Comparability of Pharmacy Profile Information, Prescription Claims Data, and Patient Self-reported Medication Use: Implications for Pharmacy Quality of Care Measurements

Final Report to the Community Pharmacy Foundation

Submitted by

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Background

Quality of care performance measurement is an emerging driver for improvements in pharmacy patient care processes and health outcomes. It also is a conduit for payment system reform in which pay-for-performance compensation mechanisms incentivize the provision of quality care. Performance measurement results are also being promoted as health plan tools to build and refine pharmacy networks.

Several national efforts are underway to create and use performance measurements related to medication therapy and pharmacy services. The Centers for Medicare and Medicaid Services (CMS) uses quality measures within the Medicare Part D program star ratings as a means of informing beneficiary prescription drug plan choices. Prescription drug plan star ratings provide a general summary of a plan's performance on processes ranging from patient satisfaction with administrative services to improving patient medication adherence. High star ratings provide plans with the potential for quality bonus payments and can enhance enrollment rates if consumers choose prescription drug plans that have higher star ratings.[1] While CMS reports star ratings at the plan level, results can be influenced by care provided at the pharmacy level. Thus, health plans are likely to incentivize pharmacies to take actions that will improve the plan's star ratings. Plans may also set pharmacy performance achievement thresholds for plan participation to ensure a high overall plan rating.

Efforts to directly measure the quality of individual pharmacies are being initiated. Pharmacy Quality Alliance (PQA) has launched a for-profit subsidiary, EquiPP that will report performance measure outcomes on the chain or independent pharmacy level. EquiPP anticipates that such data will be used for pay-for-performance compensation and/or for pharmacy network selection criteria. Other entities, such as URAC and The Center for Pharmacy Practice Accreditation (CPPA) are also seeking to accredit pharmacies based on their structure and processes of care.

Each of these performance measurement efforts uses measures built from data derived from pharmacy drug claims. Pharmacy drug claims are a convenient and inexpensive method of gaining information about prescriptions dispensed. Drug claims have been routinely used in research and by health plans and pharmacy benefit managers (PBM) to identify drug therapy problems such as medication non-adherence, duplicative or unnecessary drug therapy.[2]

However, the ability of claims data to accurately reflect patient medication use has been debated.[3-5] The use of pharmacy discount programs, coupons or other cost-savings programs can result in a claim not being submitted for a filled prescription.[6] Changes in dosages or prescription status (e.g. Rx to nonprescription) may create gaps in claims submissions that erroneously suggest non-adherence. Auto-refill programs may result in claims being generated for unneeded and/or untaken medications. Measuring drug therapy problems at the pharmacy level introduces

additional room for misrepresentation of medication use if patients are using more than one pharmacy to obtain their medications and medication refills.

Research to date has provided conflicting information about prescription claims data accuracy. A Canadian study of 189 individuals 65 years of age and older compared chronic medication adherence based on self-report versus prescription claims.[7] Self-report indicated that 90% of people were adherence to their regimens whereas pharmacy records showed that 95% were adherent. Among individual medications, adherence ranged from 73% to 85.8% based on patient self-report and from 44.6% to 96.9% based on pharmacy records. Using statistical analysis to compare adherence on the individual and medication level, the authors concluded that there was little agreement between patient self-report and prescription claims data with higher adherence rates seen with claims data. In contrast, an analysis of Medical Expenditure Panel Survey (MEPS) drug data found that the number of prescriptions filled as reported by patients tended to compare well with claims.[8] However, a study of patients discharged from an emergency room reported that patient self-reported adherence in filling a prescription was higher than that verified by prescription claims data.[9]

Using claims data to assess an individual pharmacy's performance relies on patients being loyal patrons of a particular pharmacy. Polinski et al[10] found that patients tend to fill the majority of their prescriptions at one pharmacy. Another study found that 85% to 90% of patients received medications for most selected therapeutic classes from only one pharmacy.[11] However 72% to 78% of patients used multiple pharmacies for asthma medications. In addition, only 68% to 79% of patients receive diabetes medications and antihypertensive medications from the same pharmacy. Since use of asthma, diabetes and antihypertensive medications are frequently targeted within performance measures, attribution of use to a particular pharmacy may confound the accuracy of these measures.

