Published in final edited form as:

Ann Pharmacother. 2018 September ; 52(9): 876–883. doi:10.1177/1060028018770622.

Impact of pharmacist-physician collaboration on osteoporosis treatment rates

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Keywords

pharmacist; osteoporosis; bisphosphonate; calcium and vitamin D; antifracture

Introduction

Osteoporosis is a prevalent disease affecting approximately 9.9 million US adults, and it is reported one in two women over the age of fifty will experience an osteoporosis-related fracture.[1] These fractures can increase mortality risk by approximately 17% in women one year after hip fracture and require more than half of hip fracture patients to need skilled care away from home.[2] In 2005, osteoporotic fractures totaled approximately $17 billion in healthcare expenditures; these expenditures are estimated to rise to $25 billion by 2025.[3]

Osteoporosis remains drastically undertreated. The American Association of Clinical Endocrinologists report only one in seven women who should receive osteoporosis therapy are treated.[4] In the Global Longitudinal Study of Osteoporosis in Women (GLOW), only 58% of women reporting a diagnosis of osteoporosis also reported treatment.[5] These numbers leave a significant portion of patients at undue risk for fractures and their sequelae.

Methods on how to best close this gap in care deserve examination. There have been few studies evaluating the impact of pharmacists on osteoporosis management in a general outpatient adult population. A previous study at a single site by Lai, et al. showed pharmacists can increase education in the management of osteoporosis, improving knowledge and quality-of-life.[6] Hall, et al. demonstrated that a pharmacist-driven service can increase compliance with osteoporosis guidelines in a family medicine clinic with a

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Conflict of Interest:
The authors report no financial or personal conflicts of interest with the subject matter of this manuscript.

Prior Presentation:
St. Louis College of Pharmacy Resident Research Conference, St. Louis College of Pharmacy, May 24, 2017

small group of twenty-two patients followed over six months.[7] The effects of collaborative pharmacist-physician osteoporosis management models employed over longer periods of time or in larger groups have not been evaluated.

The objective of our study was to compare pharmacist-physician management to physician-only management on osteoporosis care and to evaluate the impact of pharmacist intervention on treatment rates of osteoporosis in a family medicine clinic.

Methods

Pharmacist Referral Procedure

Our clinic design involves physicians ordering dual energy X-ray absorptiometry (DXA) scans according to published guidelines and clinical judgment during a scheduled patient visit. These physicians have the option to forward those results to the clinical pharmacist imbedded within the family medicine clinic for review and treatment recommendation. The clinical pharmacy team consists of one ambulatory care clinical pharmacist, pharmacy practice residents (PGY-1 and PGY-2) when available, and advanced practice pharmacy experiential students. All pharmacy students and residents complete additional learning experiences in osteoporosis (i.e. readings and topic discussions) prior to reviewing a DXA scan, and all recommendations are reviewed by the clinical pharmacist prior to relaying to physicians. When the clinical pharmacist receives a referred DXA scan, they review the patient chart and DXA scan to determine appropriate pharmacologic and nonpharmacologic management options. Nonpharmacologic management includes assessment and recommendations for adequate daily calcium and Vitamin D intake through diet and/or supplements (~1,200mg calcium and 800 international units Vitamin D), in accordance with Institute of Medicine recommendations.[1] Pharmacist recommendations are communicated using the electronic medical record, and the physician responds with approval or adjustment to the plan. Upon final physician approval, the clinical pharmacist contacts the patient to discuss the DXA result, provide education, and implement the approved management plan.

Study Design and Participants

This retrospective cohort analysis involved manual chart review of all outpatient encounters documented in Epic® electronic medical record. Patients were identified using the reporting function within the electronic medical record to locate those with a DXA scan ordered by a Mercy Clinic Family Medicine physician between June 1, 2008 and June 1, 2016. All female patients over the age of 65 years with a DXA scan completed at a Mercy facility were included; there were no exclusion criteria. Patients with a documented outpatient encounter with a pharmacist regarding DXA scan results within one month after the date of DXA scan were included within the collaborative pharmacist-physician management group. Patients without pharmacist documentation following DXA scan were included in the physician-only management group.

Laboratory results were reviewed for one year prior to and one month following DXA scans. If available, patient completed surveys regarding personal and/or family fracture history, current tobacco and alcohol use were reviewed. Prescription authorization history was

collected from two years prior to first DXA through the end of the study to determine prescription initiation and continuation. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Washington University.[8] REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. The study was approved by the Mercy Hospital St. Louis and St. Louis College of Pharmacy institutional review boards.

