OPEN

Evaluation of an Osteoporosis Outreach Program for Men With a Fragility Fracture and Their Physicians

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Background: Many health plans have outreach programs aimed at appropriately screening, evaluating, and treating women experiencing fragility fractures; however, few programs exist for men.

Objective: The objective of this study was to develop, implement, and evaluate an osteoporosis outreach program for men with a recent fragility fracture and their physicians.

Research Design and Subjects: A total of 10,934 male patients enrolled in a Medicare Advantage with Prescription Drug Plan with a recent fragility fracture were randomized to a program or control group. Patients and their physicians received letters followed by phone calls on osteoporosis and the importance of screening and treatment. The evaluation compared bone mineral density (BMD) test utilization and osteoporosis medication treatment (OPT) among patients who received the outreach versus no outreach at 12 months. The effect of the program was estimated through univariate and multivariable logistic regressions.

Results: The program had a significant impact on BMD evaluation and OPT initiation. At 12 months, 10.7% of participants and 4.9% of nonparticipants received a BMD evaluation. The odds ratio (OR) (95% confidence interval) was 2.31 (1.94, 2.76), and the number needed to outreach to receive a BMD test was 18. OPT was initiated in 4.0% of participants and 2.5% of nonparticipants. The OR (95% confidence interval) of receiving OPT was 1.60 (1.24, 2.07), and the number needed to outreach was 69. Adjusted ORs were similar in magnitude and significance.

Conclusion: The program was highly effective by more than doubling the rate of BMD evaluation; however, more intensive interventions may yield an even higher screening rate.

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The National Osteoporosis Foundation cites that 1 in 4 men aged 50 years or older will break a bone due to osteoporosis during their lifetime, and roughly one third of all hip fractures worldwide occur in men.[1] Historically, the female osteoporosis population has been of particular interest to most health plans due to the higher prevalence of osteoporosis in females compared with males, and its inclusion as a Healthcare Effectiveness Data and Information Set (HEDIS) quality measure.[2] In contrast to the osteoporosis-related activities for females, very little attention has been given to the evaluation and treatment of osteoporosis in males.[3,4] Evidence from a recent meta-analysis indicating the risk of death after a hip fracture is higher among men than women further underscores the importance for males to be appropriately screened, evaluated, and treated for osteoporosis.[5]

In accordance with the HEDIS postfracture quality measure, and to improve patient health and care quality, many health plans, including plans offered by Humana Inc., have had a fracture liaison service (FLS) aimed at appropriately screening, evaluating, and treating women in the period immediately following a fragility fracture. While some plans offer this type of service to males,[6] it is largely an uncommon practice. Further, while numerous studies have assessed the impact of FLS and related osteoporosis educational programs among females, few have examined the impact of such interventions among men with a fragility fracture.[7] In a systematic review and meta-analysis of FLS programs by Ganda et al,[8] FLS programs were grouped into 4 categories: those that (1) identify, assess, and treat patients as part of the service; (2) identify and assess only; (3) alert patients plus primary care physicians; and (4) provide patient education only. The meta-analysis found that the increasing intensity of the FLS was associated with increased bone mineral density (BMD) assessment and osteoporosis treatment (OPT) initiation.[8]

As a foray into providing an FLS program for postfracture males, this study aimed to evaluate the impact of a light-to-medium-intensity osteoporosis outreach program for postfracture males enrolled in Humana's Medicare Advantage with Prescription Drug (MAPD) plan on screening and OPT at 12 months following the intervention. The screening was defined as evidence of a patient's receipt of a dual-energy x-ray absorptiometry (DXA) scan, single x-ray absorptiometry, or computed tomography scan

or radiographic or photon absorptiometry test, and OPT was defined as evidence of a patient's prescription fill for an osteoporosis-specific medication [bisphosphonate antiresorptive medications (alendronate, risedronate, ibandronate, zoledronic acid), other antiresorptives (calcitonin, estrogen therapy, raloxifene, denosumab), or anabolic medication (teriparatide)]. Each was assessed during the 12 months after the index date.

