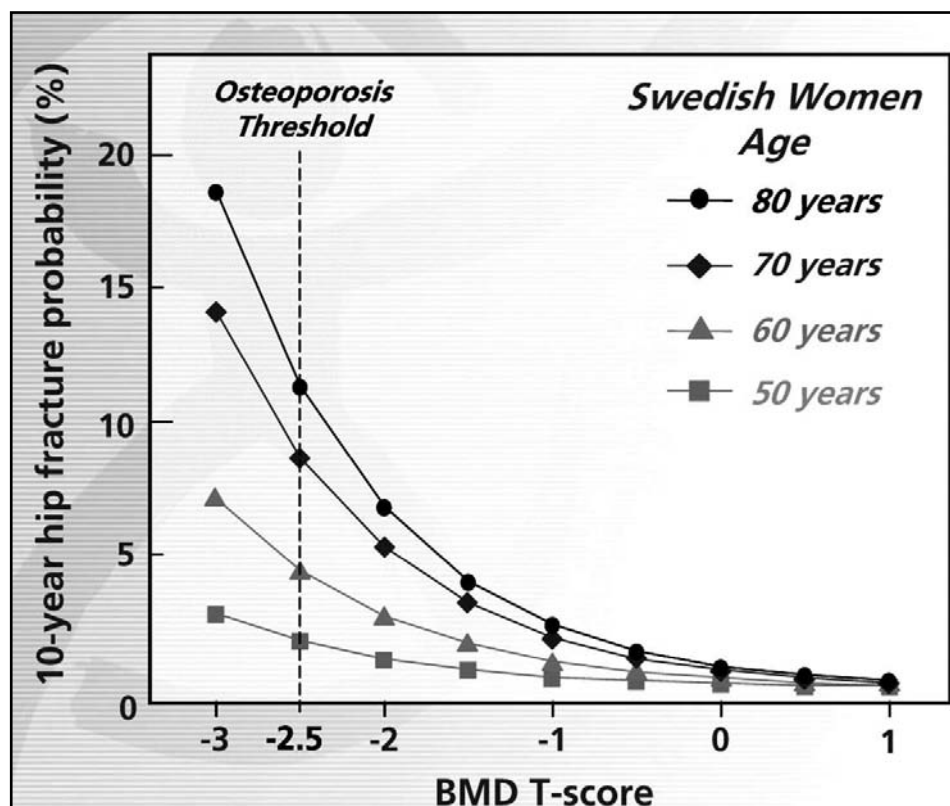
Table 2: Secondary Osteoporosis and FRAX®.

Secondary Osteoporosis Variables Used in FRAX®		
Diseases	Conditions	Drugs
Hypogonadism (premature)	Anorexia	Glucocorticoids
Diabetes	Alcoholism	Excess thyroxine
Depression	Hypercalciuria	Antiepileptics
COPD	Vitamin D Deficiency	Depo-provera
GI diseases (malabsorption)		GnRH agonists
Rheumatoid arthritis		Aromatase inhibitors
Cholestatic liver disease		SSRIs
Hyperthyroidism		Proton pump inhibitors
Hyperparathyroidism		TZDs

the predictive value of BMD alone when predicting the ten year hip fracture risk.[32] FRAX® assumes that most diseases and medications (other than rheumatoid arthritis) increase fracture risk by causing bone loss. When FRAX® is calculated without BMD, a "yes" answer to question #10

(secondary osteoporosis) increases the fracture risk (**Figure 3**). If BMD is included, FRAX® ignores the "yes" answer to secondary osteoporosis and uses the actual BMD instead.

