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Title

Evaluation of decision rules to identify postmenopausal women for intervention related to osteoporosis.

Permalink

<https://escholarship.org/uc/item/1jd1q63m>

Journal

Disease management : DM, 6(3)

ISSN

1093-507X

Authors

Brenneman, Susan K
Lacroix, Andrea Z
Buist, Diana SM
et al.

Publication Date

2003

DOI

10.1089/109350703322425509

Peer reviewed

Evaluation of Decision Rules to Identify Postmenopausal Women for Intervention Related to Osteoporosis

SUSAN K. BRENNEMAN, P.T., Ph.D.,¹ ANDREA Z. LACROIX, Ph.D.,^{2,3}
DIANA S.M. BUIST, Ph.D.,² YA-TING CHEN, Ph.D.,¹ and THOMAS A. ABBOTT, III, Ph.D.¹

ABSTRACT

Decision rules for intervention that utilize screening tools for bone mineral density (BMD) testing and incorporating the BMD findings and other risk factors to identify high-risk women to prevent fracture have not been evaluated. We examine the sensitivity and specificity of decision rules for intervention based on two pre-BMD screening tools: Simple Calculated Osteoporosis Risk Estimation (SCORE) and a Study of Osteoporotic Fractures (SOF)-based tool. Women 60 years of age and older without previous osteoporosis diagnosis were randomly selected from a managed care population and invited to receive a BMD test. Four hundred sixteen women had complete information and were included in the study. Women were classified as high risk requiring intervention using three different criteria: World Health Organization (*t*-score -2.5 or less), National Osteoporosis Foundation (*t*-score -2.0 or less, or -1.5 or less with one or more risk factors), and the SOF-based criteria (prior fracture; or age 60–64 with *t*-score less than -2.5 or age 65 or older with *z*-score less than -0.43 and five or more risk factors). SCORE identified 82% of the women as appropriate for BMD testing, whereas the SOF-based tool identified 26%. Sensitivity and specificity were 89.8%–96.5% and 23.8%–34.8%, respectively, for the decision rule using SCORE as the screening tool and 30.5%–84.9% and 76.0%–95.8%, respectively, for the decision rule based on SOF screening criteria. SCORE correctly identified more women who were at high risk for intervention, whereas the SOF-based tool correctly identified more women who do not meet intervention criteria. The appropriate selection of a screening tool depends upon the objective for intervention and trade-off between not identifying women for BMD testing who are at high risk and identifying more women for BMD testing who are at low risk.

INTRODUCTION

OSTEOPOROSIS-RELATED FRACTURES are associated with significant disability, mortality, and economic burden.^{1,2} These fractures are preventable if individuals who are at risk are

identified and provided with appropriate interventions. Low bone mineral density (BMD) is the strongest predictor for fractures related to osteoporosis in asymptomatic postmenopausal women.^{3–5} Frequently clinicians rely on BMD levels to determine intervention strate-

¹Outcomes Research & Management, Merck & Co., Inc., West Point, Pennsylvania.

²Center for Health Studies, Group Health Cooperative, Seattle, Washington.

³Division of Public Health Services, Fred Hutchinson Cancer Research Center, Seattle, Washington.

This study was presented in part as a poster at the annual meeting of the American Society for Bone and Mineral Research, held in San Antonio, Texas, September 21, 2002.

gies. While BMD testing is non-invasive and generally accessible, universal BMD screening in all postmenopausal women is not currently standard of care, particularly in early postmenopausal women. In the absence of BMD, a number of demographic and clinical factors, such as age, prior fracture, weight, and glucocorticoid use, have been found to be important in the prediction of low bone mass and/or fracture risk.^{1,6–8} Strategies that utilize information on both BMD and risk factors, whether in combination or in sequence, for clinical decision-making may provide clinicians and managed care organizations with more effective and flexible means to identify high-risk women for intervention to reduce fractures.

Attempts have been made to develop tools based on risk factors aimed at selecting patients with a high probability of low BMD, who should then be referred for BMD testing.^{9–16} They range from the very simple to more complex selection schemes that require the assessment of many risk factors. In a comparison of four risk indices—Osteoporosis Self-assessment Tool (OST),¹² Simple Calculated Osteoporosis Risk Estimate (SCORE),¹⁰ Osteoporosis Risk Assessment Instrument (ORAI),⁹ and Study of Osteoporotic Fractures (SOF) Simple, Useful Risk Factor (SOF-SURF)¹⁷—for identifying low bone density in postmenopausal women, Geusens et al¹⁸ found that all four indices predicted low bone mass equally well. The use of these and similar risk factor-based tools for selection of women for BMD testing has the potential to both improve patient care by identifying women at high risk for osteoporosis and to manage healthcare resources by only testing women who are considered high risk for osteoporosis.