METHODS

Study Design and Patient Population

This was a prospective, randomized study in which men aged 50–85 enrolled in an MAPD plan with a recent clinical fragility fracture were identified on a rolling monthly basis during the identification period of May 1, 2016, through May 31, 2017 (Fig. 1). Fragility fracture was defined as a fracture type having a high likelihood of correlation to underlying osteoporosis (score 8 or 9) based on a study conducted by Warriner and colleagues. This method consisted of a systematic literature review to formulate an evidence report of the association with osteoporosis of each fracture type recorded, followed by convening an expert panel to engage in a modified RAND/UCLA appropriateness process to provide an osteoporosis attribution grading for each fracture by anatomic site, administrative diagnosis code, and key risk factors.[9] Examples include the spine, forearm, and hip fractures.

If a fragility fracture was accompanied by evidence of trauma, the fracture did not qualify for inclusion unless it was an accidental fall from standing height or less. In addition, patients were excluded if they had evidence of a fragility fracture within 60 days before the first observed fracture date or between the observed fracture and the date of the intervention at the same fracture site. Patients with evidence of a BMD fracture assessment or the initiation of OPT during the prior year or between the date of the fracture and the date of the intervention were excluded, as were patients with evidence of Paget disease or cancer. Patients in the intervention cohort who died before contact, or who, along with their physicians, were unable to be contacted (ie, all phone numbers, facsimile numbers, and mailing addresses were invalid) were excluded.

The date of the intervention was assigned as the seventh day of the second month after the first observed fracture, for example, if the fracture occurred in May, the intervention date was set as July 7. This allowed for time to identify patients and their physicians and to administer the intervention and served as the study index date for evaluating postindex outcomes. For each month of identification, the inclusion and exclusion criteria requirements were applied, and the study sample was subsequently randomized into intervention and control groups. Eligible patients were followed for 12 months postindex.

After the initial preintervention inclusion/exclusion criteria were applied, there were 10,934 individuals available for assignment into the intervention or control group (Fig. A1). Once the intervention began, individuals continued to be excluded from the 12-month follow-up analysis due to death (n = 157) or disenrollment for other reasons (n = 2512). Other reasons were the inability to contact the patient or physician by mail, fax, or phone (all dead-ends, n = 8), or evidence of having a BMD evaluation or initiating OPT after the index fracture but before the intervention was delivered (n = 415). At 12 months postintervention, a final sample size of 7842 individuals, with 3977 men in the intervention group and 3865 men in the control group, was available for analysis (Fig. A1).

The Outreach Program

The outreach program was comprised of mailed letters to male patients with a recent fracture, mailed or faxed letters to their physicians (faxed rather than mailed if a facsimile contact number was available), and up to 3 telephone call attempts over a 1-month period to contact the patient and his primary care physician. Letters and phone calls urged each patient with a recent fracture to contact his physician to discuss his risk of osteoporosis. Similarly, letters and phone scripts were created to inform each physician that his or her patient(s) had experienced a fracture, and these messages encouraged the physicians to set up an appointment to discuss bone health and the risk for osteoporosis with his or her patient(s).

In addition, to determine an incremental response based on the increased intensity of the outreach, we compared in a secondary analysis the difference in BMD evaluation and OPT initiation stratified by the moderate or heavy intensity of outreach versus light intensity of outreach, where moderate was defined as a telephone conversation with either the patient or the physician in