Outcomes

The primary outcome was the rate of initiation or continuation of prescription antifracture therapy in patients with high fracture risk. Initiation was defined as a prescription written within the month following DXA scan and continuation defined as having an active prescription for at least one month following DXA scan. All prescription antifracture therapies were included: alendronate, risedronate, zoledronic acid, densoumab, ibandronate, raloxifene, calcitonin, and teriparatide. For the purposes of this analysis, high fracture risk was defined as a T-score of ≤ −2.5 at lumbar spine, left or right femoral neck, or 33% radius or a FRAX 10-year risk score of major osteoporotic fracture ≥ 20% or of hip fracture ≥ 3%. Secondary outcomes included the rate of prescription antifracture therapy recommendations in high-risk patients, rates of calcium and vitamin D recommendations in all patients, rates of adverse events documented, and medication authorization adherence.

Statistical Analysis

All statistical analyses were performed within SPSS IBM Statistics Software. Baseline characteristics were analyzed using the Chi-square or Fisher's Exact test, as appropriate, or student's t-test for categorical or continuous baseline characteristics, respectively. The primary outcome and secondary outcomes were analyzed using the Chi-square test or Fisher's Exact test with a two-sided p-value of 0.05. An *a priori* power calculation revealed a sample size of 340 patients (170 per group) was required to provide 80% power, sufficient to detect an absolute difference in rates of initiation or continuation of 15% between groups with and without pharmacist intervention using a two-sided Fisher's Exact test with an α of 0.05.

Results

A total of 1,015 DXA scans were included in the analysis, representing 686 unique patients with a mean of 1.5 DXA scans per patient (SD = 0.75 DXA scans per patient, median = 1 DXA per patient). Patients receiving multiple DXA scans could be managed by different groups based upon physician decision to refer to the pharmacist at time of each DXA. There were 347 unique patients found in the physician-only group, 277 unique patients within the pharmacist-physician collaboration group, and 62 patients that had multiple DXA scans included in both groups. Of the 549 physician-managed DXA scans, 237 were high-risk (174 unique patients), and of the 466 pharmacist-physician managed DXA scans, 311 were high-risk (221 unique patients). Of the 686 unique patients, only 351 were considered high-

risk at the time of at least one DXA scan. However, because patients with multiple DXA scans could have been managed by the physician-only group and pharmacist-physician collaboration group over the study period, the sum of the number of high-risk unique patients in each group exceeds 351.

Baseline characteristics at time of each DXA scan for all patients are presented in Table 1. The pharmacist-physician managed DXA scan group was older on average and more likely to be high-risk. There were some significant differences in comorbidities and medications between groups, including pharmacist-physician managed patients being more likely to have a diagnosis of osteoporosis prior to the DXA scan (Table 2). When examining characteristics at time of DXA in patients at high fracture risk, many of the significant differences found in the larger population between study groups were not evident (Table 3). However, the pharmacist-physician managed high risk patients did have significantly lower BMD and corresponding T-scores at the femoral neck which likely resulted in the significantly higher FRAX risk scores for hip fracture observed in the pharmacist-physician group.

Pharmacist-physician managed high risk patients were significantly more likely to initiate or continue prescription antifracture therapy than physician-only managed patients (66% vs. 36%, $p < 0.001$) as shown in Table 4. Initiation of drug therapy was more common in the pharmacist-physician managed high-risk patient population (58% of high-risk patients with documented continuation or initiation), and continuation was more common in the physician-only managed high-risk patients (68% of high-risk patients with documented continuation or initiation). This predominance of initiation in pharmacist-managed patients and of therapy continuation in physician-managed groups was statistically significant ($p < 0.001$).

Additionally, pharmacist-physician managed high-risk patients were significantly more likely to have a documented recommendation for prescription antifracture therapy in the electronic medical record (87% vs 32%, $p < 0.001$), regardless of whether a prescription was written or continued. Calcium and vitamin D recommendation rates were higher in all patients in the pharmacist-physician managed group regardless of risk subgroups, (96% vs 46%, $p < 0.01$).

