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Evaluation of Three Population-Based Strategies for Fracture Prevention

Results of the Osteoporosis Population-Based Risk Assessment (OPRA) Trial

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Background: The integration of bone density testing into well-designed fracture prevention programs that can be applied in populations has not been studied.

Objectives: We sought to compare the outcomes of 3 strategies for allocating bone density testing within an HMO-based fracture prevention program.

Research Design: Women were randomly sampled and allocated to one of 3 groups: (1) a universal group, in which all were offered bone mineral density (BMD) testing (1986 contacted; 415 participated); 2) the SCORE group, in which women scoring ≥ 7 on the SCORE questionnaire were invited for BMD testing (1940 contacted; 576 participated); and (3) the Study of Osteoporotic Fracture (SOF)-based group, in which women with ≥ 5 hip fracture risk factors were invited for BMD testing (5342 contacted; 2176 participated).

Subjects: Women aged 60–80 not taking hormone therapy or osteoporosis medication were included.

Measures: Outcomes ascertained during 33 months of follow-up in all women contacted included initiation of osteoporosis treatment and hip and total fracture rates. Outcomes evaluated among all participants included changes in fracture risk factors, osteoporosis knowledge, and satisfaction with the program.

Results: Osteoporosis treatment rates did not differ among all women contacted but were slightly higher among trial participants in the universal and SCORE groups (21.1% and 20.2%, respectively; versus 16.7% in the SOF-based group (P value versus universal = 0.04). Among all women contacted, fracture rates were lowest in the universal group (74.11/1000) and differed significantly compared with the SCORE (99.44/1000; $P = 0.009$) and SOF-based groups (91.77/1000; $P = 0.02$). Knowledge about osteoporosis risk factors was highest in the universal group and lowest in the SOF-based group ($P < 0.01$).

Conclusions: The degree to which BMD testing was offered to women in a fracture prevention program significantly affected total fracture rates, change in some fracture risk factors, and knowledge about risk factors.

Key Words: bone density testing, fracture prevention, osteoporosis screening programs

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In 1999, 291,000 hip fractures occurred among Americans aged 65 and older.[1] Although reducing hip fracture rates was an articulated goal of Healthy People 2000, rates have failed to decline during the past decade.[2] Not only are hip fractures a significant cause of death, morbidity and disability,[3] but they cost an estimated $8.7 million in health care annually.[4] Clearly, effective, evidence-based, public health strategies for reducing fracture risk in populations are needed.

Proponents of bone density testing argue that this measurement is among the strongest predictors of future fracture, it cannot be known from assessment of other fracture risk factors, and is necessary for directing preventive and therapeutic measures to women with greatest fracture risk.[5] Many studies have shown that bone density testing results in higher rates of osteoporosis treatment initiation.[6–11] However, large randomized trials have not been conducted to determine whether bone density testing prevents hip and other osteoporotic fractures. Moreover, the integration of bone density testing into well-designed fracture prevention programs has not been studied. The Osteoporosis Population-based Risk Assessment (OPRA) Trial was designed to compare 3 strategies for allocating bone density testing in a health mainte-

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nance organization, within the context of a fracture prevention program that included risk factor assessment, personalized feedback on risk factor reduction and education about osteoporosis, and fracture prevention for all participants. Its purpose was to evaluate the impact of these strategies on osteoporosis treatment, risk-related behaviors, osteoporosis knowledge and the occurrence of fractures to provide evidence that might inform and improve the design of fracture prevention programs in health care organizations.

METHODS

Study Setting and Population

The OPRA Trial was conducted at Group Health Cooperative (GHC), a mixed-model health maintenance organization in western Washington State with more than 47,000 women enrollees aged 60 and older. Several elements of the intervention program were modeled after Group Health Cooperative's Breast Cancer Screening program, an established population-based program for breast cancer prevention that incorporates risk factor assessment, personalized feedback and risk-based mammography screening.[12] The research protocol was reviewed and approved by the Human Subjects Review Committee at GHC.

Intervention Trial Design, Recruitment, and Follow-up

Participant Eligibility

Women aged 60–80 were eligible to participate if they had not taken hormone replacement therapy or other osteoporosis medications for at least 12 months. Potentially eligible women were identified from GHC enrollment files on the basis of age and computerized pharmacy information. From this sampling frame, women were randomly assigned to 1 of the 3 intervention groups as described below. The overall recruitment target was to randomly select and allocate a sufficient number of women to all 3 groups to yield approximately 1000 bone density testing visits in our research clinic.