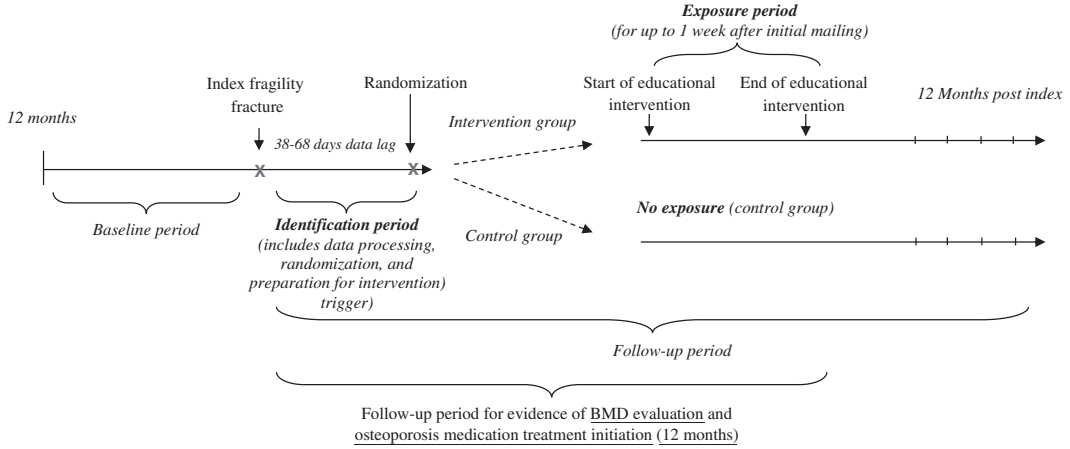

FIGURE 1. Study design schema. BMD indicates bone mineral density.

addition to notifications by mail or facsimile, and heavy was defined as a telephone conversation with both the patient and the physician in addition to notifications by mail or facsimile, depending on who was reached. Each of these was then compared with patients and physicians receiving a light intensity outreach (reference group), where the light was defined as patients and physicians receiving a letter by mail or facsimile but neither having a phone conversation with a moderator because they were unable to be reached by phone.

Data Source

The Humana Research Database (Humana Inc., Louisville, KY), which contains administrative data for Humana's fully insured commercial and Medicare individuals, was used to identify men enrolled in MAPD plans and their primary care physicians, as well as to perform analyses to evaluate the outcomes of this outreach program (Online Supplemental Appendix, Supplemental Digital Content 1, http://links.lww.com/MLR/C145). Data on MAPD enrollment, medical claims, and outpatient pharmacy claims were linked for each individual using a unique identifier. The study was reviewed and approved by Advarra Institutional Review Board (formerly known as Schulman Institutional Review Board).

Data Analysis

The effect of the osteoporosis outreach program on BMD evaluation and OPT initiation was estimated using univariate logistic regression with binary endpoints of receipt of BMD evaluation (Y/N) or the initiation of OPT (Y/N) during the 12 months after the index date. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated, as was the number needed to outreach, that is, the number of patients who would need to receive the intervention to increase by one the number having a BMD evaluation or initiating OPT. χ^2 tests were used to assess differences between heavy versus light and moderate versus light intensity of outreach.

The impact of the outreach program was further estimated through a series of multivariable logistic regression models, which included the treatment group variable (osteoporosis outreach program or control/no program) and a series of covariates based on patient demographics and clinical characteristics assessed at baseline (12 mo before index fracture). These included age, race, geographic region, index fracture site, Deyo-Charlson Comorbidity Index score, specific comorbidities (osteopenia, arthritis, myocardial infarction, cerebrovascular disease, chronic pulmonary disease, hypothyroidism, diabetes, and obesity), and prior medication use (nonsteroidal anti-inflammatory drugs and glucocorticoids). The logistic regression models were run with backward stepwise elimination using a retention value of P-value ≤ 0.10.

RESULTS

Table 1 displays the baseline descriptive characteristics of the intervention and control groups. The 2 randomized groups were balanced across demographic and clinical characteristics, as well as across index fracture sites. The exceptions were in 2 specific comorbidities: cerebrovascular disease (15.7% for intervention group vs. 17.5% for control group, $P = 0.03$) and hypothyroidism (14.5% for intervention group vs. 12.7% for control group, $P = 0.02$).

