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ORIGINAL REPORT

Agreement and validity of pharmacy data versus self-report for use of osteoporosis medications among chronic glucocorticoid users†

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SUMMARY

Purpose Pharmacy and linked claims databases are commonly used to determine medication receipt as a measure of quality of care. However, these data sources have not been previously compared with self-reported data for receipt of medications used for glucocorticoid-induced osteoporosis (GIOP).

Methods Using databases from a national managed care organization (MCO), we identified 6282 chronic glucocorticoid users (60+ days in 18 months). We compared self-reported current use of alendronate, risedronate, calcitonin, and raloxifene (reference standard) to different intervals of preceding pharmacy data to determine agreement, sensitivity, specificity, and positive and negative predictive values of the pharmacy data.

Results Survey respondents ($n = 2363$) were mean $\pm$ SD age 53 ± 14 years old, 70% women, and 78% Caucasian. Agreement between self-reported and pharmacy data ranged from Kappa = 0.64 (95%CI 0.53–0.75) (calcitonin) to 0.80 (0.76–0.84) (alendronate). The positive predictive value of a filled prescription in the pharmacy database in the prior 6 months exceeded 90% compared to the reference standard of self-reported current bisphosphonate use. However, the 6-month interval of pharmacy data failed to capture >25% of self-reported current bisphosphonate users. The optimal interval of pharmacy data to distinguish between current and past bisphosphonate users was 120–180 days.

Conclusions Among chronic glucocorticoid users enrolled in managed care, underreporting of current osteoporosis medication use was uncommon, and agreement between self-report and pharmacy data was high. Use of pharmacy data alone is unlikely to underestimate quality of osteoporosis care, but different intervals of pharmacy data have important implications on the ability to identify current users of osteoporosis medications. Copyright © 2006 John Wiley & Sons, Ltd.

KEY WORDS — self report; pharmacy; osteoporosis; agreement; sensitivity and specificity; alendronate; risedronate; bisphosphonate; diagnostic tests; survey

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INTRODUCTION

Process-of-care measures derived from administrative claims data are commonly used to assess health care quality.[1,2] In studies of glucocorticoid-induced osteoporosis (GIOP), for example, quality-of-care endpoints often include receipt of medications to prevent or treat GIOP and receipt of bone mass measurement, a screening test used to assess fracture risk.[3–5] GIOP endpoints related to medication use are often documented by a single filled prescription for medications of interest. This conservative definition of quality is a useful starting point but fails to differentiate current, ongoing use of a prescription from only one filled prescription. Because emerging evidence supports the contention that persistent use of bisphosphonate medications confers greater fracture protection,[6] improved discrimination between past and current use of osteoporosis therapies is useful. In addition to issues of medication adherence, use of only pharmacy claims may underreport medications that were received from sources outside of the typical pharmacy benefits provided through health plans (e.g., pharmaceutical drug assistance programs).

Patient self-report of medication use, therefore, may complement pharmacy databases and may also be useful in situations where pharmacy and/or claims data are unavailable. Although several studies have suggested that patients underreport *prior* use of some osteoporosis therapies (e.g., estrogens),[7–9] little is known about how pharmacy and claims data compare with self-reported *current* use of newer osteoporosis medications and the receipt of bone mass measurement.

Among chronic glucocorticoid users enrolled in a large U.S. managed care plan, we examined agreement between filled prescriptions in the pharmacy database and self-reported current use of several osteoporosis medications. Using covariates available from a linked administrative claims database and a patient survey, we also identified factors associated with discordance between the two data sources. Finally, we determined the optimal interval of pharmacy data to distinguish between current and past bisphosphonate use.