Universal Testing Group

In the universal testing group, bone mineral density testing was offered to all women via written invitation. Letters of invitation were sent to 1986 potentially eligible women (Fig. 1). In all of the intervention groups, a second letter of invitation was sent to women who did not respond to the first letter. Of the 1986 women originally contacted, 1116 (56.2%) did not respond, 419 (21.1%) refused participation, and 23 (1.2%) could not be contacted. A total of 428 women (21.5%) agreed to participate and completed the bone density

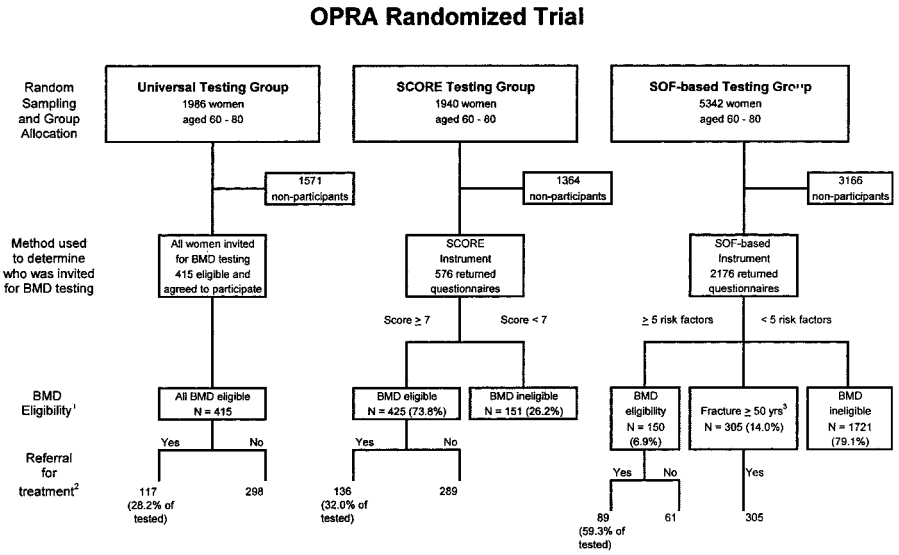

FIGURE 1. Sampling strategies and which women had BMD screening and osteoporosis treatment referral for the 3 arms of the OPRA randomized trial. [1]All women in group A were eligible for BMD testing. Only women with a score of ≥ 7 on the SCORE instrument were eligible for BMD testing in group B. Women with ≥ 5 risk factors from the SOF-based instrument were BMD eligible in group C. [2]The criterion for referring women to their personal physicians was identical for the 3 study groups. Women with ≥ 5 fracture risk factors and low bone density (T-score of less than −2.5 for women 60–64 years or a z-score less than −0.43 for women ≥ 65 years) along with all women who reported a fracture after age 50 were referred for work-up and treatment of possible osteoporosis. [3]Women with a personal history of fracture who did not "risk-in" to BMD testing were referred for work-up and treatment in accordance with the GHC osteoporosis guideline; all women with a personal history of fracture in the universal and SCORE groups were offered BMD testing and referred as described above.

testing clinic examination; of these, 13 were later found to be ineligible because of osteoporosis medication use, leaving 415 participants in this group.

Simple Calculated Osteoporosis Risk Estimation (SCORE) Testing Group

In the SCORE testing group, women were sent a letter about the osteoporosis prevention program and asked to complete the SCORE, a 6-item instrument developed by Merck & Co (Appendix Fig. 1). Details about the development and validation of the SCORE are published elsewhere.[13] Briefly, the SCORE instrument was specifically developed to identify women with bone density T-scores −2.0. Thus, the instrument was calibrated to have 90% sensitivity for detecting women with bone density T-scores less than this threshold (approximately 70–80% of women in previous reports) and also identified the 20–30% of women least likely to have low bone density. A total of 1940 women were sent letters describing the program and the SCORE questionnaire (Fig. 1). Of these, 1079 (55.6%) did not respond, 213 (11%) refused participation, and 51 (2.6%) could not be contacted. Completed SCORE questionnaires were received from 597 women (30.8%). Of these, 21 were found ineligible because of osteoporosis medication use, resulting in a final sample size of 576 participants in this group. A total of 425 women (73.8% of those completing the SCORE questionnaire) had a score of 7 or higher and were invited to the bone density testing examination. A score of 7 or higher was used based on recalibration in the original development cohort to achieve sensitivity of 90% in women aged 60 and older.