TABLE 1. Baseline Demographic and Clinical Characteristics for Intervention and Control Group

Measures	Intervention Group [n (%)]	Control Group [n (%)]	*P*
N	3977	3865	
Age [mean (SD)] (y)	71.1 (8.4)	71.0 (8.4)	0.67
Race			
White	3579 (90.0)	3458 (89.5)	0.81
Black	258 (6.5)	272 (7.0)	
Other	103 (2.6)	99 (2.6)	
Unknown	37 (0.9)	36 (0.9)	
Geographic region			
Northeast	85 (2.1)	103 (2.7)	0.47
Midwest	877 (22.1)	863 (22.3)	
South	2714 (68.2)	2611 (67.6)	
West	301 (7.6)	288 (7.5)	
Index fracture location			
Hip	562 (14.1)	588 (15.2)	0.18
Femur	116 (2.9)	103 (2.7)	0.50
Humerus	355 (8.9)	330 (8.5)	0.54
Wrist/forearm	474 (11.9)	430 (11.1)	0.27
Pelvis	160 (4.0)	152 (3.9)	0.84
Spine	1207 (30.3)	1139 (29.5)	0.39
Ribs	1210 (30.4)	1231 (31.8)	0.17
Ankle	195 (4.9)	188 (4.9)	0.94
Deyo-Charlson Comorbidity Index [mean (SD)]	1.6 (2.1)	1.7 (2.1)	0.35
Key comorbid conditions			
Osteopenia	43 (1.1)	53 (1.4)	0.24
Arthritis	1191 (29.9)	1125 (29.1)	0.42
Myocardial infarction	100 (2.5)	100 (2.6)	0.84
Cerebrovascular disease	625 (15.7)	677 (17.5)	0.03
Chronic obstructive pulmonary disease	1189 (29.9)	1224 (31.7)	0.09
Hypothyroidism	576 (14.5)	491 (12.7)	0.02
Diabetes	1487 (37.4)	1413 (36.6)	0.45
Obesity	670 (16.8)	650 (16.8)	0.97
Concomitant medication use			
NSAIDs	776 (19.5)	719 (18.6)	0.31
Glucocorticoids	742 (18.7)	751 (19.4)	0.38

NSAID indicates nonsteroidal anti-inflammatory drug.

Figure 2 compares the proportion of individuals obtaining a BMD evaluation and/or initiating OPT. Evaluated at 12 months postindex, there was a significant difference between the intervention and control groups in the uptake of BMD evaluation (10.7% for the intervention group vs. 4.9% for the control group), with an OR (95% CI) of 2.31 (1.94, 2.76) and the number needed to the outreach of 18. While the absolute percentages were lower, there was also a significant difference between the intervention and control groups in the initiation of OPT (4.0% for the intervention group and 2.5% for the control group), with an OR (95% CI) of 1.60 (1.24, 2.07) and the number needed to outreach to initiate OPT of 69. Among patients receiving a BMD evaluation, close to 30% initiated OPT (data available upon request). In measuring the uptake of either BMD evaluation or osteoporosis-specific medication initiation (composite measure), results were similar to BMD evaluation or osteoporosis-specific medication initiation alone, with an OR (95% CI) of 2.09 (1.77, 2.46) (Fig. 2).

There was an incrementally larger impact of the intervention on both BMD evaluation and OPT initiation, as the intensity of the intervention increased moving from light to moderate and heavy exposures (Fig. 3). In absolute percentage terms, 25.0% of patients

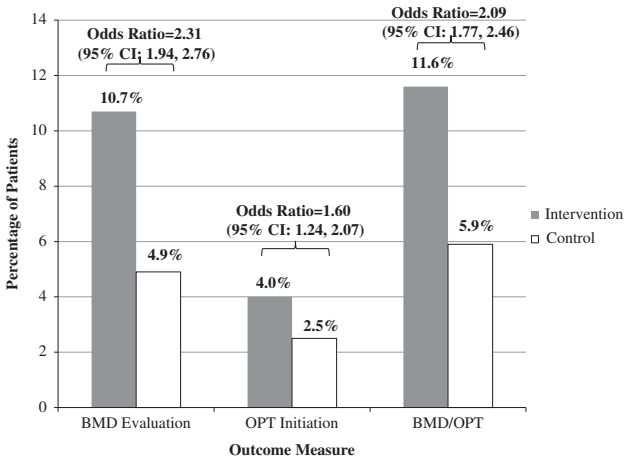

FIGURE 2. Evaluation of BMD and initiation of osteoporosis treatment postintervention. BMD indicates bone mineral density; CI, confidence interval; OPT, osteoporosis treatment.