METHODS

Study Population

Chronic glucocorticoid users were identified within a national managed care organization (MCO) population covering approximately 14 million members.[3] These users and their demographic and disease characteristics were identified from the linked claims and pharmacy databases of the MCO's health maintenance organization, point of service, and preferred provider organization health plans. Diseases, medications, and procedures were identified using International Classification of Diseases 9th revision codes (ICD-9), National Drug Codes (NDC), and Common Procedural Terminology (CPT-4) codes, respectively. All individuals in the cohort had pharmacy benefits with variable copayments.

Cohort inclusion criteria

Chronic glucocorticoid use was defined by 60 or more days of filled outpatient oral glucocorticoid prescriptions from 1 July 2001 to 31 December 2002 (the 'glucocorticoid eligibility period'). Each member was required to be at least 18 years of age and enrolled in the health plan at least 6 months prior to their first qualifying glucocorticoid prescription (the 'index date') and throughout the study period. Qualifying glucocorticoids identified using pharmacy data included prednisone, prednisolone, dexamethasone, and other oral systemic glucocorticoids commonly used in the United States. Because patterns of bisphosphonate use might differ by disease indication or in persons with certain comorbidities, we excluded individuals with history of organ transplantation, Paget's disease of bone, malignancy (excluding nonmelanoma skin cancers), HIV/AIDS, alcoholism, and dementia. A total of 6282 health plan members met these criteria and were selected for further examination.

Administrative data source

Pharmacy data from 1 January 2001 to 31 October 2003 was used to ascertain the frequency of filled prescriptions, days supply for each refill, and dosages for medications used to prevent or treat GIOP. These medications included alendronate, risedronate, raloxifene, and calcitonin. Patients filling oral bisphosphonates at dosages used for Paget's disease (i.e., alendronate 40 mg daily, risedronate 30 mg daily) were excluded from the study. The same 34-month time period was examined for procedure codes indicating that bone mass measurement had been performed. Because our multivariable models required unique observations, and to ensure that the calculated medication exposure time based on dispensed dosage (i.e., the legend duration)[10] fell within 180 days, individuals reporting current use of both alendronate and risedronate and those receiving more than 3 months of bisphosphonate in a single

prescription were excluded from analysis ($n = 4$ individuals excluded for either reason).

Mailed patient survey

In August of 2003, we mailed a four-page, 69-question survey to 6282 eligible members meeting our definition of chronic glucocorticoid use. A follow-up postcard and a second survey were mailed to non-responders within 60 days of the first mailing. In the survey, individuals were asked, 'Are you currently taking . . .' for each of the medications of interest. Both the generic and brand name of the drug were included for each question. Respondents were also asked, 'Have you ever had a measurement done of your bone mineral density with a DXA machine (a DXA scan is an X-ray test to measure your bone density and your risk for osteoporosis)?' The exact date each member returned the survey was recorded and linked to corresponding pharmacy and administrative data to allow comparison between self-report and pharmacy/claims data. Survey questions left blank or with multiple responses were treated as missing data and excluded from analysis.

Statistical analyses

Descriptive statistics were used to compare patient characteristics using administrative data. Categorical variables were examined using the Chi-square test of independence, and continuous variables were compared using the two-tailed *t*-test. Agreement between filled prescriptions within 180 days prior to the return of the survey and self-reported current use of each osteoporosis medication (the reference standard) was analyzed using Kappa statistics, and 95% CIs were calculated using the method suggested by Fleiss *et al.*[11] Various intervals of pharmacy data (i.e., 30, 45, 60, 90, 120, 180, and 270 days) were used to examine the sensitivity, specificity, positive, and negative predictive values of pharmacy data compared to the reference standard of self-reported current oral bisphosphonate use. These data were used to plot receiver operator curves (ROC) to identify the interval of pharmacy data that maximized sensitivity and specificity. ROC curves were plotted for both the entire cohort (i.e., bisphosphonate users and non-users) and separately for individuals that had ever filled at least one bisphosphonate prescription during the study period (i.e., current and past bisphosphonate users).