FRAX® does have some limitations: (1) the model is relevant only for untreated patients and should not be used to follow treatment protocols. (2) The model only accepts ages between 40 and 90 years. If a patient is younger or older, the program will compute probabilities at 40 and 90 years, respectively. (3) The model does not take into account the number of prior fractures. Prior fracture is defined as a previous fragility fracture after 40 years of age excluding fractures of the face, fingers and toes. (4) The model does not account for dose response effects of smoking or glucocorticoid use. Smoking applies to current use only and glucocorticoid use with oral steroids of ≥ 5mg/day prednisone equivalent or ≥ 3 months. (5) The model uses femoral neck BMD only in g/cm² and not BMD of the spine. (6) The model generates a T-score based on NHANES III young white female normative database from 1998. The FRAX® generated T-score can vary from the result produced following DXA due to use of different normative databases. (7) The model does not account for the effect of vitamin D deficiency (low serum levels of 25-hydroxyvitamin D) unless calculations occur without BMD testing where secondary osteoporosis can be marked as "yes" (**Table 2**). (8) The model does not account for patient factors that can increase fracture risk including visual acuity, fall risk or level of physical activity. (9) The model originally overestimated fracture risk. Readjustments of the hip and major fracture rates were completed in July 2009 based on new epidemiologic data on fractures and mortality rates in the USA (version 3).

If one is concerned by these limitations, there are alternative methods of fracture risk determination.[33] However, FRAX®

Figure 3. FRAX® WHO Fracture Risk Assessment Tool: www.shef.ac.uk/FRAX. *The US Caucasian calculation tool is shown. In this example a 5'6", 124 lb 65-year-old patient has current alcohol and smoking use and had a mother with a history of fractured hip as well. The height and weight is entered and the FRAX® tool converts the measurements to kg and cm and automatically populates questions #3 and #4 as well as calculates the BMI of 20.0. Questions are answered following patient history with the BMD measurement entered for #12 which has a drop down menu to select the scanner used for testing (note: determination can be completed without BMD measurements). In this patient, a Hologic scanner was used with femoral neck BMD 0.59 g/cm². FRAX® generates the T-score based on its normative data set (T-score -2.2, which would frequently not generate pharmacologic management). For this example patient, the ten year absolute risk of hip fracture is 5.1% and major osteoporotic fracture is 23%. The fracture risk determination would support the decision for pharmacological management in this patient which would not have been supported using BMD and T-score alone.*

is internationally validated and can serve to enhance clinical judgment of the physician, especially when access to appropriate bone health resources is limited. FRAX® provides a clear-cut identification of patients at risk for fracture, facilitating discussion and treatment decisions including medication avoidance in patients with low risk for fracture.

Conclusions

Osteoporosis is a major public health concern in West Virginia. Our state has taken an active role in the management of this epidemic by establishing the Osteoporosis and Arthritis Plan with priorities established by the passage of House Bill 4198 (Osteoporosis) and House Bill 4685 (Arthritis) in 1996. Part of the goal of this paper is to present evidence-based tools not included in the programs promoted by this Plan.

Our state's residents are particularly susceptible to low bone mass and osteoporosis due to demographics, poor bone health indicators and access barriers to evidence-based health promotion and care services. The new FRAX® tool is available for free online at http://www.shef.ac.uk/FRAX/ and is used to generate the patient's ten year absolute risk of hip and

major osteoporotic fracture. When the absolute risk of sustaining a hip fracture within the next ten years is 3% or above, or the risk of major orthopaedic fracture is 20% or above, treatment is considered cost effective and has been shown to decrease the rate of subsequent fractures. Incorporation of this internationally validated screening tool into clinical practice would be expected to help minimize the expanding burden of osteoporosis in West Virginia.

Available Visual References

Osteoporotic Fracture Probability is Country Specific. (Available for viewing at www.iofbonehealth.org/health-professionals/educational-tools-and-slide-kits.html.) *There is over a tenfold variation of osteoporotic fracture probability depending on country of origin with US Caucasians having the greatest fracture risk. Within the US, Caucasians have the greatest risk of fracture followed by US Hispanics, US Asians and US African Americans. Females have a greater risk of osteoporotic fracture in all countries.*

Accumulation of Risk Factors Increases the Fracture Probability. **(Available for viewing at www.iofbonehealth.org/health-professionals/educational-tools-and-slide-kits.html.)** *For the same BMD, BMI and age, fracture probability varies depending on the accumulation of clinical independent risk factors for fracture. This increase in fracture risk is greater than predicted from BMD alone. FRAX® takes into account the complex relationships among risk factors to provide a ten year absolute fracture risk.*

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Please contact the authors for a complete list of references.