Study of Osteoporotic Fracture (SOF)-Based Testing Group

In the SOF-based intervention group, women were sent a letter about the osteoporosis prevention program and asked to complete a 17-item risk assessment adapted from known predictors of hip fracture in the large SOF cohort (Appendix Fig. 2).[14] Women with 5 or more risk factors were invited by telephone to the research clinic for bone mineral density testing. In the original report from SOF, women aged 65 and older with 5 or more risk factors (15% of the total cohort) and bone mineral density in the lowest third of their age-specific distribution (ie, z-score < -0.43) experienced one-third of all hip fractures in the population.[14]

Because the SOF strategy would result in a low percentage of women being offered bone density testing examinations, more women were allocated to this group initially. 5342 women were sent letters describing the program and the SOF-based risk factor questionnaire (Fig. 1). Of these, 2941 (55.1%) did not respond, 120 (2.2%) refused participation and 20 (0.4%) could not be contacted. 2261 (42.3%) women sent in a completed SOF-based risk assessment. 85 women were determined to be ineligible due to osteoporosis medication use, resulting in a final sample size of 2176 participants in this group. Of these, 150 women (6.9%) reported ≥ 5 risk factors and were invited by telephone to schedule a bone density testing examination.

Components of the Intervention Program

The intervention program was identical for the 3 study groups with the exception of how liberally bone density testing was offered as described above. The program had 3 main components: (1) All women who completed a risk factor questionnaire received personalized feedback identifying their risk factors for osteoporosis and providing suggestions for changing modifiable risk factors. (2) Accompanying the personalized feedback was a professionally printed educational brochure developed by the investigators providing information about osteoporosis and fracture and how it can be prevented and treated. The information in this brochure was consistent with prevention and treatment guidelines in place at GHC. (3) Bone density testing examinations took place from April 1998 through May 1999. Bone density was measured at the total hip and posterior–anterior spine by a trained, certified technician with dual-energy x-ray absorptiometry using a Hologic QDR 2000 densitometer (Hologic, Inc., Bedford, MA). Women who received bone density testing received enhanced personalized feedback on their hip and spine bone density. Their individual risk of hip fracture in the next 10 years was estimated based on Rochester, Minnesota, data and compared with the hip fracture risk of a woman with average bone density of the same age. Pictorial images showing the number of women in a thousand expected to have a hip fracture at the 2 levels of bone density were used.

The criterion for referring women to their personal physicians was identical for the 3 study groups. Consistent with GHC Guidelines (based on the original SOF report),[14] women with ≥ 5 fracture risk factors and low bone density (T-score less than −2.5 for women 60–64 years or a z-score less than −0.43 for women ≥ 65 years), along with all who reported a prior fracture after the age of 50, were referred to their personal physicians for work-up and treatment of possible osteoporosis. For these women, a copy of their personalized feedback was also sent to their personal physician.

Data Collection

Details of the baseline data collection have been described in detail in a previous report.[15] Briefly, all women who participated in the bone density testing examination completed a detailed baseline questionnaire assessing their demographic characteristics, fracture risk factors (personal history of fracture, dietary and supplemental calcium, physical activity, weight, height, use of selected medications), and knowledge about osteoporosis and fracture prevention. For women in the SCORE and SOF-based testing groups who were not invited for bone density testing, the only informa-

tion available at baseline was that provided on the respective questionnaires.

Women who received bone density testing were randomly allocated to receive a follow-up interview by telephone at 6–18 months after their clinic examination to collect information on the main trial outcomes. Interviews took place from February 1999 through September 2000. Multiple attempts were made to contact every screened woman. Telephone interviews were completed with 399 women in the universal group (96.1%), 391 women in the SCORE group (92.0%), and 137 women in the SOF-based group (91.3%). A paper-and-pencil follow-up questionnaire with a subset of the interview items was mailed in May-July 2000 to women in the SCORE and SOF-based testing groups who were not offered bone density testing because of too few risk factors. A second questionnaire mailing was used to maximize response rates. Completed mailed questionnaires were received from 91 of 151 women (60.3%) in the SCORE testing group and from 1416 of 2026 women (69.9%) in the SOF-based testing group. The responses from the telephone interview and mailed questionnaires were merged within each group to evaluate outcomes in the randomized groups.