Among unique patients that self-reported current use of an oral bisphosphonate ($n = 465$), we performed multivariable stepwise logistic regression to identify factors associated with lack of a filled bisphosphonate prescription in the preceding 180 days. We also used multivariable logistic regression to examine factors associated with survey respondents reporting that they had *never* taken glucocorticoids, despite the fact that pharmacy data indicated that every individual in our cohort had filled at least 60 days of oral glucocorticoids prior to receiving the survey. For all multivariable models, covariates of significant interest (e.g., income) were 'forced in.' Those significant at a univariate p value < 0.25 were also entered, and using a backward elimination procedure, a p value < 0.05 was required to remain in the model. Pre-hypothesized interactions were examined to look for important effect modification as described in table footnotes. Model building was conducted according to Hosmer and Lemeshow,[12] and model discrimination was assessed using a c statistic.[13] Data management and statistical analysis was performed using SAS (SAS Institute, Cary, NC).

RESULTS

Thirty-eight per cent ($n = 2363$) of the managed care enrollees that met the definition for chronic glucocorticoid use returned the survey. Their characteristics, stratified by whether or not they filled at least one prescription for an anti-resorptive agent for osteoporosis (i.e., alendronate, risedronate, calcitonin, risedronate) during the 34-month study period, are described in Table 1. Individuals receiving anti-resorptive medications were older, more likely to be female and Caucasian, and had a greater number of comorbid conditions. Alendronate was the most commonly filled prescription for GIOP. Compared to the cohort of survey responders, the survey non-responders were younger (48 vs. 53 years) and more likely to be men (36% vs. 30%) (data not shown). Their duration of enrollment in the health plan, mean prednisone dose, and average number of comorbid conditions was similar to survey responders.

Agreement and diagnostic properties of pharmacy data compared to self-reported current use of osteoporosis medications (reference standard)

Agreement between self-reported current use of four osteoporosis medications and filled prescriptions for these drugs is shown in Table 2. The 180 days of pharmacy data prior to the date of each member's returned survey was used for comparisons. Agreement was highest for alendronate (Kappa = 0.80) and was

Table 1. Characteristics of chronic glucocorticoid (GC) users enrolled in managed care responding to mailed survey (October 2003) according to osteoporosis treatment status ($n = 2363$)

	Treated ($n = 660$)*	Untreated ($n = 1703$)	
	Mean (SD) or *N* (%)	Mean (SD) or *N* (%)	*p* value
Demographics			
Age (years)	56 (12)	52 (14)	<0.0001
Women	530 (80)	1126 (66)	<0.001
Length of enrollment in the health plan prior to index glucocorticoid prescription (months)	27 (13)	27 (13)	NS
Ethnicity†			<0.001
Caucasian	516 (83)	1225 (76)	
African American	67 (11)	234 (14)	
Other (e.g., Asian, Hispanic)	37 (6)	157 (10)	
Did not graduate from high school†	55 (9)	153 (9)	NS
Married †	431 (67)	1117 (67)	NS
Employed†	273 (45)	934 (59)	<0.0001
Annual household income < $40 000†	253 (44)	606 (39)	NS
Glucocorticoid Use			
Average prednisone equivalent dose (mg/day)	15 (13)	16 (14)	NS
Duration of prednisone use during the study period (months)	11 (6)	9 (6)	<0.0001
New glucocorticoid user (≥90 days without prior prescription)	362 (55)	1104 (65)	<0.0001
Medical comorbidities			
Number of comorbid conditions	7.7 (3.4)	6.3 (3.1)	<0.0001
Medical diagnoses from claims data			
Diabetes	108 (16)	278 (16)	NS
Hypertension	327 (50)	718 (42)	<0.01
Chronic kidney disease	52 (8)	136 (8)	NS
Congestive heart failure	58 (9)	130 (8)	NS
Diagnoses associated with GC use			
Rheumatoid arthritis	290 (44)	664 (39)	<0.05
Chronic obstructive pulmonary disease	112 (17)	206 (12)	<0.01
Systemic lupus erythematosus	95 (14)	180 (11)	<0.01
Asthma/reactive airway disease	93 (14)	192 (11)	NS
Inflammatory bowel disease	35 (5)	144 (8)	<0.01
At least one osteoporosis medication filled prescription during the 34-month study period‡			
Alendronate	422 (64)	N/A	N/A
Risedronate	184 (28)		
Calcitonin	89 (13)		
Raloxifene	58 (8)		

