

## Concordance of Medicaid and pharmacy record data in inner-city children with asthma <sup>☆</sup>

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### Abstract

**Background:** Management of asthma involves adherence to medication regimens. Assessing adherence is difficult for health care providers and researchers. Self-reported medication use is subjective, so objective methods of data collection for medication use are frequently used in asthma research. The aim of this project is to examine the concordance between asthma medication pharmacy data culled from Medicaid claims data (“Medicaid pharmacy data”) and patient pharmacy record data obtained from individual pharmacies (“pharmacy record data”).

**Methods:** Medicaid pharmacy data and pharmacy record data were obtained from inner-city children enrolled in a prospective study of children with persistent asthma. A subject level comparison of pharmacy records and Medicaid pharmacy data pharmacy records was done to determine concordance between the 2 data collection methods.

**Results:** Of 513 children recruited for inclusion, 221 were consented and randomized. Medicaid claims data were collected on 72.8% ( $n=161$ ) of the 221 enrolled subjects. Pharmacy record data were available on 96.8% ( $n=214$ ) of the 221 subjects. Data presented represent the 159 subjects who had both Medicaid claims data and pharmacy records data available throughout the study period. There was complete agreement between Medicaid pharmacy data and pharmacy record for 26% ( $n=42$ ) of subjects. A total of 1858 asthma medication claims were captured by the Medicaid pharmacy data. Medicaid pharmacy data missed 149 claims that were capture by the pharmacy record data. Medicaid pharmacy data failed to capture a single claim on 4.4% ( $n=7$ ) of subjects. The pharmacy record data captured a total of 1627 asthma medication claims and missed 371 claims that were captured by the Medicaid pharmacy data. Pharmacy record data failed to capture a single claim in 1.9% ( $n=3$ ) of subjects.

**Conclusions:** There was overlap between the pharmacy data captured by the Medicaid pharmacy dataset and pharmacy record dataset, but the overall concordance between the two data collection methods was low. Pharmacy records collected directly from the pharmacy included data on more subjects and pharmacy data culled from Medicaid claims captured more total number of claims. In spite of the differences in the methods used to collect data, pharmacy fill records are a rich source of data with both

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clinical and research applications. Clinicians and researchers must weigh the benefits and limitations of each method used to collect pharmacy data.

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## 1. Introduction

Asthma is a chronic disease with significant impact especially on young children. According to the Centers for Disease Control, in 2002, children under 17 years old had 5 million outpatient visits, 727,000 emergency department (ED) visits and 196,000 hospitalizations due to asthma. Hospitalization and ED rates were highest in the youngest children (age 0–4 years) and African–American children had an asthma-related death rate over 200% higher than non-Hispanic whites [1]. Several studies indicate significant asthma morbidity and mortality for African–American children and those from lower socioeconomic status [2–9].

Because of the chronic nature of the disease, management of persistent asthma involves adherence to medication regimens emphasizing inhaled steroids to decrease airway inflammation [10]. Adherence to medications is difficult for patients to achieve, tough for health care providers to assess and challenging for researchers to track. Because relying on self-reported data to assess adherence either from telephone surveys [6], or from face-to-face interviews [11,12] can introduce reporting bias, more objective methods of data collection for medication use are frequently used in asthma research.

Pharmacy records have been used to assess medication adherence and have been shown to be a proxy of patient “drug exposure” [13] but collecting pharmacy data is a challenge due to the use of multiple pharmacies by consumers. As a result, many researchers have focused on the use of integrated databases that may include patient demographic information, encounter data (data related to medical services and hospitalizations) and pharmacy claims data [2,14–17]. Pharmacy claims data culled from integrated databases are less prone to reporting bias because the data collection is not dependent on patient self-report. However, these types of databases exclude populations who are “self-pay” and limit data collection to patients within a specific type of insurance program [15,18,19] which limits its generalizability to broad populations.

Many state Medicaid programs use integrated databases and these data are often used to analyze healthcare parameters in underserved populations [2,3,7,20]. However, the data are only available for patients served by Medicaid programs excluding those who self-pay or patients with no insurance. This limitation can be addressed by collecting pharmacy records directly from the individual pharmacies. Data collected in this manner are less subjective than those obtained from self-report and can potentially be generalized to populations outside those served by Medicaid.

The primary aim of this study is to examine the concordance between pharmacy data culled from Medicaid claims data (“Medicaid pharmacy data”) and patient pharmacy record data obtained from individual pharmacies (“pharmacy record data”) in a sample of inner-city children with persistent asthma. We hypothesized that pharmacy record data would be highly concordant with Medicaid pharmacy data with regard to the number of asthma medication prescriptions filled over a 12-month period.