Main Trial Outcomes

Several main trial outcomes were obtained for all women via computerized GHC records. Initiation of osteoporosis therapy, including hormone replacement therapy, alendronate, raloxifene, and calcitonin, was ascertained through computerized GHC pharmacy records, indicating one or more dispensed prescriptions for these agents during follow-up through December 31, 2000. Hip and other fracture events were regarded as exploratory outcomes and ascertained through December 31, 2000, by searching automated hospitalization and outpatient visit records for ICD-9 codes indicating the occurrence of nonpathologic fracture. Follow-up time for osteoporosis therapy initiation and fracture occurrence ranged from 24–33 months with an average duration of 28 months.

The follow-up telephone and mailed questionnaires included items asking women if they had made any changes to their diet or lifestyle in the last year because of concerns about osteoporosis. A calcium intake scale was calculated by summing the frequency of eating 4 types of dairy products (milk, ice cream, yogurt, and cheese). An exercise scale was calculated by summing the frequency of 3 types of usual physical activity (taking walks, working around the house, regular physical activity like brisk walking, jogging, bicycling, etc.). Women were asked to rate their own risk of ever getting a bone fracture compared with other women their age. They were also asked to estimate how much of the time they worry about taking a bad fall. Knowledge of osteoporosis risk factors was ascertained by asking women which of 11 factors increased a woman's risk of developing osteoporosis.

Several elements of the intervention program were also evaluated including: (1) the degree to which the women read the educational brochure on osteoporosis; (2) the degree to which they found the brochure useful; (3) whether the women discussed osteoporosis with their primary care provider after receiving their personalized feedback; (4) whether they would like to see a fracture prevention program incorporated into their usual care; and 5) how much they would like a bone density testing program like this one to become part of their routine preventive care (scale 1–10).

Statistical Analysis

Demographic characteristics and baseline levels of selected fracture risk factors were compared among the 3 intervention groups using χ^2 tests. Rates of treatment initiation and fractures were calculated as the number of events per 1000 women. Age-adjusted rates were calculated using the direct method by using the age distribution of all trial participants as the standard population. All women randomly selected and allocated were included in these outcome analyses. Rates are presented separately for all randomly selected women who were invited to participate (an intention-to-screen analysis) and for the subgroup who responded to the invitation and became intervention program participants (participant-only analysis). Note that all women were included in these analyses regardless of whether they were offered BMD testing or whether they provided follow-up data by interview or mailed questionnaire.

Self-reported outcomes could only be evaluated among women who participated in the intervention and provided follow-up information. Contingency tables analyses compared levels of these outcomes by intervention group. Statistical tests comparing the 3 testing groups were calculated using linear or logistic regression models with indicator variables for intervention group and adjustment for age and education. Inclusion of terms in the model indicating the time of the follow-up interview produced identical results.

RESULTS

Baseline characteristics of women who agreed to participate are shown in Table 1. The average age of the 3 intervention groups ranged from 69.1 to 70.3 years with the SOF-based testing group having a higher frequency of women aged 75 and older (Table 1). Most women had at least some college education (62–69%). Most participants were Caucasian (90–93%). History of fracture was highest in the universal testing group (22.5%) and lowest in the SCORE testing group (11.8%; $P < 0.0001$). Approximately three quarters of women reported walking for exercise.

Bone density testing was performed among 415 (100%) women in the universal testing group, 425 (73.8%) women in the SCORE testing group, and 150 (6.9%) women in the SOF-based testing group (Fig. 1). Among the women who

TABLE 1. Baseline Characteristics of Trial Participants According to Intervention Group in the OPRA Trial

Screening Strategy	Universal, n = 415 (%)	SCORE, n = 576 (%)	SOF-Based, n = 2176 (%)
Age group†			
60–64	24.8	25.2	20.1
65–69	29.6	25.9	24.4
70–74	26.0	27.1	26.9
75+	19.5	21.9	28.6
Age, mean (SD)	69.1 (5.5)	69.3 (5.5)	70.3 (5.6)
Ethnicity			
White	93.0	91.8	90.1
Black	1.5	2.0	2.4
Asian	3.6	4.0	4.6
Hispanic	1.5	1.2	1.4
Other	0.5	1.0	1.6
Total	(n = 415)	(n = 502)	(n = 1389)
Education*			
High school or less	30.7	38.2	32.0
Some college	36.2	33.5	38.8
College grad or higher	33.1	28.3	29.2
Total	(n = 414)	(n = 508)	(n = 1508)
History of fracture since age 50†	22.5	11.8	17.3
History of rheumatoid arthritis	9.9	9.9	
Current smoker	9.0		6.8
Walk for exercise	74.5		74.4