Although more prescription antifracture therapy was initiated or continued by the pharmacist-physician managed group, there was a similar rate of adverse events documented. There were low- to moderate-risk patients that received prescriptions for antifracture therapy, and adverse event rates were calculated in the whole study population regardless of risk. There were 16 reported adverse events out of 221 patients who initiated or continued antifracture therapy in the pharmacist-physician managed group compared to 4 documented cases of adverse events out of the 107 patients in the physician-only managed group at all risk levels (7.2% vs 3.7%, $p=0.32$). Specific type of adverse event was not always documented in the record but gastrointestinal upset was commonly reported.

As actual refill history was not able to be obtained from the electronic medical record, prescription adherence was assessed with a modified proportion of days covered (PDC) calculation reliant upon prescription authorizations. Each analysis period for prescription

usage began on the date of initial DXA scan included in this study and ended on the date of next DXA scan included within this study period or date of death. The analysis period under the care of either pharmacist-physician collaboration or physician-only management based upon this definition ranged from 14 days to 2832 days, and mean time under care was longer in the physician-managed group (843 ± 585 days in the pharmacist-managed group vs. 982 ± 603 days in the physician-managed, p = 0.046) The PDC calculation incorporated all prescriptions and refills authorized within the analysis period and provided the total days possibly covered. The total number of days covered was then divided by the total number of days in the analysis period. Using this modified PDC calculation method, the pharmacist-managed group had a modified PDC of 0.75 compared to physician-managed group of 0.68 (p = 0.02).

Discussion

The gap between osteoporosis diagnosis and osteoporosis treatment rates is well-documented. [4,5,9,10] Several team-based approaches in different environments have been studied, with variable success.[7, 11–13] The study by Nadrash, et al. evaluated the impact of a clinical pharmacist-physician collaboration also in an ambulatory setting to indicate improved treatment rates but this was solely evaluated in a post-atraumatic fracture population. As this was a quality initiative, the Nadrash, et al. study had a relatively small population with less than 100 participants and did not contain a control group.[11] Heilmann, et al. evaluated a similar population with atraumatic fractures and the appropriate osteoporosis management, either bone mineral density testing or initiating drug therapy, was significantly greater by the clinical pharmacists compared to nurses.[13] To our knowledge, this is the first study of its size that evaluated pharmacist-physician collaboration for osteoporosis management of a general adult female population, with high-risk defined by history of fracture as well as DXA results, in a family medicine clinic. We found that pharmacist-physician partnership is associated with higher antifracture therapy prescription rates in patients classified as high-risk by clinical guidelines. Furthermore, more patients received recommendations for the use of calcium and vitamin D when pharmacists and physicians collaborated. These findings are consistent with a previous study by Hall, et al. of a pharmacist-run osteoporosis service, in which pharmacotherapy rates increased from 32% to 77% after implementation of the pharmacist protocol. Similar to our study, calcium and vitamin D usage also increased from 41% to 100% when a pharmacist-run service was implemented.[7] The concordance between the short-term prospective findings by Hall, et al. and our retrospective long-term data lend weight to the incorporation of pharmacists into osteoporosis management in a family medicine clinic.

The retrospective nature of this study has some inherent limitations, including a heavy reliance on physician and pharmacist documentation within the electronic medical record. We chose to collect data via manual chart review in an attempt to address the potential for documentation outside of fields that are accessed by medical record reporting functions and provide a more thorough picture of each patient at the time of DXA. However, the possibility that important data used in evaluating presence of previous fractures, current adherence, or even presence of adverse events would not be located within the chart or documented after one month of initial DXA remains. Also, a prescription authorization is

not the same as an actual prescription received and taken by a patient. This study utilized prescription authorization to provide the initiation or continuation of prescription antifracture therapy. There was a higher percentage of DXA scans deemed high-risk in the pharmacist-physician group compared to the physician-managed group and this could limit the opportunities for the physician-managed group to initiate or continue antifracture therapy. Perhaps there was a greater likelihood for referral to pharmacists if DXA results included low T-scores, known fractures, or previous trials of medications. While the physician rationale for referrals to pharmacist group was not evaluated in this study, we might consider that anticipated time needed to discuss results and management recommendations could be a factor. Interestingly, the pharmacist-physician collaboration group had a significantly higher number of initiations over continuations when compared to the physician-managed group, which may support the idea that the time devoted to patient counseling and education necessary to successfully initiate therapy was a driver of pharmacist referrals by physicians. Finally, the retrospective nature of our study may have limited our ability to detect recommended drug holidays, an important concept in osteoporosis management, thereby falsely lowering the antifracture treatment rates.