The accuracy of claims data for measuring quality of care related to a specific health plan or pharmacy is also dependent upon an adequate sample size. For example, CMS star ratings require a sample size of at least 30 persons. A common problem for quality measurement is the small number of plan participants that may frequent an individual pharmacy. One strategy for overcoming this problem is to combine a provider's data from multiple health plans.[11] A concern with this remedy is that plans differ in features, such as deductibles and co-payments requirements, that influence prescription purchasing.[12] A pharmacy that has a significant proportion of patients with high co-payment prescription plans may have many patients using its discount program resulting in their medication use not being fully captured in pharmacy claims data. Based on claims data alone, such a pharmacy could be rated as a low performing pharmacy when measured on patient care aspects such as medication adherence.

Studies examining claims data accuracy were often conducted before pharmacy discount programs, prescription transfer programs and mail service pharmacies

were widely available and promoted. More recent studies[5,6] suggest that use of pharmacy discount programs is resulting in a loss of prescription use capture by pharmacy claims. One study suggested that this loss may be higher for patients using more prescription medications[14] Thus, for some patients the pharmacy profile will be a more accurate source for medication use information than claims data. Use of prescription transfer programs and mail service pharmacies can make attribution of claims to a given pharmacy difficult. Use of these services also interferes with the completeness of the community pharmacy profile. Therefore, patient self-report of medication use becomes an increasingly important source of medication use information. Patient self-report of medication use may also be more likely to include nonprescription medicines and herbal and dietary supplements.

Thus, three sources of measuring medication use exist: pharmacy profile information, drug claims data, and patient self-report. Which source provides the most accurate and appropriate data for evaluating drug therapy management performance by an individual pharmacy is not known. The degree to which current cost-saving measures implemented by prescription plans or undertaken by patients impact the accuracy of these sources on an individual pharmacy level is also not known. Fully understanding the accuracy related to data sources used for performance measures is critical due to the potential impact of performance and accreditation measures on pharmacy compensation and network selection. This information can also inform pharmacy performance measure creation, interpretation and reporting processes.

Study Goal

This project collected and compared the medications reported by three data sources: the pharmacy profile, claims data and patient self-report.

The study objectives were to:

1. Compare chronic medication use as characterized by the three data sources;
2. Investigate the degree to which out-of-pocket prescription expenditures influence data captured from the three data sources; and
3. Recommend tactics for improving data capture accuracy to promote fair assessments of pharmacy performance

Methods

Study design

This study was a cohort comparison of medication information available within the pharmacy profile, the claims data submitted to a pharmacy benefit manager (PBM), and patient self-report of medication use obtained through a pharmacist-patient interview.

The study was conducted within a Michigan-based chain pharmacy in partnership with the University of Michigan College of Pharmacy. The pharmacy management and participating pharmacists actively participated in creating the study design and data collection processes. The University of Michigan Investigational Review Board – Health Sciences and Behavioral Sciences approved the study.

Study population

Study subjects were adults (aged 18 or older) who, based on pharmacy profile data, received six or more chronic prescription medications on a routine basis at one of six selected pharmacies between June 2014 and August 2015. Patients must have received an oral anti-diabetes medication, renin-angiotensin receptor antagonist (RARA) or statin to be included in the study. Subjects were required to provide written consent and completed a study-specific HIPAA (Health Information Portability and Accountability Act) form, if needed.

Initially patients who met the inclusion criteria were selected on a random basis using central access to the pharmacy profiles of the selected pharmacies and extended a written invitation to participate in the study. Using this process resulted in a low participation rate so the recruitment method changed to a personal invitation by the pharmacists at the selected pharmacy sites.

Study patients completed a medical history form and a short questionnaire about their use of medications lists and were requested to bring in all prescription, nonprescription medications and dietary supplements to the patient interview visit. A telephone reminder call was made one to two days prior to the appointment. To encourage study participation, individuals were given a $20 gift card for pharmacy merchandise upon completion of the visit.