Analyses were restricted to women who participated in the trial including those who did and did not receive BMD testing.
*χ^2 $P \leq 0.05$.
†χ^2 $P \leq 0.0001$.
SD indicates standard deviation.

received bone density testing, 117 (28.2%) women in the universal testing group, 136 (32.0%) women in the SCORE testing group, and 89 (59.3%) women in the SOF-based testing group met the GHC criteria for referral to their personal physicians for work-up and possible treatment of osteoporosis. An additional 305 (14%) women in the SOF-based testing group who did not meet the BMD testing criteria, but who reported prior history of fracture were referred to their physicians for further evaluation.

Among all women randomly selected and contacted, GHC computerized records yielded a total of 98 hip fractures (25 in participants) and 747 total fractures (307 in participants) during follow-up. Among all women contacted, age-adjusted rates of total fracture were lowest in the universal testing group (74.11/1000), highest in the SCORE testing group (99.44/1000; $P = 0.009$) and intermediate in the SOF-based testing group (91.77/1000; $P = 0.02$). Hip fracture rates were also lowest in the universal group (8.54/1000), intermediate in the SCORE testing group (9.04/1000), and highest in the SOF-based testing group (13.31/1000; Table 2) but these differences were not statistically significant. Rates of initiation of osteoporosis therapy did not differ significantly among all women contacted but were slightly higher among women who participated in the universal and SCORE groups (21.1 and 20.2/100, respectively; $P = 0.76$, compared with 16.7/100 in the SOF-based group; $P = 0.04$). Higher rates of alendronate initiation appeared to account for most of this difference (Table 2).

Self-reported outcomes are shown for all women who participated in the intervention, including those who were not offered BMD testing (Tables 3 and 4). Changes in diet or lifestyle because of concerns about osteoporosis were reported on the follow-up questionnaires more commonly among women in the universal (49%) and SCORE testing groups (44%) than in the SOF-based testing group (35%; Table 3). The most commonly reported change was taking calcium supplements, reported by one-third of women in the universal testing group, 28% of women in the SCORE testing group ($P = 0.65$), and 27% of women in the SOF-based testing group ($P = < 0.0001$). In contrast, women in the SOF-based group more commonly reported increasing dietary calcium ($P < 0.0001$ versus universal). Self-reported

TABLE 2. Age-Adjusted Rates of Osteoporotic Fracture and Initiation of Osteoporosis Treatment According to Intervention Group in the OPRA Trial*

Screening Strategy	Universal	SCORE	SOF-Based
All randomly selected women invited to participate	1986	1940	5342
Intervention program participants	415	576	2176
Osteoporotic fracture rate* per 1000			
All randomly selected women invited to participate			
Hip	8.54	9.04	13.31
Any fracture	74.11	99.44†	91.77†
Intervention program participants			
Hip	3.22	7.95	8.74
Any fracture	89.26	116.34	92.76
% initiation of antiosteoporosis therapy			
All randomly selected women invited to participate			
Any type of therapy	12.60	13.78	13.33
HRT	9.62	10.61	10.59
Alendronate	2.67	2.81	2.11
Other	0.08	0.11	0.13
Intervention program participants			
Any type of therapy	21.14	20.22	16.73†
HRT	14.71	14.67	13.30
Alendronate	6.51	4.62	3.26
Other	1.89	2.44	1.60

*Fracture rates after initial contact. Mean follow-up (in months) was 27.0 (universal), 28.2 (SCORE), and 28.6 (SOF-based); range (23.5–33.2 months).

†P value compared with the universal group ≤ 0.05.

HRT indicates hormone replacement therapy.

data on osteoporosis therapy initiation was somewhat lower than detected through the automated pharmacy data (Table 3) caused, at least in part, by a shorter follow-up interval for the self-report data. For self-reported hormone therapy and alendronate, the highest initiation rates occurred in the universal testing group and the lowest rates occurred in the SOF-based group (Table 3). Women in the universal and SCORE testing groups were much more likely to self-rate their risk of bone fracture as "higher" or "much higher" than other women of the same age as compared with women in the SOF-based testing group (40–46% versus 8.3%, respectively; Table 3). Intake of dairy products and exercise scale scores appeared similar among the testing groups.