Despite these limitations, our study supports the incorporation of a pharmacist into osteoporosis management as a strategy to improve treatment rates. The possibility of improving osteoporosis treatment rates is imperative from the patient-care standpoint, as antifracture therapies have been shown to have a relative risk reduction in fractures by up to 50%.[14] Furthermore, the economic burden of osteoporosis-related fractures has prompted their inclusion as measures in quality-based physician-reimbursement systems, providing further incentive to healthcare providers to seek novel opportunities for improving care.[15–16] While this study was unable to collect actual refill data, the proportion of days covered with appropriate antifracture therapy was greater in the pharmacist-physician group. A previous study evaluated adherence to bisphosphonate therapy to fracture risk reduction in postmenopausal women and found that increased refill compliance was associated with lower fracture rates. The improved fracture risk reduction was significantly pronounced at compliance rates of 75% and higher.[17]

The targeted education provided by a pharmacist in this area coupled with their accessibility as a healthcare provider is an intriguing idea to overcome some common patient-reported barriers such as underestimating risks associated with untreated osteoporosis, fear of side effects or long-term safety of antifracture therapies, and choosing over-the-counter supplementation or lifestyle changes over prescription antifracture therapy.[18] With the implementation of pharmacist partnerships and protocols, future prospective studies could focus on the clinical impact on morbidity and mortality related to fractures as well as questions that were not examined in this analysis, such as underlying barriers to adherence to antifracture therapy and the effect drug holidays may have on treatment rates with collaborative pharmacist-physician care.

Conclusion and Relevance

This study adds to the growing evidence that pharmacists, in collaboration with physicians, improve the care of the individual with osteoporosis and further close the gap seen in

osteoporosis treatment. Continued exploration and implementation of this multidisciplinary approach could yield substantive improvements in the disheartening figures presented for treatment rates and clinical outcomes in osteoporosis today.

Acknowledgements:

We are grateful for Shefali Barot, PharmD for her work in data collection and chart review to extend the scope of this analysis.

Support:

Supported by Clinical and Translational Science Award (CTSA) Grant [UL1 TR000448] and Siteman Comprehensive Cancer Center and NCI Cancer Center Support Grant P30 CA091842

Abbreviations:

DXA	dual energy X-ray absorptiometry
BMD	bone mineral density
REDCap	Research Electronic Data Capture

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Table 1:

Demographic Characteristics at Time of DXA for All Patients by Study Group

Characteristic	Physician-Managed (n = 549 DXA scans[a])	Pharmacist-Managed (n = 466 DXA scans[a])	p-value
Age (yrs), mean ± SD	73.36 ± 6.5	75.26 ± 7.2	< 0.001
Race, n (%)			0.084
Caucasian	471 (86.1)	421 (90.3)	
African American	52 (9.5)	25 (5.4)	
Hispanic	4 (0.7)	5 (1.1)	
Height (cm), mean ± SD	160.7 ± 8.1	160.0 ± 7.0	0.208
Weight (kg), mean ± SD	72.6 ± 16.8	68.3 ± 14.6	< 0.001
BMD (g/cm^2), mean ± SD			
Lumbar spine	1.14 ± 0.208	1.07 ± 0.201	< 0.001
Right femoral neck	0.836 ± 0.127	0.780 ± 0.124	< 0.001
Left femoral neck	0.837 ± 0.134	0.797 ± 0.501	0.078
Radius	0.740 ± 0.125	0.695 ± 0.121	< 0.001
T-scores, mean ± SD			
Lumbar spine	−0.340 ± 1.705	−0.861 ± 1.642	< 0.001
Right femoral neck	−1.418 ± 0.938	−1.840 ± 0.899	< 0.001
Left femoral neck	−1.411 ± 0.967	−1.855 ± 0.989	< 0.001
Radius	−1.531 ± 1.494	−2.055 ± 1.384	< 0.001
FRAX Scores, mean ± SD			
Major osteoporotic	12.99 ± 4.83	14.71 ± 6.53	< 0.001
Hip fracture	2.95 ± 2.19	4.39 ± 4.24	< 0.001
Fracture history[b], n (%)	156 (28.4)	155 (33.2)	0.101
High risk, n (%)	237 (43.2)	311 (66.7)	< 0.001
High risk based on T-score	122 (22.2)	224 (48.1)	< 0.001
High risk based on FRAX	135 (42.6)	174 (56.3)	0.001
High risk based on both T-score and FRAX	20 (3.6)	87 (18.7)	< 0.001
TSH (uIU/mL), mean ± SD	3.37 ± 20.02	2.31 ± 2.25	0.463
Vitamin D[c] (pg/ml), mean ± SD	35.1 ± 14.2	36.3 ± 14.0	0.574
Documented ADR to antifracture therapy[d], n (%)	24 (4.4)	38 (8.2)	0.012
Alcohol use[e], n (%)	18 (3.3)	16 (3.4)	0.891
Current smoker, n (%)	23 (4.2)	31 (6.7)	0.081