## 2. Methods

The study protocol was approved by the Institutional Review Boards of the Johns Hopkins University Medical Institutions, the University of Maryland School of Medicine, and the Maryland Department of Health and Mental Hygiene. Medicaid pharmacy data and pharmacy record data were obtained from children enrolled in a prospective study of children with persistent asthma [21]. Informed consent was obtained from all caregivers and child assent was obtained for children over age 7 years. Consent forms also included specific permission to obtain pharmacy claim records from Medicaid as well as from all pharmacies used over the course of the study. A separate HIPAA specific form was added when required by patient pharmacies as well as for all subjects enrolled after the HIPAA implementation.

### 2.1. Study subjects

Children, aged two through nine, were recruited from pediatric and emergency department practices affiliated with two large urban university hospitals and followed for 12 months. Caregivers were surveyed at baseline, 6 months and 12 months after enrollment to identify the pharmacies used in prior 6-month time period. Subjects with incomplete data, those who were not continuously enrolled in Medicaid during the entire study period and those with incomplete claims data from either Medicaid or individual pharmacies used during the study period, were excluded from the concordance analysis.

### 2.2. Medicaid pharmacy data

Medicaid claims, including fee-for-service (FFS) and managed care organization (MCO) data, were obtained with permission from the Department of Health and Mental Hygiene. Subjects were matched to their corresponding Medicaid data using full name, gender, social security and/or Medicaid numbers. Enrollment records were extracted and the number of enrollment days was summed for the follow-up period (either 12 months or date of death, whichever came first). Pharmacy specific data culled from claims data included dispensing date, National Drug Code (NDC), quantity dispensed, days supply, and payment. A table for asthma relievers and controllers was created to convert NDC to generic drug name and medication code (medcode). Medcodes were developed and used to group multiple NDCs for the same drug and dosage form. For example, all albuterol metered dose inhalers (generic, Proventil, Ventolin, etc.) were assigned the same medcode; all forms of albuterol nebulizer solution were assigned another medcode, different from the metered dose inhaler medcode. After FFS and MCO data were put in the same format, all records for asthma medications dispensed during the study period were extracted. Duplicate records (those with the same patient identifiers, same dispensing date, and same medcode) were then excluded. Frequencies and cross-tabulations were performed to confirm completeness and validity of the data. When validity was suspected, the data were adjudicated using the payment, dispensing year, and quantity data for all records with the same medcode. Once the discrepancies were adjudicated, a person-level aggregate dataset was created to provide the number of pharmacy claims for individual drugs and drug classes during the study period.

### 2.3. Pharmacy records data

Prescription records were requested from all pharmacies identified by caregivers during the baseline, 6-, and 12-month study surveys. Complete pharmacy claims records for a specific date range were requested by faxing a subject's consent forms to all pharmacies reported by the subject's caregiver. Pharmacies were asked to fax pharmacy records or indicate "No record of subject" or "No pharmacy claims during specified date range" in the data collection form. Pharmacies that did not respond within 1 week were contacted by phone. Study personnel visited those few pharmacies not responding to either fax or phone request. When a pharmacy refused to release claims records to someone other than the caregiver, a program was developed to reimburse for costs associated with obtaining the records. Pharmacy records were considered complete if every pharmacy identified by the caregiver at each of the 3 data collection points (baseline, 6 and 12 months) responded with data for the specified period, indicated that they had no record of the subject or had no pharmacy claims during the specific time period requested.

Once pharmacy claims records were received, a nurse asthma specialist reviewed the records to ensure complete data retrieval. Pharmacy claims data (dispensing date, product name, strength, dosage form, quantity dispensed, days supply) and corresponding medcodes were double entered into Epi Info™ Version 6 (CDC/WHO) and discrepancies, including duplicates, were adjudicated. A person-level file was developed. A claim was considered "missed" if it was captured by one data collection method but not by the other.

### 2.4. Data analysis

Person-level pharmacy and Medicaid files were merged after matching by subject Study ID. Differences between the pharmacy records data and Medicaid pharmacy data were calculated. Concordance (percent agreement) between Medicaid pharmacy data and pharmacy record data was calculated for each subject as well as for the most frequently reported asthma medications used over the study period (inhaled corticosteroids (ICS), leukotriene modifiers (LTM),

short-acting beta-2 agonists (SABA) and oral corticosteroids (OCS). Due to low use in this population, long-acting beta agonists, mast cell stabilizers and xanthine derivatives were excluded from the analysis. Concordance data were presented with total agreement, number of subjects with a single missing claim and those with 2 or more missing claims.