Knowledge about osteoporosis risk factors varied dramatically across the intervention groups (Table 3). Women in the universal testing group reported the highest mean proportion of correct answers (57%) as compared with women in the SCORE testing group (53%; $P = 0.13$) and women in the SOF-based testing group (43%; $P < 0.0001$). Across the intervention groups, a third or fewer women knew that losing a lot of weight or having a previous broken bone increased risk of fracture.

About 77% of women in the universal testing group reported having read all or some of the educational brochure compared with 72% of women in the SCORE group and 44% of women in the SOF-based group (Table 4). Women in the universal testing group also were significantly more likely to have discussed osteoporosis with their healthcare provider (45%) than women in the SOF-based testing group (19.3%; $P < 0.0001$); in contrast, about 38% of women in the SCORE testing group had a discussion with their healthcare provider ($P = 0.72$ for SCORE versus universal testing group).

Interest in seeing a fracture prevention program incorporated into routine clinical care was high, ranging from 82% of women in the SOF-based testing group to 93% of women in the universal testing group (Table 4). Levels of interest in seeing a bone density program offered as part of routine care were also high.

DISCUSSION

Many studies, both observational[6–9] and experimental,[10,11] have shown that bone density testing is associated with higher rates of treatment initiation. In 8020 women enrollees of a health maintenance organization in Northern California, 24% of women undergoing bone density testing filled a prescription for an osteoporosis drug within 6 months,[7] a rate similar to the 21% of women initiating treatment who participated in the universal group of the OPRA Trial. Initiation of treatment appears to be associated with having a bone density test regardless of the result,[10] in addition to test results indicating low bone density or osteoporosis.[7–9] Ultimately, as many have noted,[16,17] the outcome of greatest importance is not treatment initiation but reduction in fracture rates. Thus, the effects of bone density testing on treatment adherence[18] and long-term continuance deserve further evaluation.

Previous studies have shown that women identified as having low bone density are more likely to report increasing their calcium intake, physical activity levels or making other lifestyle changes compared with women without low bone density.[6,11,19–23] Few studies have been population-based or randomly assigned women to different intervention groups.

Knowledge about osteoporosis was highest among women in the universal group, even though all women received the educational brochure and personalized risk factor

TABLE 3. Osteoporosis Risk Factors, Behaviors, and Knowledge of Fracture Risk Factors at Follow-Up According to Intervention Group in the OPRA Trial

	Universal n = 399 (%)	SCORE n = 482 (%)	SOF-based n = 1510 (%)
Made changes in diet or lifestyle in last year because of concerns about osteoporosis	48.9	43.6	35.3†
Changes made in last year			
Ate more calcium	18.8	20.5	26.8†
Ate fewer fatty foods	12.0	15.2	25.5†
General diet improvement	11.5	15.2	23.4†
Take calcium supplements	33.1	28.4	27.3†
Exercise more often	24.6	24.9	23.4
Other	14.8	10.0	4.3†
Self-reported initiation of any of the following medications in last 12 months			
Hormone replacement therapy	10.0	7.7	4.8*
Alendronate (Fosamax)	4.8	3.5	2.7
Calcitonin (Miacalin or Calcimar)	0.3	0.4	0.5
Raloxifene	0.0	0.6	0.5
Compared with other women of the same age, self-rated personal risk of bone fracture§			
Lower	13.0	16.2	37.6†‡
Much lower	40.4	34.0	16.9
About the same	0.5	5.0	14.8
Higher	32.3	29.9	6.0
Much higher	8.0	6.6	2.3
Calcium intake scale			
Never or rarely	7.3	5.8	7.4‡
Several times per month	44.9	44.4	49.5
Several times per week	45.6	47.9	38.9
Every day	2.0	1.5	2.5
Exercise scale* mean (standard deviation)	2.39 (0.54)	2.35 (0.58)	2.26 (0.66)
How much time do you worry about taking a bad fall?			
All or most	8.5	11.6	9.8
A good bit or some	38.4	37.6	29.7
A little or none	52.6	49.6	56.3
Knowledge of osteoporosis risk factors			
Menopause	76.9	71.4	51.9*
Family history of osteoporosis	85.5	82.1	67.3*
Smoking	75.4	68.1	53.3†
Being Caucasian	37.8	29.3	24.6*
Not getting enough calcium	97.2	95.6	82.0*
Not getting enough exercise	97.2	91.9	80.3*
Being overweight ("no" is correct)	13.5	12.0	11.9
Drinking caffeinated beverages	41.4	36.3	27.2*
Small build	40.4	34.2	25.4
Losing a lot of weight	29.8	28.8	16.6*
Previous broken bone	27.6	29.3	34.5†
Proportion of correct responses	0.57	0.53	0.43†‡

Analyses were restricted to women who participated in the trial including those who did and did not receive BMD testing.
*$P \leq 0.05$ adjusted for age and education compared with universal.
†$P \leq 0.0001$ adjusted for age and education compared with universal.
‡$P \leq 0.05$ adjusted for age and education compared to SCORE.
§Percentages do not sum to 100% because of "don't know" and "already have had fracture" responses.