Ultimately, the purpose of screening and subsequent BMD testing is to determine which women are at high risk for future fractures and therefore require treatment. Treatment decision rules that utilize these screening tools for BMD testing and then incorporate the BMD findings into high-risk definitions to identify women to prevent fracture have not been evaluated. Treatment decision rules that are of particular interest in the current study incorporate the results of two screening tools—SCORE and an SOF-based screening tool—for the selection of women for BMD testing and subsequent treatment decisions.

SCORE, developed on a cohort of 1,279 women age 50 and over and validated on a population of 259 women, consists of six questions relating to a woman's demographic characteristics and medical history.¹⁰ The SCORE-based decision rule includes prescreening of women for BMD testing using SCORE and intervention decision based on the BMD results among those tested and other risk factors. The SOF-based screening tool was adapted from a report on prediction of hip fracture in the SOF cohort of women aged 65 and older.¹⁹ As part of early osteoporosis guideline development work at the Group Health Cooperative (GHC) of Puget Sound, a 17-item risk factor screening instrument was derived from previous findings for clinical use. The SOF-based decision rule includes intervention in all women with a prior fracture and, among those without a prior fracture, screening of women for BMD testing using the SOF-based screening tool. A decision to intervene is based on the BMD results and other risk factors.

In previous work we examined the prevalence of women meeting three high-risk definitions for intervention.²⁰ These definitions included the World Health Organization (WHO) diagnostic criteria for osteoporosis, the National Osteoporosis Foundation (NOF) treatment guidelines, and a high-risk definition based on findings from SOF. In the current study we examine the sensitivity and specificity of decision rules for intervention according to three high-risk criteria that use SCORE or a SOF-based screening tool to select the women for BMD testing.

METHODS

Study sample

The Osteoporosis Population-based Risk Assessment (OPRA) study was a randomized controlled trial that compared three pre-BMD screening programs and evaluated the relationship among risk factors for osteoporosis, measures of BMD, and subsequent treatment outcomes. A random sample of women aged 60–79 years who had not used hormone replacement therapy (HRT) for at least 12 months and who were enrollees of the GHC of Puget Sound and resided in the greater Seattle region

was selected. For the complete trial, women were randomized into one of three pre-BMD screening groups: (1) universal screening—all women were invited to have BMD testing regardless of their osteoporosis risk ($n = 1,986$); (2) SCORE screening—women at risk for fracture were identified for a BMD test using SCORE ($n = 1,940$); and (3) SOF-based screening—women in the top 15% of hip fracture risk were identified for a BMD test using a SOF-based instrument ($n = 5,342$).

Data for this report came from the first arm of the trial only where BMD testing was aimed at all women. Eligible subjects were contacted by a mailing that invited all women to receive a DEXA bone scan free of charge. The women

who responded and came to the clinic for a DEXA bone scan also completed a questionnaire that included both pre-BMD screening instruments evaluated in the study.

Out of the 1,986 women who were sent an informational brochure about osteoporosis and were invited to receive a bone density scan, 847 (42%) responded, of whom 419 (49.5%) refused participation and 428 (50.5%) came to the clinic to have a DEXA bone scan. Complete information was available for 416 women.

Decision rules and pre-BMD screening instruments

Table 1 summarizes the criteria that clinicians are recommended to use in deciding

TABLE 1. SELECTION CRITERIA FROM THE PRE-BMD SCREENING TOOLS FOR POSTMENOPAUSAL WOMEN CONSIDERING TREATMENT AND SUBSEQUENT DECISION RULES FOR INTERVENTION