[a]Unique patients: n = 347 physician-managed group, n = 277 unique patients pharmacist-physician collaboration, n = 62 patients with DXAs in both groups

[b]Determined by the patient's response on the pre-procedure DXA scan form.

[c]Total 25-hydroxy vitamin D

[d] Determined from review of chart notes within one year of DXA and documented allergies.

[e] Defined as a documented alcohol consumption of > 3 drinks per day within the patient's social history or chart note or patient response on the pre-procedure DXA scan form.

Table 2:

Comorbidities and Medications at Time of DXA for All Patients by Study Group

Characteristic	Physician-Managed (n = 549 DXA scans[a])	Pharmacist-Managed (n = 466 DXA scans[a])	p-value
Comorbidities[b], n (%)			
Osteoporosis	104 (18.9)	182 (39.1)	< 0.001
Diabetes mellitus	67 (12.2)	38 (8.2)	0.035
Chronic kidney disease	36 (6.6)	64 (13.7)	< 0.001
COPD	22 (4.0)	22 (4.7)	0.578
Hyperthyroidism	2 (0.4)	7 (1.5)	0.089
Paget's disease	0 (0.0)	1 (0.2)	0.459
Vitamin D deficiency	23 (4.2)	21 (4.5)	0.805
Breast cancer or history of solid organ transplant	21 (3.8)	40 (8.6)	0.001
Rheumatoid or osteoarthritis	167 (30.4)	176 (37.8)	0.014
Medications[c], n (%)			
Proton pump inhibitor	122 (22.2)	103 (22.1)	0.964
Inhaled corticosteroid	28 (5.1)	26 (5.6)	0.735
Systemic corticosteroid	7 (1.3)	5 (1.1)	0.767
SSRI	96 (17.5)	50 (10.7)	0.002
Warfarin	25 (4.6)	12 (2.6)	0.094
Thiazolidinedione	1 (0.2)	0 (0.0)	1.000
Thyroid supplementation	129 (23.5)	125 (26.8)	0.223
Hormone replacement therapy	33 (6.0)	21 (4.5)	0.287
Aromatase inhibitor	13 (2.4)	8 (1.7)	0.468
Chemotherapy	3 (0.5)	7 (1.5)	0.201
Vitamin D replacement[d]	13 (2.4)	14 (3.0)	0.530
Calcium and vitamin D	237 (43.2)	318 (68.2)	< 0.001
Raloxifene	7 (1.3)	12 (2.6)	0.128
Bisphosphonate	78 (14.2)	90 (19.3)	0.029
Denosumab	2 (0.4)	8 (1.7)	0.051
Teriparatide	1 (0.2)	1 (0.2)	1.000

[a]Unique patients: n = 347 physician-managed group, n = 277 unique patients pharmacist-physician collaboration, n = 62 patients with DXAs in both groups

[b]Comorbidities were collected from the most recent documented problem list within chart notes prior to DXA scan. Less than 1% incidence (and p-value greater than 0.05) for the following comorbidities: alcoholism, Grave's disease, hyperparathyroidism, Celiac disease, Crohn's disease or ulcerative colitis, malabsorption. Although data was collected for additional disease states, no patients with Hashimoto's disease, calcium deficiency, hypophosphatemia, or AIDS/HIV were identified.

[c]Medications were collected from the most recent medication list within chart notes prior to DXA scan. Although data was collected for additional medications, no patients on lithium, heparin derivatives, or calcitonin were identified.