Data collection

For each selected subject, pharmacy computer profile information for four months of therapy was reviewed to determine if the patient met the study inclusion criteria. From this profile information, an initial medication list was generated as a guide for the interview visit. If an extended time occurred between the initial patient recruitment and the patient visit the baseline profile information was updated just prior to the visit. At the visit, demographic information was recorded and the patient was interviewed about the medications they were taking. Information was gathered about prescription and nonprescription medicines and dietary supplement use. This information was used to generate a final medication list. Telephone interviews were conducted for homebound patients and those for whom an in-pharmacy visit was inconvenient.

Using a separate study form the pharmacists noted the following information for each medication: the medication type (prescription, nonprescription or dietary supplement), whether it appeared on the original profile list, had been submitted as

claims data to a PBM, and/or was reported at the patient visit. If a medication was not included within the three drug information sources (i.e., profile, claims data, patient report) the reason for the discrepancy was noted. Pharmacists could choose among the following reasons: prescription paid by cash or through a pharmacy discount program, dose changed, medication discontinued by prescriber, medication discontinued by patient, prescription filled via mail-order, or prescription filled at a different pharmacy and "other". The pharmacist could also elect to provide a written explanation for the discrepancy. While we initially hoped to collect prescription drug plan information on patients, this information proved difficult to obtain. Therefore, to measure patient financial burden related to medications a standardized 12-month period of out-of-pocket expenditures was recorded. Within the data collected and within this report, medications names cited correspond to the name of the product dispensed.

The pharmacists provided health and medication-related counseling during the visit. Patients were advised to seek additional care from their prescribers as deemed appropriate.

Data Analysis and Results

The analysis focused on characterizing the study patients, comparing the number of medications recorded from each information source and the number and types of discrepancies that occurred between the patient self-report and the other sources. Confounding variables such as age, gender, number of medications, and patient out-of-pocket prescription drug expenditures were considered. All patient forms were de-identified prior to being received by the data analyst.

Fifty-two individuals were recruited into the study and 38 completed the study visit. Study dropouts either did not show for scheduled visits or indicated that they had decided not to participate for various reasons.

Demographic data and patient characteristics were summarized with means and standard deviations. Participant average age was 68.4 years ($\pm$10.9) with a range from 40 to 89 years. Half (19) of participants were women. Participants reported a mean of 6.7 ($\pm$2.9) health conditions. All subjects had prescription drug insurance with 12-month out-of-pocket expenditures for prescription medications ranging from \$15.08 to \$3,124.11 with a mean annual expenditure of \$926.13 ($\pm$826.18).

Medication use As reported by the profile, claims cata and patient self-report

Based on the profile medication list generated closest to the study visit, the average number of medications being dispensed per person was 11.9 ($\pm$4.1) with a range from five to 23. The number of medications reported in claims data averaged 11.0 ($\pm$3.9) with a range from three to 22. The average number of medications reported by the patient at the study visit was 15.7 ($\pm$6.1) with a range from 7 to 30.

The study cohort reported the use of 611 medications including 453 prescription medications, 55 nonprescription medications and 103 dietary supplements. The number of medications reported by source is shown in Table 1.

Chi-square analysis of independence found that there was no difference among the number of prescription medications reported by source ($p=0.75$) however a significant different was seen between the number of dietary supplements and nonprescription medications reported ($p<0.001$). Analysis of variance (ANOVA) was used to determine whether the categories differed globally. The categories were then assessed for pair-wise difference by using the Tukey post-hoc test correction. No difference was found between the number of medications reported on the pharmacy profile and claims data ($p=0.92$). However, a significant difference was seen between patient self-report and the pharmacy profile ($p<0.001$) and the claims data ($p<0.001$) with patients reporting taking more medications than were listed within either source. Most discrepancies among the profile, claims data and patient report were related to dietary supplements and nonprescription medications.

A univariate logistic regression found an association between discrepancies and gender with men more likely to have discrepancies (OR=0.87 (female as reference), $p<0.001$) No association was found between discrepancies and age or the number of chronic health conditions (analysis not shown). The relationship between discrepancies and source of information was also examined on a per-person basis. A similar relationship as described above was found for the mean number of prescription medications, nonprescription medications and dietary supplements.