<i>Guideline/rule</i>	<i>Selection cutpoint</i>	<i>Scoring system</i>
SCORE	Score ≥ 7	Points for Race: 5 if not black Rheumatoid arthritis: 4 if applicable History of minimal trauma fracture after age 45: 4 for each fracture of the wrist, hip, or rib, to a maximum of 12 Age: 3 times first digit of age in years Estrogen therapy: 1 if never used Weight: -1 (weight in lb divided by 10)
SCORE-based decision rule:		
<ul style="list-style-type: none"> • Pre-screening with SCORE for BMD testing • Measure BMD if SCORE ≥ 7 • Intervene among those tested for BMD according to high-risk definition (see Table 2) 		
SOF-based screening tool	Score ≥ 5	1 point each for First-degree relative with hip fracture Current weight less than at age 25 Diagnosed with dementia Using corticosteroids Using seizure medication Using benzodiazepines Had a fracture age 50+ Not taking HRT On feet <4 h/day Heart rate >80 beats/min Was $\geq 5'7"$ at age 25 80+ years old Subtract 1 point for African American Walk for exercise Can rise from chair without arms
SOF-based decision rule:		
<ul style="list-style-type: none"> • Intervene if fracture after age 50 • If without fracture, measure BMD if SOF-based tool is ≥ 5 • Intervene among those tested for BMD according to high-risk definition (see Table 2) 		

which women should undergo bone densitometry under the two pre-BMD screening tools and the subsequent decision rules for intervention. In the development cohort for SCORE it was determined that a threshold of 6 would result in 90% sensitivity and 50% specificity. Because the current study included only women age 60 years and older, a cutpoint of 7 was used after recalibration using women from the original development cohort age 60 years and older such that the sensitivity was approximately 90%. For the SOF-based screening instrument a threshold of five or more risk factors was used to identify women for BMD testing. Because the occurrence of clinical fracture in later life is the most presumptive sign of osteoporosis, women who report a fracture after age 50 are selected for direct referral for treatment without BMD testing in the SOF-based decision rules. These two intervention decision rules are illustrated graphically in Figure 1a and b.

BMD testing

BMD was measured using a Hologic QDR 2000 DEXA machine. Scans of the proximal femur, total hip, and spine (L1–L4) were taken on each subject. The *t*-scores and *z*-scores were

calculated using the BMD distributions from National Health and Nutrition Examination Survey (NHANES) III.²¹ Low BMD at either the hip or lumbar spine is clinically relevant for deciding about prophylactic treatment to prevent osteoporosis and fragility fractures.²² Therefore, BMD outcomes in this study were calculated as the minimum *t*-score or *z*-score at any of these two sites.

Definition of high risk for intervention

Three definitions of “high risk” for intervention purposes were used as intervention thresholds against which to evaluate the sensitivity and specificity of the two screening tools since the ultimate outcome of interest is identification of women who would benefit from treatment or intervention. As shown in Table 2, the WHO provides operational definition for a diagnosis of osteoporosis based solely on *t*-scores of -2.5 and below.²² The NOF guidelines recommend pharmacological treatment in postmenopausal women with a BMD *t*-score below -1.5 if other risk factors are present, or below -2.0 in the absence of risk factors.²³ Cummings et al¹⁹ reported a prediction model for hip fracture based on data from the SOF that incorpo-

FIG. 1. A: Decision rule for intervention using SCORE as the screening tool. B: Decision rule for intervention using the SOF-based screening tool.

TABLE 2. DEFINITIONS USED FOR IDENTIFYING WOMEN AT HIGH RISK FOR TREATMENT PURPOSES WITHIN THE DECISION RULES

<i>High-risk definition</i>	<i>Criteria for intervention</i>
NOF	<i>t</i> -score ≤ -2.0 or less (no risk factors) or ≤ -1.5 or less (≥ 1 risk factor) or age ≥ 80 years ^a
WHO	<i>t</i> -score ≤ -2.5 or less
SOF-based instrument	Prior fracture after age 50 ^b or <i>t</i> -score ≤ -2.5 (60–64 years) or z-score ≤ -0.43 or less (≥ 65 years) and ≥ 5 risk factors or age ≥ 80 years

^aNOF uses “older age” in their algorithm. For purposes of this report, ≥ 80 years is considered.

^bFracture after 50 is an automatic referral for treatment.

rates BMD values and the presence of a number of risk factors. The SOF-based algorithm identifies women as high risk for fracture and needing further intervention if they are: (1) less than 65 years with BMD *t*-scores below -2.5 ; (2) 65 years and older with five or more risk factors and z-score below -0.43 ; or (3) women with a previous fracture after age 50.