*Filling at least one prescription for alendronate, risedronate, calcitonin, or raloxifene during the entire study period.
†Total less than 2363 because of missing survey data.
‡Totals > 100% because some individuals received more than one type of medication during the study period.

similar in magnitude for the other three medications. The positive predictive value of the pharmacy data (180-day interval) compared to the reference standard of self-reported current medication use exceeded 90% for both oral bisphosphonates and was only slightly lower for calcitonin and raloxifene. Using progressively shorter intervals of pharmacy data (e.g., 60 days), the positive predictive value of the pharmacy data approached 100% (data not shown). However, the sensitivity of the pharmacy data was lower. For the oral bisphosphonates, for example, sensitivity was 70–74%, meaning that examination of the pharmacy data for filled prescriptions in the prior 180 days failed to identify more than one-quarter of individuals that reported they were currently taking the drug. However, more than 90% of self-reported current bisphosphonate users filled at least one bisphosphonate prescription during the entire study period (data not shown).

Figure 1 shows ROC comparing the tradeoff between sensitivity and specificity for various intervals of pharmacy data compared to the reference standard of self-reported current use of alendronate. The solid line represents the entire cohort and includes

Table 2. Diagnostic properties of a 180-day Pharmacy Fill Window* compared to the reference standard of self-reported current use of osteoporosis medications among chronic glucocorticoid users enrolled in managed care

Drug name	n†	Kappa (95% CI)	PPV (95% CI)	NPV (95% CI)	Se (95% CI)	Sp (95% CI)
Alendronate	327	0.80 (0.76–0.84)	93 (90–96)	96 (95–97)	74 (69–79)	99.1 (99–100)
Risedronate	142	0.78 (0.72–0.84)	91 (85–96)	98 (97–99)	70 (62–77)	99.5 (99–100)
Calcitonin	63	0.64 (0.53–0.75)	78 (66–90)	99 (98–99)	56 (43–68)	99.5 (99–100)
Raloxifene	31	0.70 (0.56–0.83)	77 (61–93)	99.5 (99–100)	65 (48–81)	99.7 (99.5–100)

PPV, Positive predictive value; NPV, Negative predictive value; Se, Sensitivity; Sp, Specificity; CI, Confidence interval.
*The Pharmacy Fill Window refers to the 180-day period of time preceding the return date of each member's mailed survey.
†Number of individuals self-reporting current use of each drug on the mailed survey.

alendronate users and non-users. Because specificity was high for all intervals of pharmacy data, sensitivity was the largest determinant of the area under the ROC curve and was maximized using an 'ever' filled interval that covered the entire study period. The area under this ROC curve was 0.96. Among individuals who filled at least one alendronate prescription during the entire study period, the area under the ROC curve was 0.87 and was maximized between 120 and 180 days. The area under similarly shaped ROC risedronate curves was 0.92 and 0.85, respectively (data not shown).