receiving the heavy exposure went on to have a BMD evaluation, which was higher than those receiving the moderate exposure (13.7%) and higher than those receiving the lighter exposure (6.5%, $P < 0.01$ for both comparisons). Results were qualitatively similar for initiation of OPT, and the uptake of either BMD evaluation or OPT (Fig. 3).

Table 2 displays the multivariable logistic regression models for BMD evaluation and initiation of OPT. The ORs for intervention versus control were directionally and statistically consistent with the results in Figure 2, indicating that increased odds of receiving a BMD evaluation or OPT remained, even after adjusting for several key baseline characteristics. In the BMD evaluation model, Black race [OR (95% CI): 0.35 (0.21, 0.57)] and diagnosis of myocardial infarction [0.44 (0.19, 1.00)] were associated with lower odds of receiving a BMD evaluation, while in the OPT model, Black race [0.51 (0.27, 0.98)] and a diagnosis of diabetes [0.76 (0.56, 1.04)] were associated with lower odds of receiving treatment. In both models, index fractures of the hip [2.07 (1.60, 2.68) for BMD evaluation and 3.68 (2.58, 5.25) for OPT] or vertebrae [1.57 (1.26, 1.95) for BMD evaluation and 2.29 (1.65, 3.17) for OPT] and the use of glucocorticoids [1.52 (1.21, 1.91) for BMD evaluation and 1.79 (1.30, 2.47) for OPT] were associated with higher odds of receiving a BMD evaluation or OPT, as well as a chronic obstructive pulmonary disease [1.33 (0.98, 1.79)] for higher odds of initiating OPT (Table 2).

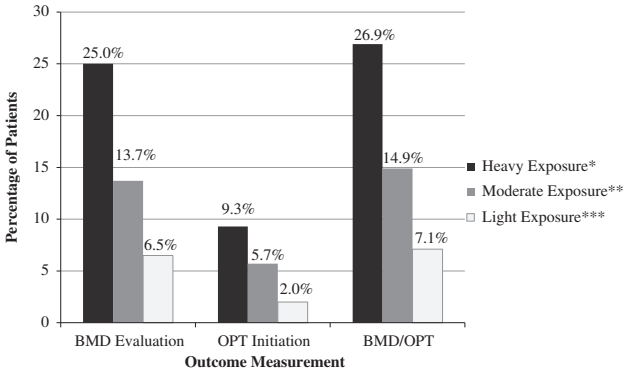

FIGURE 3. Evaluation of BMD and initiation of osteoporosis treatment postintervention—moderate and heavy versus light exposure. BMD indicates bone mineral density; OPT, osteoporosis treatment.

TABLE 2. Multivariable Logistic Regression Models

Independent Variables	BMD Evaluation [AOR (95% CI)]	OPT Initiation [AOR (95% CI)]
Intervention (reference = control)	2.13 (1.74, 2.62)	1.59 (1.19, 2.12)
Age 60–69 (reference = 50–59)	1.15 (0.96, 1.37)	—
Age 70–79 (reference = 50–59)	1.22 (1.04, 1.42)	—
Age 80–85 (reference = 50–59)	1.02 (0.83, 1.25)	—
Black race (reference = White)	0.35 (0.21, 0.57)	0.51 (0.27, 0.98)
Other/unknown race (reference = White)	2.04 (1.38, 3.02)	1.37 (0.74, 2.56)
Northeast region (reference = South)	—	—
Midwest region (reference = South)	—	—
West region (reference = South)	—	—
Index fracture = hip	2.07 (1.60, 2.68)	3.68 (2.58, 5.25)
Index fracture = humerus	—	—
Index fracture = pelvis	—	—
Index fracture = vertebral	1.57 (1.26, 1.95)	2.29 (1.65, 3.17)
Index fracture = ankle	—	—
Deyo-Charlson Comorbidity Index	—	—
Osteopenia	—	—
Myocardial infarction	0.44 (0.19, 1.00)	—
Cerebrovascular disease	—	—
Chronic obstructive pulmonary disease	—	1.33 (0.98, 1.79)
Hypothyroidism	—	—
Diabetes	—	0.76 (0.56, 1.04)
Obesity	—	—
Use of glucocorticoids	1.52 (1.21, 1.91)	1.79 (1.30, 2.47)