TABLE 4. Participant Evaluation of the OPRA Fracture Prevention Program

	Universal n = 399	SCORE n = 482	SOF-Based n = 1510
Read the informational brochure on osteoporosis			
All	61.9	56.0	44.4†‡
Some	14.8	15.6	15.8
None	0.3	0.8	1.4
Never received or do not remember	3.8	8.3	20.3
How useful was the informational brochure?§			
Very useful	22.1	23.4	26.0†‡
Somewhat useful	38.6	33.4	27.3
Slightly useful	7.5	8.1	4.0
Not at all	0.8	0.6	0.5
Had a discussion with healthcare provider during follow-up	44.9	37.8	19.3†
Interested in seeing a fracture prevention program incorporated into care at GHC (range, 1–100)	93.0	89.2	81.9
Scale of interest in seeing a bone density program as part of routine care offered at GHC (range, 1–100)	85.8 (20.8)	84.5 (22.0)	82.9 (24.6)

Analyses were restricted to women who participated in the trial including those who did and did not receive BMD testing.
*$P \leq 0.05$ adjusted for age and education compared with universal.
†$P \leq 0.0001$ adjusted for age and education compared with universal.
‡$P \leq 0.05$ adjusted for age and education compared with SCORE.
§Percentages do not sum to 100% because of "don't know" responses.

feedback. Less than one-third of women realized at follow-up that losing a lot of weight or having a previous broken bone increased risk of fracture. Reinforcement of intervening on these important risk factors among both women and their physicians is an important direction for improving fracture prevention in populations.[16]

This trial was not designed to have sufficient numbers of women or duration of follow-up to provide definitive data on risks of fracture associated with the various testing strategies. Fracture rates were evaluated during a 2-year period and based on physician assigned ICD-9 codes, which were not further adjudicated. These limitations argue for a cautious interpretation of the fracture data. Nonetheless, in our exploratory analyses, total fracture rates were significantly lower in the universal testing group among all women contacted. The pattern was similar for hip fracture, but the differences were not statistically significant because few hip fractures occurred. Similarly, hip fracture rates were lower in the Cardiovascular Health Study among older adults offered bone density testing compared with those receiving usual care (relative risk = 0.58 95% confidence interval 0.35–0.97).[24] It would be highly desirable to subject bone density testing to evaluation in large randomized trials with osteoporotic fractures as the primary outcome of interest. The prospects of conducting such a trial are daunting because testing and consumer demand have grown dramatically during the past 10 years. In the interim, the fracture rates presented here offer more evidence than has been available heretofore for evaluating cost-benefit trade-offs as a basis for practice guidelines in health care organizations.

Strengths of this trial include its population-base, relatively large sample size, the ability to target the intervention at older women not already receiving osteoporosis therapies, the development and use of an innovative personalized feedback system, and the use of automated data to ascertain treatment and fracture outcomes among all women invited to participate. The strategies tested did not require a physician recommendation for screening and thus, do not generalize to interventions that rely on physician referral. More than 1000 clinicians were practicing at GHC when this trial was conducted, and no attempt was made to evaluate physician variation in osteoporosis treatment. Nonetheless, a widely promulgated osteoporosis guideline likely decreased practice variation and improved the quality of clinical care in all intervention groups.

The fact that participation rates ranged from 21% to 42% across the intervention groups has important health services implications. First, participation rates were higher in the SCORE and SOF-based groups compared with the universal group, suggesting that the requirement to return a risk factor questionnaire at the initial contact did not discourage participation. Many potentially eligible women were not persuaded to participate by 2 letters of invitation or the promise of bone density testing, suggesting that

health care systems will not be overwhelmed by high response rates to offering fracture prevention services. Differences between participants and nonparticipants are beyond the scope of this paper and the subject of a separate report.[25] We necessarily elected to randomly allocate women to the various testing strategies at the earliest contact, so that participation rates could be evaluated in response to a realistic packaging of the risk factor questionnaires and letters of invitation.