Data analysis

Demographic and clinical characteristics of the study population were tabulated as means and standard deviations (SD) or proportions as applicable. Sensitivity, specificity, and corresponding 95% confidence intervals (CI) were calculated for the recommended decision point for each high-risk definition. For this analysis, sensitivity was defined as the proportion of women meeting the high-risk definitions who tested positive on the prescreening tool (having index values in the range considered increased risk). Specificity was defined as the proportion of women not meeting the high-risk definitions who tested normal on the prescreening tool (index values in the range considered low risk). The area under the receiver operating characteristic (AUROC) curve was used as a measure of the overall ability of each screening strategy to discriminate between women according to the high-risk definitions for intervention. SAS version 6.12 (SAS Institute, Cary, NC) was used for all analyses.

RESULTS

The mean age of the 416 women studied was 69.3 years (SD, 5.5 years). Table 3 presents frequency distributions of demographics, risk factors, and BMD status. The population was largely composed of white women (93.5%). Just over 42% of women had used HRT in the past, 77% were aged 65 and over, and 8.62% had five or more risk factors. Approximately 22% of women experienced a fracture after age 50 ($n = 96$). More than 54% of women reported very good or excellent health status, 44% reported high levels of physical activity, and only 3% reported use of corticosteroids. The percentages of women with *t*-scores at or below -2.5 , -2.0 , and -1.0 (at either the spine or hip) were 30%, 49%, and 81%, respectively.

The sensitivity and specificity and the AUROC curve for the two decision rules to detect women who meet the high-risk definitions for intervention are presented in Table 4. The numbers of women who met the intervention criteria based on *t*-score ≤ -2.5 or less, NOF guidelines, and SOF-based guidelines were 126 (30%), 275 (66%), and 115 (28%), respectively. The percentage of women identified for BMD testing was 82% by SCORE and 26% by the SOF-based tool.

The SCORE had the best discriminatory performance for the WHO (*t*-score ≤ -2.5 or less) and NOF intervention definitions (AUROC = 0.73 for each). For the SOF-based intervention

TABLE 3. SUMMARY OF DEMOGRAPHICS, RISK FACTORS FOR OSTEOPOROSIS, AND BMD STATUS IN THE STUDY COHORT

<i>Characteristics</i>	<i>No. (%)</i>
Demographics	
Age (years)	
60–64	96 (23.1)
65–69	120 (28.9)
70–74	112 (27.0)
≥75	88 (21.0)
Caucasian race	389 (93.5)
Osteoporosis risk factors	
Smoking status	
Never	201 (48.2)
Past	195 (46.8)
Current	20 (5.0)
Calcium intake	
Rarely or never	31 (7.5)
Several times/month	237 (57.0)
Several times/week	148 (35.5)
Alcohol (drinks/week)	
None	252 (60.5)
≤2	49 (11.7)
3–6	52 (12.4)
7–35	63 (15.4)
Family history of	
Hip fracture	74 (17.9)
Osteoporosis	231 (55.5)
Personal medical history of	
Fracture after age 50	93 (22.4)
Rheumatoid arthritis	41 (9.8)
Dementia	2 (0.5)
Current use of	
Corticosteroids	14 (3.3)
Benzodiazepines	5 (1.2)
Anti-seizure medications	4 (0.9)
HRT (current use)	12 (3.0)
Calcium supplements	237 (56.9)
Physical activity	
Low	19 (4.6)
Medium	212 (51.0)
High	185 (44.4)
Self-rated health	
Fair/poor	44 (10.5)
Good	145 (34.9)
Very good	178 (42.9)
Excellent	49 (11.7)
On feet >4 h/day	329 (79.0)
Cannot get out of chair not using arms	67 (16.1)
Walk for exercise	105 (25.2)
SF36 Physical Functioning	
≤67.0	117 (28.2)
67–84	87 (21.0)
85–94	92 (22.1)
≥95	119 (28.7)
Resting pulse >80 beats/min	34 (8.2)
Height at age 25 >5'7"	91 (21.9)
Weight less now than at age 25	32 (7.7)
Five or more fracture risk factors	36 (8.6)
BMD <i>t</i> -scores	
–2.5 or less	126 (30.3)
–2.0 or less	205 (49.3)
–1.5 or less	281 (67.6)
–1.0 or less	335 (80.5)

TABLE 4. SENSITIVITY, SPECIFICITY, AND AUROC FOR DECISION RULES TO IDENTIFY WOMEN AT RISK ACCORDING TO HIGH-RISK DEFINITIONS