Relationship between prescription out-of-pocket costs and discrepancies

Linear regression was used to compare the association between prescription out-of-pocket costs and the number of discrepancies on a per-person basis. Because the number of medications a person reports is correlated with both the number of discrepancies and out-of-pocket spending, the number of medications was treated as a confounder variable. Out-of-pocket expenditure data was only reliably available from the pharmacy profile, therefore our analysis focused on the relationship between expenditures and profile discrepancies. The average number of discrepancies found between the pharmacy profile and patient report tended to increase as the patient's 12-month out-of-pocket prescription drug costs increased as shown in Table 2 ($\beta=94.22$, $p=0.006$). Number of prescription medications had a negative, but statistically insignificant, association with out-of-pocket spending. A univariate regression showed that it had a positive slope but was also not significant. The negative direction comes from the multivariate adjusted modeling.

Reasons for discrepancies among the profile, claims data and patient self-report

Reasons for discrepancies among the profile, claims data and patient report are listed in Table 3. For some medications more than one reason was given for a discrepancy. For example, one medication was discontinued by the patient and then

later by the prescriber. The most common reason mentioned under the "Other" category was medication samples received from a prescriber.

Overall, 214 discrepancies were noted between patient self-report of medication use and either profile or claims data. Of these, slightly more discrepancies occurred between the claims data and patient self-report. Chi-square analysis revealed that there was a significant difference (P=0.02) among the reasons for discrepancies. By far, the most common reason for a medication not appearing on the pharmacy profile or claims data was that the medication was an out-of-pocket purchase.

Reasons for discrepancies among prescription, nonprescription and dietary supplements

The number of discrepancies by drug type was also analyzed using Chi-square analysis of independence (Table 4). There was a significant difference ($p<0.001$) found among total discrepancies related to prescription medications, nonprescription medications and dietary supplements with about half (47.2%) of total discrepancies related to dietary supplements.

Discrepancies for prescription medications were due to multiple reasons, with dosage changes and discontinuations by the prescriber or patient being the major reasons. Out-of pocket purchase was the major cause of discrepancy for nonprescription medications and dietary supplements. Since nonprescription medications and dietary supplements were uncommonly reported on the pharmacy profile or within claims data, discrepancies due to dose and discontinuation of these products discrepancies were not recorded.

Medication list use among study patients

Twenty-eight subjects (75.5%) reported having a written medication list (e.g., wallet care, printed list from clinic visit). Of those about half (58.6%) carried the list with them and either posted a copy of their medication list at a home or shared a copy with a family member or friend (51.7%). About one-third (35.5%) used the list to fill a pill container.

Discussion

This study was undertaken to compare medication use information among pharmacy profiles, claims data, and patient report and to determine if profile and claims data provided adequate data for evaluating pharmacy quality of care. Since claims data only is currently used by health plans, purchasers and others to evaluate medication use and pharmacy performance, incomplete claims data could lead to erroneous conclusions about patient medication use.

Although study findings are clearly limited by the small number of patients included, the detailed comparison of the sources provides insight into the ability of claims

data to accurately measure patient medication use. The study results showed that study patients were taking significantly more medications than were recorded within the claims data. This lack of information could influence health plans assessments of patient therapy and, since claims data are fed into some electronic health record systems, could also influence prescriber drug therapy assessments.

Nonprescription medications and dietary supplements constituted the majority of medications missing from the claims data. While many quality measures currently focus on prescription medications, the use of medications such as low-dose aspirin, omeprazole, calcium with vitamin D, Vitamin D, and ferrous sulfate are key components in the prevention and treatment of disease and are considered as necessary primary or adjunctive therapy for diseases such as cardiovascular disease, diabetes, osteoporosis and anemia. Reliance on claims data alone may exclude the recognition of use of such medications suggesting that therapy is not following treatment guidelines when in reality patients are receiving recommended medications.

Increasing evidence of the clinical effects and side effects of nonprescription medications and dietary supplements also warrants that use of these medications be known. Some interactions, such as those occurring with omeprazole therapy, can be clinically significant.[13] Lack of recording dietary supplement use could also hamper diagnostic evaluations such as when gastrointestinal distress or bleeding occurs in the presence of ferrous sulfate use.