AOR indicates adjusted odds ratio; BMD, bone mineral density; CI, confidence interval; OPT, osteoporosis treatment.

DISCUSSION

The osteoporosis outreach program had a significant impact on BMD evaluation and initiation of OPT at 12 months. In addition, the more intensive the program, that is, phone calls in addition to mailings to patients and mailings/faxed communications to physicians, the greater the impact. These results are encouraging in that the odds of receiving a BMD evaluation in the intervention group was 2–3 times the rate of that in the control group, and the odds of receiving OPT in the intervention group was 1.5–2 times the rate of that in the control group. In absolute terms, however, the proportion of patients in the outreach program receiving the BMD evaluation was only ~11%, and those receiving osteoporotic medication ~4% by the end of the 12-month follow-up period, suggesting additional room for improvement. Note that patients who already received a BMD evaluation or osteoporosis medication in the 12 months before observed fragility fractures were not

eligible for participation in this outreach program, and so this patient population was not representative of the entire population of male patients with a fragility fracture. As such, it is possible that patients that qualified for our study were more difficult to reach and/or more resistant to screening or treatment.

These study results are similar to an inexpensive, low-effort, mail-based intervention to providers and patients reported by Majumdar et al,[10] where the intervention resulted in an increase in the rate of OPT starts by 4%–6%. Another program, while mail-based, was sent directly from the medical center at which primary care physicians of patients were affiliated. Patients were informed their physician was aware of this study (physicians were contacted prior), and patients were provided a telephone number for the medical center's DXA scan scheduling department.[11] This intervention resulted in 17.3% of the intervention group receiving DXA screening in comparison to 5.2% in the control group, with a number needed to outreach for BMD evaluation of 9. In our study, the number needed to outreach to receive a BMD evaluation was 18 over 12 months of follow-up suggesting that patients may be more likely to follow-up if the communication came from the medical center and their physician was referenced. Other, more intensive interventions reported in the literature include clinician-driven outreach to patients[12,13] and FLS programs run by nurses specializing in osteoporosis disease management within medical centers.[14–16] The numbers needed to outreach to receive a BMD evaluation in that program were under 10, suggesting coordinator-based models linking multiple departments within medical centers may have a larger impact on outcomes. One caveat is the numbers needed to outreach may be less reliable in programs where patients were not randomly assigned to the exposure and control groups. Of the studies cited above, only Majumdar et al[10] and Warriner et al[11] were randomized. In our study, randomization ensured the intervention and control groups were similar, thereby mitigating selection biases.

Another distinctive feature of this study was that it focused solely on men with a fragility fracture, an uncommon practice in the United States where many programs exist for women in accordance with the HEDIS postfracture quality measure. A review of the literature globally indicates recent FLS programs involve both sexes, even though a majority (three quarters or more) of participants in each of the FLS programs are women, as evidenced in Majumdar et al,[17] van Geel et al,[18] and Pflimlin et al.[19] In a study examining reasons for low attendance in FLS programs, van den Berg et al[20] found male sex to double the odds of nonparticipation. The one exception in FLS programs where the vast majority of participants were male (98%) was a program in Salt Lake City's Veterans Affairs Healthcare System by Lawrence et al,[21] likely reflecting the population base. Regardless of sex, however, the programs were effective in increasing the rate of screening, and to a lesser extent treatment for osteoporosis among participants.