[d]Defined as vitamin D2 or D3 at a dose of 50,000 units/week or greater

Table 3:

Demographic Characteristics at Time of DXA for High-Risk Patients by Study Group

Characteristic	Physician-Managed (n = 237 DXA scans[a])	Pharmacist-Managed (n = 311 DXA scans[a])	p-value
Age (yrs), mean ± SD	77.06 ± 6.2	77.26 ± 7.2	0.733
Race, n (%)			0.218
Caucasian	214 (91.1)	282 (90.7)	
African American	14 (6.0)	11 (3.5)	
Hispanic	1 (0.4)	5 (1.6)	
Height (cm), mean ± SD	159.6 ± 9.3	159.6 ± 6.9	1.000
Weight (kg), mean ± SD	66.0 ± 13.2	63.9 ± 11.8	0.051
BMD (g/cm^2), mean ± SD			
Lumbar spine	1.040 ± 0.170	1.026 ± 0.200	0.387
Right femoral neck	0.749 ± 0.084	0.729 ± 0.101	0.014
Left femoral neck	0.745 ± 0.084	0.722 ± 0.099	0.004
Radius	0.655 ± 0.101	0.654 ± 0.106	0.911
T-scores, mean ± SD			
Lumbar spine	−1.190 ± 1.343	−1.238 ± 1.598	0.709
Right femoral neck	−2.058 ± 0.646	−2.213 ± 0.731	0.010
Left femoral neck	−2.081 ± 0.603	−2.233 ± 0.684	0.007
Radius	−2.549 ± 1.137	−2.514 ± 1.229	0.733
FRAX Scores, mean ± SD			
Major osteoporotic	16.620 ± 4.316	17.446 ± 6.556	0.093
Hip fracture	4.656 ± 2.261	6.053 ± 4.543	< 0.001
Fracture history[b], n (%)	49 (20.7)	60 (19.3)	0.746
TSH (uIU/mL), mean ± SD	2.292 ± 1.515	2.309 ± 2.341	0.923
Vitamin D[c] (pg/ml), mean ± SD	34.2 ± 11.8	36.8 ± 14.4	0.025
Documented ADR to antifracture therapy[d], n (%)	20 (8.4)	31 (10.0)	0.557
Alcohol use[e], n (%)	8 (3.4)	11 (3.5)	1.000
Current smoker, n (%)	10 (4.2)	20 (6.4)	0.344

[a]Unique patients: n = 174 physician-managed group, n = 221 pharmacist-physician collaboration

[b]Determined by the patient's response on the pre-procedure DXA scan form.

[c]Total 25-hydroxy vitamin D

[d]Determined from review of chart notes within one year of DXA and documented allergies.

[e]Defined as a documented alcohol consumption of > 3 drinks per day within the patient's social history or chart note or patient response on the pre-procedure DXA scan form.

Table 4:

Rates of Therapy Initiation, Continuation, and Recommendations

Outcome	Physician-Managed	Pharmacist-Managed	p-value
Primary Outcome			
Rate of initiation or continuation[a] in high-risk patients[b], n[c] (%)	85[d] (35.8)	206[e] (66.2)	< 0.001
Secondary outcomes			
Rate of prescription antifracture therapy recommendation[f] in high-risk patients[b], n[c] (%)	76 (32.1)	271 (87.1)	< 0.001
Calcium and vitamin D recommendation[f] in all patients[f], n[c] (%)	253 (46.1)	446 (95.7)	< 0.001
Calcium and vitamin D recommendation[f] in low- to moderate-risk patients[h], n[c] (%)	142 (45.5)	151 (97.4)	< 0.001

[a] Initiation and continuation rates were determined by reviewing prescription authorization history, as detailed in Methods.

[b] High risk patient groups: physician-managed (n = 237 DXA scans in 174 unique patients) vs. pharmacist-managed (n = 311 DXA scans in 221 unique patients)

[c] Number of DXA scans

[d] Initiation in 27 patients and continuation in 58 patients in physician-managed group

[e] Initiation in 119 patients and continuation in 87 patients in pharmacist-managed group

[f] Recommendations were determined from reviewing all documented chart notes, letters, physician-to-patient emails, telephone calls, office visits, and hospital admissions within the month following DXA scan.

[g] All patient groups: physician-managed (n = 549 DXA scans) vs. pharmacist-managed (n = 466 DXA scans)

[h] Low-to-moderate risk patient groups: physician-managed (n = 312 DXA Scans) vs. pharmacist-managed (n = 155 DXA scans)