<i>High-risk definition</i>	<i>SCORE</i>	<i>SOF-based</i>
Total recommended for BMD testing (or treatment)	339 (81.5%) ^a	110 (26.4%) ^b
NOF treatment guidelines (<i>n</i> = 275)		
Sensitivity (95% CI)	89.8 (79.9, 99.6)	30.5 (12.1, 41.3)
Specificity (95% CI)	34.8 (23.7, 45.8)	81.1 (72.9, 89.4)
AUROC (SE)	0.73 (0.03)	0.56 (0.03)
WHO (<i>t</i> -score ≤ -2.5 or less) (<i>n</i> = 126)		
Sensitivity (95% CI)	93.7 (88.3, 99.1)	32.6 (26.6, 38.6)
Specificity (95% CI)	23.8 (9.6, 38.0)	76.0 (63.5, 88.6)
AUROC (SE)	0.73 (0.03)	0.54 (0.03)
SOF-based intervention (<i>n</i> = 115)		
Sensitivity (95% CI)	96.5 (92.7, 100)	84.9 (77.8, 91.9)
Specificity (95% CI)	24.3 (9.7, 38.8)	95.8 (89.0, 102.6)
AUROC (SE)	0.68 (0.03)	0.90 (0.03)

SE, standard error.
^aWomen tested for BMD.
^bWomen tested for BMD or with prior fracture after age 50.

definition, the SOF-based screening tool was more discriminative than SCORE (AUROC of 0.90 and 0.68, respectively).

The SCORE decision rule identified more than 89%, 93%, and 96% of the women below the thresholds for intervention according to the NOF, WHO, and SOF-based guidelines, respectively. The SOF-based decision rule identified 30% of the women below the threshold for intervention according to NOF guidelines, 32% of women with *t*-score ≤ -2.5 or less, and 85% according to the SOF-based criteria. However, SCORE would also recommend 65.2% (NOF guidelines), 76.2% (WHO), and 75.7% (SOF-based) of women for BMD testing who do not meet the guidelines, compared with 19% (NOF), 24% (WHO), and 4% (SOF) with the SOF-based screening tool.

DISCUSSION

In recent years, an increasing awareness of osteoporosis and the availability of new pharmacological treatments with proven efficacy have put pressures on managed care organizations and primary care physicians to screen patients at risk for low bone mass and fragility fracture with BMD testing. This will require resources for its diagnosis and assessment. The clinical challenge is to identify those at great-

est risk, while limiting unnecessary testing in those with normal BMD who have a low risk for fracture. The use of clinical risk factors to predict low bone mass in order to limit need for BMD testing is a recommended method. Lists of indications for BMD testing as found in clinical guidelines are difficult for a managed care organization or primary care physician to use for clinical practice. Decision rules or screening algorithms use a more limited, but selective, set of factors to guide decisions for BMD testing.

The use of risk factors in testing and treatment decisions is advocated by experts and included in practice guidelines.^{1,7,24} In a risk-based approach, treatment decisions are based on the overall risk of fracture rather than on the bone measurement test alone. The assumption underlying this approach is that the number needed to treat is lower, and the cost-effectiveness of treatment is higher, for higher-risk patients. Despite the extensive body of literature about clinical risk factors for osteoporosis and fractures, few studies evaluate how to use these risk factors to identify individual women at risk. Those that perform well when originally tested perform less well in other population settings, or have not yet been widely tested.²⁵⁻²⁸

The purpose of these screening tools is to select women for bone mineral testing based on the likelihood that they have osteoporosis (low

bone density). Important questions need to be asked of these screening instruments in order to recommend their use within a screening, prevention, and treatment program. Do these risk-based screening instruments accurately identify women who may benefit from bone density testing? If so, is the screening program worthwhile in that they adequately reduce the amount of BMD testing? Since the ultimate purpose of BMD testing is to assist in identifying women who may need treatment for osteoporosis and fracture prevention, this approach must be related to the assumptions about who can benefit from treatment (ie, WHO diagnostic criteria, NOF treatment guidelines, or a health system-defined intervention algorithm [SOF-based]). It is important to consider how the screening selection for BMD testing relates to the subsequent use of the BMD testing results for treatment decisions. Appropriate selection of women for BMD testing should improve the identification of women who actually meet the criteria for subsequent intervention and treatment.