Few prescription medications were not included within claims data; however, those missing from claims data could have an impact on quality measure results. Medications such as lisinopril, atenolol and simvastin were out-of-pocket purchases through prescription discount programs. Other prescription-only medications purchased directly by the patient included Xyzal, hydrocodone/APAP, oxycontin, and amiodarone.

Chronic medications also “disappeared” from claims data due to the receipt of prescription samples. While samples are often used as starter doses, some patients received samples for medications that had previously been dispensed from the pharmacy. Without knowledge of sample use, non-adherence to a product may be assumed based on claims data.

Patients also reported medication dosage changes that had been previously unknown. Examples of medications with dosage changes included: lisinopril, Asteopro, glyburide/metformin, losartan/hydrochlorothiazide, dicyclomine, glipizide, clonazepam, tizandine, Baclofen, and Duoneb. The lack or inaccuracy of information about these agents could influence evaluations of drug therapy appropriateness, side effects and the need for additional therapy

While the lack of medication information within the claims data was concerning, equally concerning was medication use data missing from the pharmacy profile.

Nonprescription medications and dietary supplement information was also largely missing in this database. While medications received through out-of-pocket purchases and discount programs were included in the profile, prescriptions received from mail-order pharmacies and dosage changes were often not noted. Of particular concern was the lack of pharmacy profile information about medications that were being filled at specialty pharmacies (e.g., Copaxone, compounded prescriptions). Given that patients receiving specialty medications often have serious illnesses that put them at high-risk for side effects, the pharmacists' lack of awareness about these medications is worrisome. Pharmacists often perceive themselves as a safety net for the prevention of drug interactions and the most convenient and effective point for addressing medication adherence and other problems. But how can they fulfill this role if they have incomplete data?

Our study raises concerns about the adequacy of medication use information from claims data and pharmacy profiles. Others have raised concerns about the lack of accurate and complete medication use data at the prescriber level. While there is overwhelming agreement that knowledge of overall medication use is essential for appropriate care, complete data is not routinely collected by health professionals or shared by patients. The emphasis on motivational interviewing is striving to improve provider-patient communication, but patients may still be reluctant to share their medication use practices. Furthermore there are few financial incentives given to support the attainment or the provision of and sharing of such information, particularly information related to nonprescription and dietary supplement use. In addition, the lack of electronic connectivity among prescribers, pharmacists and PBM hinders data sharing among health providers. Even if pharmacists do record all medications used, PBM financially discourage the sharing of such data by exacting data transmission charges.

How can medication use information in the pharmacy profile and claims data become more accurate and complete? The ideal solution will likely include a mix of technology, improved awareness of the value of these data, actions undertaken by patients, pharmacists, prescribers and PBM and financial incentives to encourage data provision and sharing.

We suggest the following be undertaken as a systems approach to improving medication use data and thus the monitoring and assessment of quality of care:

- Increase awareness and interest in maintaining and using accurate and complete medication lists among the health care sector stakeholders and the general public

- Incentivize consumers to provide complete and accurate information about their use of medications, including nonprescription medications and dietary supplements to all their healthcare providers
- Create electronic information linkages among pharmacies and between pharmacies and other healthcare providers, PBM and health information

exchanges to ensure that all have complete access to medication use information

- Create a no-charge transmission process for information-only transmissions from pharmacies to PBM to encourage the documentation of cash-only medications

- Create a compensation mechanism for pharmacy-obtained medication lists separate from the medication therapy management process

- Include the attainment of nonprescription medication and dietary supplement use information within quality measures for both prescribers and pharmacists

- Ensure that state laws and pharmacy policy and procedures allow for certified pharmacy technicians to assist with medication use information attainment and facilitate technician training in medication list creation and maintenance as a means to improve the efficiency of medication data gathering

- Encourage public and private funding agencies and foundations to support additional studies of larger, broader populations to increase knowledge about the completeness and accuracy of medication lists

While these suggestions are ambitious, they represent needed steps to ensure that all parties have accurate data by which to measure pharmacy performance. . Without complete data, quality measures cannot adequately measure, improve or reward quality care.