As the intensity of FLS programs increase, the resources needed to implement the programs would increase. In our outreach program, the cost per patient of developing, implementing, and evaluating the program was ~$70 per patient, with approximately half of the cost devoted to program development and evaluation and the other half to program implementation. A review of the literature indicated other programs globally ranged in cost from $97 (Canadian) to £420 (British).[22–24] In our study, the cost of program development and evaluation was relatively fixed, while program implementation was a variable cost per person, with some overhead included. This cost per patient could be reduced by expanding the program to a larger population, given the increased economy of scale.

When evaluating existing programs, assessing the time and resource requirements, as well as the ease of scalability as a desirable characteristic of the intervention, would add to the utility of evaluating these patient outreach programs.

Ultimately, the goal of these types of outreach programs is to reduce the rate of subsequent fractures and slow the course of osteoporosis as a disease. In a prospective study following men and women 50 years and older with nonvertebral fractures in an FLS program in the Netherlands, researchers found the incidence of subsequent fractures to be similar between the 2 groups in the first year but found significantly lower rates of subsequent fractures for patients in the FLS by the end of the second year (hazard ratio = 0.44, 95% CI: 0.25, 0.79).[25] Another prospective randomized controlled trial screening women 70–85 years of age in UK community-based practices found a reduction in hip fractures over a 5-year period relative to women not screened, with a hazard ratio (95% CI) of 0.72 (0.59, 0.89, $P = 0.02$).[26] In that study, patients in the intervention arm were evaluated using the Fracture Risk Assessment Tool (FRAX) and those at high risk for hip fracture were recommended to receive a BMD evaluation, followed by treatment recommendation for women with BMD *T*-scores of −2.5. There the use of osteoporosis medications was higher in the screening group than the control group by the end of the first year (15% vs. 4%). Notably, uptake was highest in those identified as a subgroup with the highest risk (78%). These studies suggest targeting patients at the highest risk may yield greater results in treatment rates, and ultimately in reducing subsequent fractures.

We took a traditional approach of sending mailed letters and facsimiles and making phone calls to landlines only to reach patients and their physicians for this outreach program. One lesson learned was that when patients and their physicians were both reached by phone (the most intensive exposure), as much as one quarter of the patients went on to obtain a BMD screening, which is encouraging. These findings suggest that continuing to explore means of reaching more patients and their physicians to have a live conversation is important. In our outreach program, there was no follow-up communication after the letters and phone attempts. Exploring alternative lengths of exposure may shed further light for public health decision-makers wishing to implement successful programs in the future. Furthermore, understanding barriers to receiving the BMD screening, such as lack of transportation to a facility with DXA scan equipment, will be important. This barrier may potentially be addressed by bringing portable DXA scans into the home. In addition, future research could focus on segments of the population most responsive to each alternative type of outreach program to raise the screening rate among those at high risk.

One limitation of the study was that it was not possible to know whether a letter or facsimile was read by the

recipient. The only insight was that it was not returned to the sender due to the wrong address or contact number. Another limitation was that we applied the Warriner et al[9] algorithm to define a fragility fracture in an attempt to limit fractures to those with a high likelihood of underlying osteoporosis, but we could not be certain that patients had in fact been diagnosed with osteoporosis. This and other potential sources of misclassification are the exclusion of patients having a documented fracture within 60 days before the index fracture at the same site as the index fracture, and exclusion of fractures due to trauma. Finally, the secondary analysis of the impact of intensity levels of the intervention may be subject to self-selection bias, that is, a reflection of patient and physician motivation rather than accurately reflecting an impact of the intervention. Hence, these results should be interpreted with caution.

In conclusion, the osteoporosis outreach program had a significant impact on BMD evaluation and OPT initiation at 12 months, with a higher impact on patients receiving increased intensity of the contact. However, a more intensive outreach program identifying and enrolling patients at the highest risk may be needed to yield a greater impact on BMD evaluation, initiation of OPT, and ultimately a reduction in subsequent fractures.