Factors associated with discordance between pharmacy data and self-reported use of oral bisphosphonates and glucocorticoids

The variables screened for multivariable model building are shown in Table 1 and also included bisphosphonate dosing frequency (84% of bisphosphonate users were dosed weekly). Among the 465 unique individuals filling at least one bisphosphonate prescription during the study period, the results from the multivariable logistic regression models in Table 3 showed that income <$40 000 was the most sig-

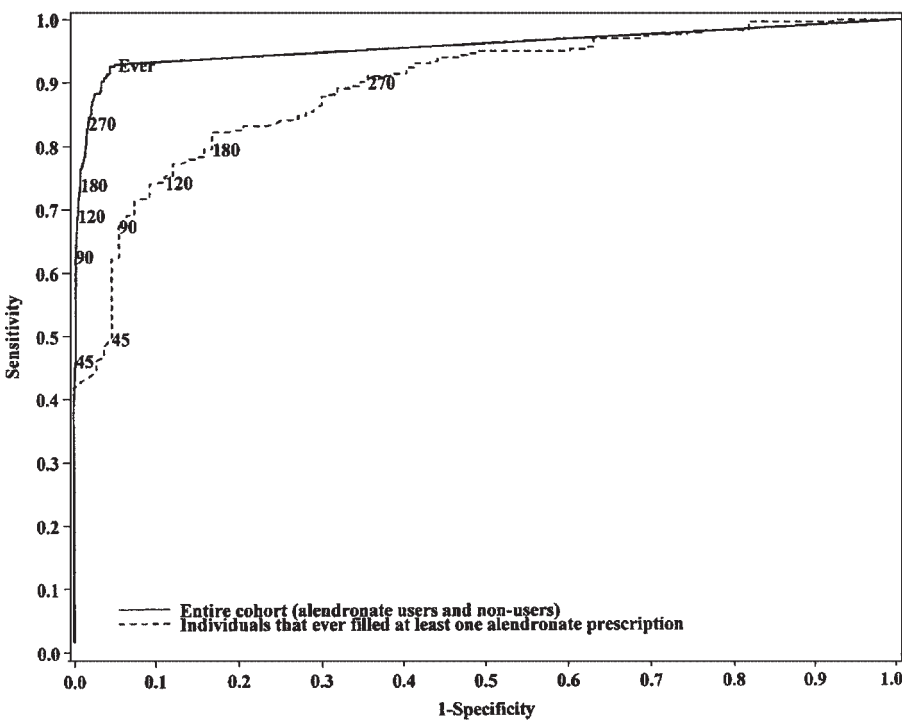

Figure 1. Receiver operator curve examining the sensitivity and specificity of various Pharmacy Fill Windows compared to reference standard of self-reported current use of alendronate. Numbers shown on curves are variable filled days of alendronate. c statistic = 0.96 (solid line) and 0.87 (dotted line)

Table 3. Factors associated with respondents not having a Pharmacy Fill for a bisphosphonate in the 180 days preceding self-reported current use among chronic glucocorticoid users enrolled in managed care ($n = 465$)*

	Odds ratio†	95% Confidence interval
Annual income < $40 000	2.08	1.31–3.30
Education (did not graduate from high school)	1.73	0.77–3.88
Age (10-year increment)	0.84	0.70–1.01
c statistic for model = 0.61		

*Includes unique individuals that self-reported current use of a bisphosphonate on the mailed survey.
†Covariates screened include all those listed in Table 1, bisphosphonate dosing frequency (e.g., weekly vs. daily) and two-way interaction terms between combinations of age, income, education, and ethnicity.

nificant factor associated with lack of pharmacy confirmation of a filled bisphosphonate prescription in the prior 180 days. Trends also suggested that less education and younger age were associated with discordance between the pharmacy database and self-reported current medication use.

Over 91% of survey respondents indicated that they had 'ever' taken glucocorticoids, 7% said that they had never taken them, and 2% did not answer. Sixty-five per cent of the 'ever' users reported 'current' use at the time they completed the survey. Factors associated with patients reporting that they had 'never' taken steroids despite pharmacy data confirming that they had filled at least 60 days of oral glucocorticoid prescriptions are presented in Table 4. Even after the multivariable adjustment described in the table, non-Caucasians and older individuals were more likely to report that they had never taken glucocorticoids despite pharmacy records confirming that they had filled at least 60-day supply. Inclusion of income and education into the model somewhat attenuated but did not change the overall results, and these terms are not shown as they were not significant after multivariable adjustment.