Study Limitations

This study had several limitations. The degree of detail and the need for patient interviews limited study sample size, thus indicating a need for more extensive research to determine if the findings can be generalized to a larger population. The study population did not include individuals with very high out-of-pocket costs. It is unknown if higher medication expenditures would have influenced the results. We hypothesize that patients with very high expenditures may be more likely to enroll into pharmacy discount programs or pharmaceutical company program assistance programs or to receive sample medications thus resulting in more discrepancies among information sources. Finally, most patients were directly recruited by the study pharmacists and thus had existing relationships with the pharmacists. The degree to which this relationship influenced patient medication purchasing decisions and completeness of data is not known. Patients lacking a pharmacist relationship may be more likely to receive medications from multiple sources thus affecting pharmacy profile completeness.

Conclusion

Compared to patient self-report, pharmacy profiles and claims data are missing data, particularly as related to nonprescription medication and dietary supplements use. Lack of specialty medicine information is also a concern for community pharmacies. Inadequate and inaccurate data can hinder and confuse attempts to characterize pharmacy performance related to drug therapy management and quality of patient care. A systems approach is advocated for improving the quality of medication use data documented.

Appendix 1

Table 1: Total Counts of Medications Reported in the Pharmacy Profile, Claims Data, and Patient Report

	Total # of prescription medications	Total # of nonprescription medications	Total # of dietary supplements
Pharmacy profile	425	3	7
Claims data	416	1	2
Patient report	438	55	103

Note: Nonprescription medications such as omeprazole that were obtained via a written prescription were recorded as prescription medications. Prescriptions that were filled at another pharmacy were reported to be associated with PBM claims submission unless the patient indicated that the prescription had not been covered by insurance.

Table 2: Twelve-Month Out-of-Pocket Costs and Number of Per-Person Discrepancies

	Slope	Standard Error	P Value
(Intercept)	1044.89	376.10	0.009
Number of discrepancies	92.44	31.36	0.006
Number of medications	-49.92	31.40	0.121

Table 3: Reasons for Reported Discrepancies Between the Profile, Claims Data and Patient Self-Report

	Overall discrepancies #(%)	Pharmacy profile vs. patient report # (%)	Claims data vs. patient report # (%)
Out-of-pocket purchase	156 (72.9)	148 (77.5)	156 (77.2)
Medication dose different	15 (7.0)	10 (5.2)	13 (6.4)
Medication discontinued by prescriber	9 (4.2)	9 (4.7)	8 (4)
Medication received from mail-order pharmacy	8 (3.7)	8 (4.2)	0 (0)
Medication discontinued by patient	6 (2.8))	6 (3.1)	5 (2.5)
Medication received from another pharmacy (not mail-order)	3 (1.4)	3 (1.6)	1 (0.5)
Other reason/no reason given	22 (10.2)	8 (4.2)	21 (10.4)
Total	214 (100)	191(100)	202 (100)

Note: Some medications had more than one type of discrepancy reported.

Table 4: Number (%) of Discrepancies Reported between the Patient Report and Either the Pharmacy Profile or Claims Data by Medication Type

	Overall	Prescription	Non-prescription	Dietary Supplement
Out-of-pocket purchase	156 (76.5)	6 (10.2)	52 (96.3)	98 (97.0)
Medication dose different	15 (7.0)	15 (25.4)	0 (0)	0 (0)
Medication discontinued by prescriber	9 (4.2)	9 (15.3)	0 (0)	0 (0)
Medication discontinued by the patient	8 (3.7)	8 (13.6)	0 (0)	0 (0)
Medication received through mail-order pharmacy	6 (2.8)	6 (10.2)	0 (0)	0 (0)
Medication received through another pharmacy (not mail-order)	3 (1.4)	3 (5.1)	0 (0)	0 (0)
Other reason/no reason given	22 (10.3)	17 (18.8)	2 (3.7)	3 (3.0)
Total	214 (100)	59 (100)	54 (100)	101 (100)

Note: Some medications had more than one type of discrepancy reported.

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