APPENDIX

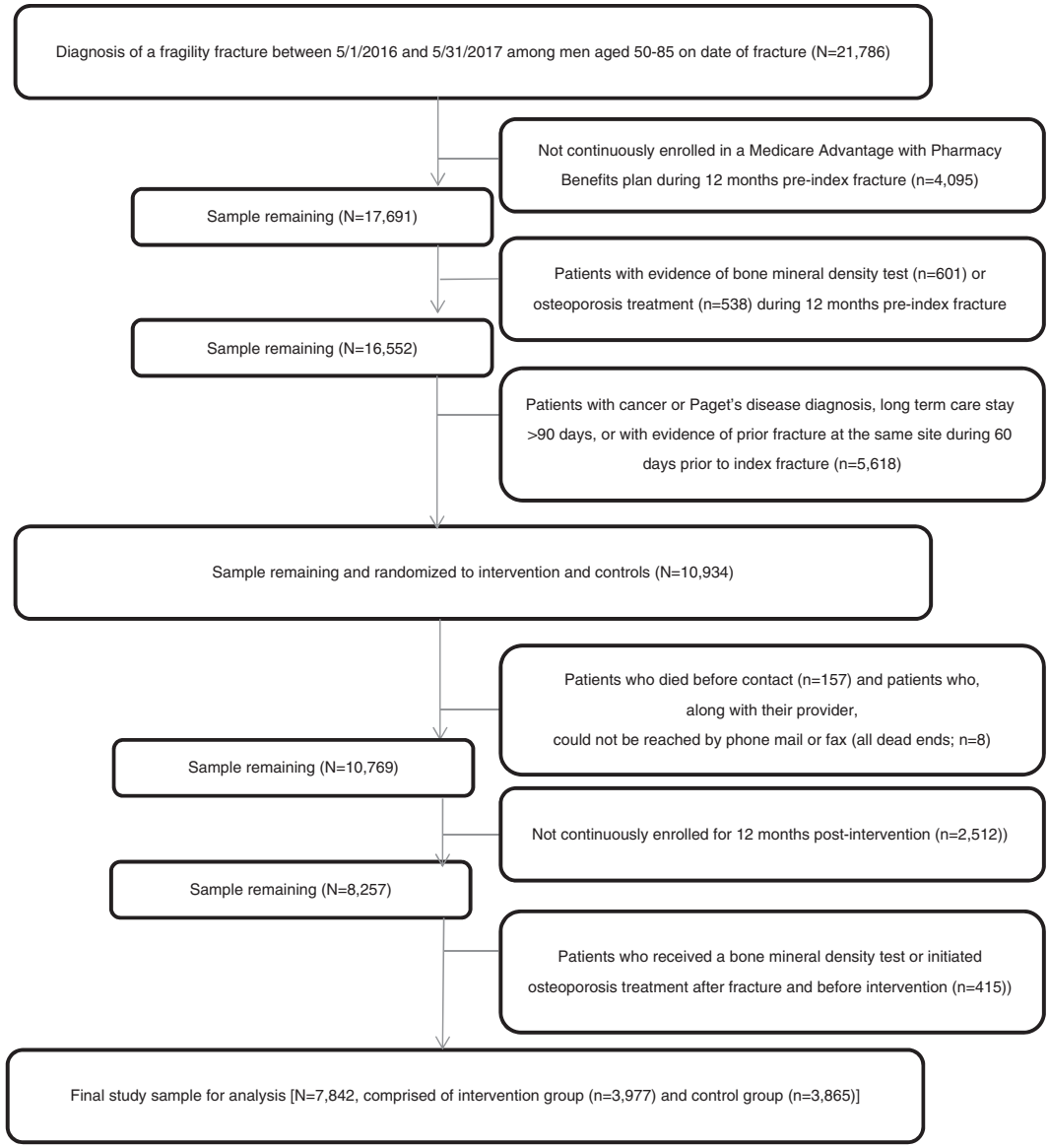

FIGURE A1. Attrition diagram for study cohort.

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