One of the screening instruments in this study (SCORE) identified 89% and 96% of the women below the treatment thresholds based on NOF intervention criteria and SOF-based intervention criteria, respectively, and 94% of the women with osteoporosis according to WHO criteria. In contrast, the SOF-based screening tool identified 31% and 85% of the women who met the intervention thresholds for NOF and SOF-based, respectively, and 33% of the women with osteoporosis. However, SCORE selected 65% of the women who did not meet the NOF intervention criteria and more than 75% who did not meet the SOF-based intervention criteria. The specificity of the SOF-based screening was significantly better, selecting only 19% and 4% of women who did not meet these intervention criteria.

Overall, SCORE selected 82% and the SOF-based screen selected 22% of the study population for BMD testing. Additional criteria were then applied before deciding whether to treat. The decision to base patient management programs on one of these tools must weigh the benefit of limiting unnecessary testing among women with low risk against the

risk of not identifying a large number of women who are at higher risk according to certain criteria (ie, BMD). Clinicians may not favor using a screening tool that limits BMD testing in women who may appropriately be selected for treatment based on BMD results, preferring instead to use clinical judgment or test everyone. At this time, however, a policy for BMD testing in all menopausal women has not been accepted, and clinicians find it difficult to assign the appropriate weight to various risk factors. Therefore, tools that identify women who are at risk and are more likely to benefit from intervention are useful in terms of clinical decision-making.

These findings are dependent on how prevalent the outcome, "women meeting treatment thresholds," is under the three different decision rules. Buist et al²⁰ demonstrated how the prevalence varies according to the definition used to define high-risk populations. In this population, the NOF intervention criteria threshold identified 66% and the SOF-based criteria identified 28% of the women as needing treatment, while 30% had osteoporosis according to the WHO definition. The more women who are identified as meeting the treatment threshold because of low BMD and risk factors, the more poorly a screening tool will perform that selects out very many women. The SOF-based screening tool demonstrates low sensitivity (31%) and high specificity (81%) for identifying women according to the NOF intervention criteria (higher prevalence), but high sensitivity (85%) and specificity (96%) when used to identify women who will meet the SOF-based intervention threshold (lower prevalence).

How might these data help the clinician, patient, and managed care organization deal with the issues surrounding osteoporosis screening? Targeting high-risk populations for BMD measurements is important for achieving cost-effective interventions. Selection of the women who meet treatment criteria that will be used in patient management limits unnecessary testing, anxiety, and subsequent treatment costs. If clinicians and managed care organizations identify the criteria that will be used for intervention decisions, a screening tool that sends

the majority of women who meet the criteria for BMD testing will result in a program that is more likely to achieve favorable outcomes.

There are several limitations to this study. Data in this study provide information based on DEXA results at one point in time. The purpose of initial DEXA testing is to identify those who would benefit from treatment to reduce the risk of fractures. The ultimate outcome of interest in any intervention program is fracture. Future studies should evaluate the proportion of cases missed by each of the screening tools that eventually fracture. In addition, the intervention thresholds used in this study to group women are based on guidelines that are not necessarily accepted as standard of care in the United States. The best approach for intervention remains controversial. Therefore, the utility of the screening instruments must be assessed in relation to the goals of the screening, prevention, and intervention program. There may be a participation bias in that patients who participated were volunteers responding to a mailed invitation and may not be representative of an unselected population. Among initial contacts, 21% agreed to participate by having a BMD test and completing a demographic questionnaire. Therefore, the cohort may be biased in favor of health-conscious individuals or perhaps, because the study focused on risk factors for osteoporosis, a different self-selection bias where those at higher risk or with a family history were more likely to participate in the study.

Further evaluation of screening tools in other populations to identify women for BMD testing is important to determine the generalizability of these findings. Since DEXA testing is important for the evaluation of bone loss and is a vital component of most treatment guidelines, the determination of who is referred for BMD testing remains an important question. The SCORE demonstrates better utility for targeting women at high risk for low BMD than a more selective SOF-based screening tool. Future research should include a cost-effectiveness analysis to identify the benefits of identifying more women for BMD testing who are at high risk while also testing women who are not high risk.

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Address reprint requests to:

Susan Brenneman, P.T., Ph.D.

Outcomes Research & Management, WP39-160

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P.O. Box 4

West Point, PA 19486

E-mail: Susan_brenneman@merck.com