Among the 2264 enrollees answering the survey question about whether they ever had a DXA, 988 reported that they had not received one. However, 57 of these persons had evidence from administrative data that they had this procedure at least once in the preceding 34 months (i.e., negative predictive value 94%, 95%CI 93–96%). Of the 1276 individuals that reported that they ever had a DXA, 60% ($n = 764$) had this procedure documented during the preceding 34-month study period.

DISCUSSION

Pharmacy and administrative claims data are commonly used to assess medication exposure and processes of care in studies of health care quality. However, reliance on administrative data alone may underreport or over-report care that patients actually receive. Among chronic glucocorticoid users enrolled in a national managed care plan, the high positive and negative predictive values of pharmacy data suggest that this information source is unlikely to significantly misclassify medication receipt as a process measure of quality of osteoporosis care. We also found high rates

Table 4. Factors associated with respondents reporting that they had 'never' taken glucocorticoids despite at least 60 days of filled glucocorticoids prescriptions in the pharmacy database among chronic glucocorticoid users enrolled in managed care ($n = 2156$)*

	Odds ratio†	95% Confidence interval
Ethnicity		
Caucasian (referent)	1.0	—
African American	1.96	1.19–3.21
Other non-Caucasian	2.82	1.69–4.72
Receipt of bone mass measurement	0.24	0.16–0.37
Age (10-year increments)	1.39	1.22–1.58
Number of filled glucocorticoid prescriptions	0.95	0.92–0.97
c statistic for model = 0.75		

*Does not total the 2363 that returned the survey because of missing data for ethnicity.
†Covariates screened include all those listed in Table 1 and two-way interaction terms between combinations of age, income, education, and ethnicity.

of agreement between self-reported current use of osteoporosis medications and recently filled prescriptions. Although we are not aware of other studies comparing pharmacy data to patient self-report for osteoporosis drugs, agreement for self-reported prior estrogen use compared to medical and/or pharmacy records range have shown moderate to good agreement (Kappas 0.5–0.7).[8] In our study, most patients filling osteoporosis medications in the 6 months prior to returning the survey self-reported current use. In contrast to underreporting commonly observed in other studies comparing self-report to pharmacy databases for past medication use,[8] the majority of the discordance we observed represented self-reported current use that could not be confirmed by a recently filled prescription in the pharmacy database. Our results are similar to other studies that show that approximately 70–80% of self-reported medication use could be validated using recently filled prescriptions in pharmacy databases,[10,14,15] although confirmation rates for other medication classes such as anti-hypertensives are higher.[16,17]

Several possibilities might explain the somewhat lower-than-expected rates of recently filled prescriptions observed among self-reported current users of osteoporosis medications. First, patients may be receiving medications from other sources including pharmaceutical samples or through a drug assistance program. The result that lower income was significantly associated with discordance between self-report and recently filled prescriptions in the pharmacy database supports this possibility. Secondly, although we used a 6-month interval of pharmacy data, and patients received no more than 3 months supply of medication for any single prescription, poor adherence (i.e., less than 50%) to the prescribed dose could explain our result. Supporting this possibility is our comparison of 'ever' filled bisphosphonate prescriptions to those filled within 180 days. Despite more than 25% of self-reported current bisphosphonate users not having a filled prescription in the preceding 180 days, less than 10% never filled a bisphosphonate prescription during the entire study period, suggesting suboptimal adherence. Finally, patients may have over-reported their medication use (a 'false positive' report), although based on prior work in other drug classes, medication over-reporting is generally uncommon.[8]

The optimal duration of pharmacy data needed to identify current drug use across the spectrum of all medication classes is largely dependent on the type of drug, physician prescribing habits, and reimbursement. For bisphosphonates, data from the ROC for the entire cohort (i.e., bisphosphonate ever users and non-users) showed that the gain in sensitivity by using progressively longer intervals of pharmacy data was offset by only negligible decreases in specificity. It also showed that distinguishing between 'current' bisphosphonate users and 'past' users was best accomplished by identifying individuals that filled prescriptions in the preceding 120–180 days. Because some studies may require precise characterization of current drug exposure and thus favor maximal specificity at the expense of sensitivity, the ROC curve demonstrated that examination of the preceding 45 days of pharmacy data is optimal for this purpose. Additionally, a definition of a past bisphosphonate user should probably exclude any individual filling medication within the prior 6 months (or longer), since many of these individuals self-reported current use.