For the self-reported outcomes that required participation, we cannot rule out selection factors as an explanation of some differences among the intervention groups. For example, women in the universal group who self-selected to participate reported making more behavioral changes because of concerns about osteoporosis in the last year; calcium supplementation was the most commonly reported change. Thus, the universal invitation may result in selection of women who are highly motivated to make changes based on personalized feedback, whereas risk-based strategies would exclude some of these women.

The findings presented here should also be evaluated in the context of recent evidence from large pharmacologic trials. First, randomized trials have shown that women without established osteoporosis (vertebral fracture or low bone density) do not significantly lower their risk of hip or clinical fracture by treatment with bisphosphonates.[26,27] Furthermore, the idea that universal treatment of women with hormone therapy is warranted because of its cardioprotective effects has been disproven.[28,29] These findings argue for targeting osteoporosis therapies at the women most likely to benefit, specifically, those with established osteoporosis as defined by vertebral fracture, history of clinical fracture after age 50 and/or low bone density.[30] Moreover, women in this trial overwhelmingly indicated their desire for fracture prevention programs that incorporate bone density testing. These factors are compelling reasons for incorporating bone density testing into well-designed programs for osteoporosis detection and education in populations. Our findings illustrate the fracture and risk reduction trade-offs for directing services to women at greatest risk in health care environments where BMD-testing resources are scarce.

We conclude that the degree to which bone density testing was offered to women in a fracture prevention program significantly affected total fracture rates, change in some fracture risk factors and osteoporosis knowledge. This evidence supports the recent U.S. Preventive Services Taskforce recommendations that all women aged 65 and older be screened routinely for osteoporosis.[31]

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APPENDIX

The SCORE Questionnaire (Appendix Fig. 1) and the SOF-Based Questionnaire (Appendix Fig. 2) used in the present study.

SCORE Questionnaire

1. What is your current age ___ years	Take the number in the shaded area, multiply by 3, and enter	_____
2. What is your race or ethnic group? African –American/Black American Caucasian, Hispanic, Asian Native American/American Indian/Other	 Enter 0 Enter 5 Enter 5	 _____
3. Have you ever been treated for or told you have Rheumatoid arthritis?	If yes, enter 4	_____
4. Since the age of 45, have you experienced a fracture (broken bone) at any of the following sites? • Hip • Rib • Wrist	Enter 4 for **each** site	_____
5. Do you currently take or have you ever taken estrogen? (examples include Premarin, Estrace, Estraderm, Estratab)	If no, enter 1	_____
Add score from questions 1-5		_____ Subtotal
6. What is your current weight? ___ pounds	Take the numbers in the shaded area and subtract from subtotal	_____
IF YOUR FINAL SCORE IS 7 OR HIGHER, YOU SHOULD BE EVALUATED FUTHER FOR OSTEOPOROSIS		_____ FINAL SCORE

APPENDIX FIGURE 1. SCORE Questionnaire.

SOF-Based Questionnaire

	+1 for any shaded box		
1. I would rate my health as: (circle one) excellent good fair poor very poor	fair	poor	very poor
2. I am African-American	Yes	No	**–1**
3. I am a smoker	Yes	No	
4. My mother, father, sister or brother had a hip fracture	Yes	No	
5. I weigh less now than I did at age 25 (when not pregnant)	Yes	No	
6. I have been diagnosed with dementia	Yes	No	
7. I am currently using oral corticosteroids (prednisone)	Yes	No	
8. I am currently taking medicine to prevent or control seizures (such as dilantin, phenobarbital)	Yes	No	
9. I am currently taking long acting Benzodiazepines (such as librium, librax, hyperstat, proglycem, dalmane, flurazepam)	Yes	No	
10. I walk for exercise	Yes	No	
11. I can get up out of a chair without using my arms to help me	Yes	No	
12. I had a fracture at age 50 or older	Yes	No	
13. I am 80 years or older	Yes	No	
14. I am postmenopausal and I do not take hormone replacement therapy	Yes	No	
15. I am up on my feet less than 4 hours per day	Yes	No	
16. My heart rate (pulse) when I am sitting quietly is more than 80 beats per minute (heart rate = number of heartbeats in one minute)	Yes	No	
17. I was 5'7" or taller at age 25	Yes	No	

IF SCORE ≥ 5 INVITE FOR BMD SCAN _____

APPENDIX FIGURE 2. SOF-Based Questionnaire.