Only 7% of survey respondents said that they had never taken glucocorticoids despite having filled at least 60 days' supply. Similar to studies of other medication classes,[7,9,18] factors associated with individuals failing to confirm that they had ever taken glucocorticoids included non-Caucasian ethnicity, fewer numbers of filled glucocorticoid prescriptions, and older age. Conversely, receipt of bone mass measurement was associated with a decreased likelihood that patients failed to confirm that they had received glucocorticoids. We speculate that patients screened using DXA may have a heightened sensitivity to being at-risk for osteoporosis on the basis of glucocorticoid exposure. The 94% negative predictive value of self-report of receipt of DXA screening suggests that bone mass measurement may be reasonably assessed using a mailed questionnaire.

Our population-based study has several strengths, including a large and diverse group of patients with or at risk for GIOP. Because we asked about *current* use of osteoporosis medications, recall bias should be significantly lessened. The linkage between administrative data and the mailed patient survey allowed us to capture demographic covariates such as ethnicity, education, and income that are infrequently available but have been shown to be important for assessing the validity of claims data.[7,18] Indeed, for discordance between self-report and pharmacy data for current bisphosphonate use, income and education were among the most significant factors. Finally, we asked separate, medication-specific questions on the survey (rather than using an open-ended list), a technique known to enhance accuracy.[19,20]

Study participants were relatively young and enrolled in a national managed care plan. Thus, our work may not be generalizable to older individuals

enrolled in other types of health plans (e.g., Medicare) or to those living outside the U.S. We recognize that neither pharmacy databases nor patient self-report on a mailed questionnaire represent a true gold standard for medication exposure, and some have recommended that in-home medication inventories are best.[21] Similarly, using pictorial memory aids (i.e., photographs of medication pills) have been shown to enhance patient recall.[20,22] However, these techniques are usually used to overcome low 'false negative' rates of patient-self report (i.e., underreporting of medication use),[15] which we did not observe in our study.

The unique dosing instructions, frequency, and route of administration for some osteoporosis medications may have contributed to the high concordance between self-report and pharmacy data observed in our study. The bisphosphonates, for example, are often prescribed as once-weekly doses of a single tablet that must be taken while upright with a full glass of water with nothing else to eat or drink for more than 30 minutes. Also somewhat uniquely, calcitonin is administered via a daily nasal inhalation or subcutaneous injection. For medications with less unique dosing instructions or routes of administration, and those that are used a by less selected group of patients and practitioners, concordance between self-reported current use and pharmacy data may differ. Finally, despite our large sample size and the similarity between survey responders and non-responders in almost all administrative data-derived covariates, response bias may have impacted our results in ways that are difficult to predict. It is possible that agreement between self-report and pharmacy data was greater among survey responders than would be found among non-responders.

In conclusion, agreement between pharmacy data and patient self-report to assess current osteoporosis medication use was high among chronic glucocorticoid users enrolled in managed care. Thus, both sources of information appear appropriate to assess exposure to osteoporosis medications. In contrast to prior studies, patient underreporting current use of osteoporosis therapies was rare, and most patients with recently filled prescriptions described themselves as current users on a mailed survey. However, a 6-month interval of pharmacy data had less than optimal sensitivity to identify current users of commonly prescribed osteoporosis medications, suggesting the need for a longer assessment period in studies that rely on pharmacy data alone.

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