### 3. Results

#### 3.1. Study subjects

Of 513 children recruited for inclusion in the prospective study of children with persistent asthma [21], 259 met eligibility criteria and 221 were consented and randomized into the study. The children were primarily African–American (89%), male (66%), received Medicaid health insurance (82%), lived with their biological mother (91%) and were a mean age of 4.5 years (SD 2.0). Most caregivers reported a high school education or higher (76%), were

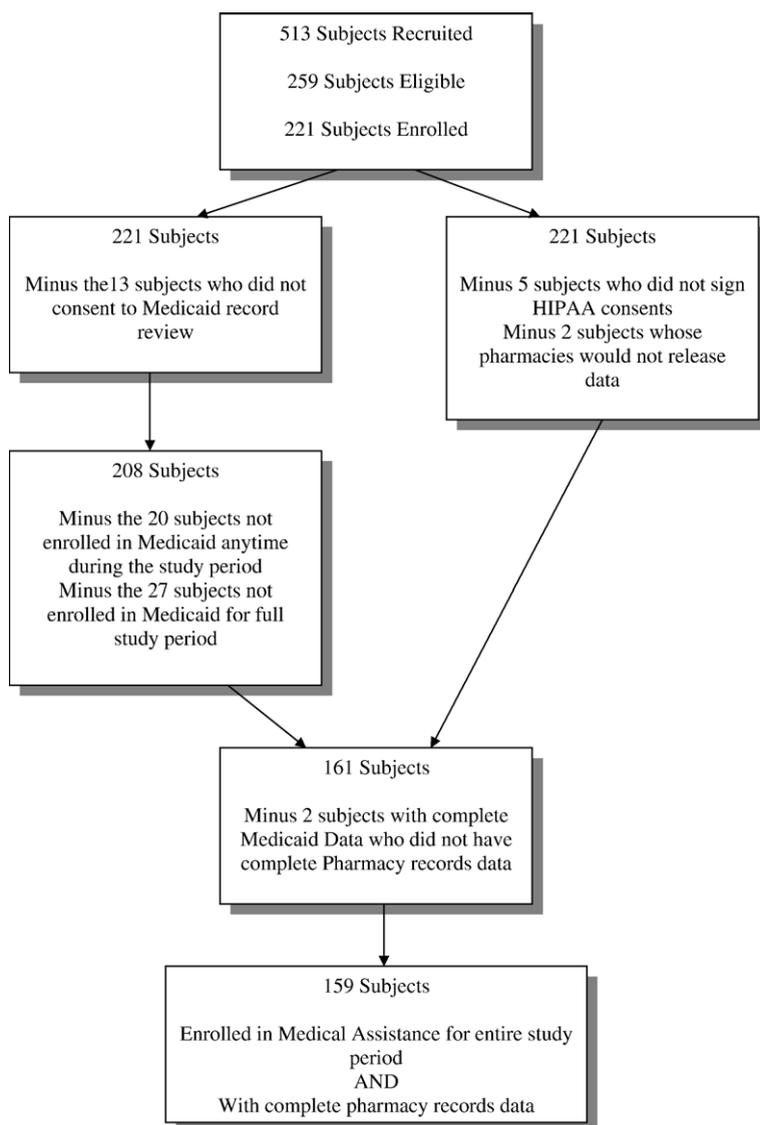


Fig. 1.

employed outside the home (53%) and over half (54%) reported household incomes of less than \$20,000. All subjects were persistent asthmatics at the time of enrollment.

### 3.2. Medicaid pharmacy data

Of the 221 subjects enrolled in the prospective study (Fig. 1), 94.1% ( $n=208$ ) consented to having their Medicaid claims data reviewed. Of those 208 subjects, 9.6% ( $n=20$ ) were not eligible for Medicaid at any time during the study period and an additional 13% ( $n=27$ ) of subjects were not Medicaid eligible for the entire 12-month data collection period. Medicaid claims data were collected on 72.8% ( $n=161$ ) of the 221 enrolled subjects. Validation of FFS Medicaid pharmacy data showed some claims with unexpected low quantities of drug dispensed (e.g., <1 ml of albuterol nebulized solution, <1 tablet of montelukast, <1 fluticasone MDI). Conversely, the MCO data validation showed some unexpectedly high quantities of drug dispensed (e.g., 34,000 g of albuterol MDI, 360,000 ml of albuterol nebulized solution, 26,000 g of fluticasone MDI, 60,000 ml of prednisolone oral solution, 70,000 tablets of montelukast). There were a total of 10.7% of records with unexpectedly low or high quantity values that required adjudication to ensure validity.

### 3.3. Pharmacy record data

Pharmacy record data were available on 96.8% ( $n=214$ ) of the 221 subjects (Fig. 1). Of the seven subjects who didn't have pharmacy record data, five never signed the HIPAA release form required by the pharmacies (two families moved out of state, one caregiver lost custody of the child, one subject died and one family could not be located) and two children used pharmacies that would not release data to the study staff or to the caregiver despite being provided with the necessary consent forms. Data presented in this manuscript represent the 159 subjects with complete pharmacy records data, who had consented to a review of Medicaid records and had been continuously enrolled in Medicaid during the entire 12-month study period. During the study, there were 3 deaths. Data from 2 of these 3 subjects were included in the final analysis.

The 159 subjects averaged 1.84 pharmacies/subject with each subject requiring between 1 and 14 fax contacts (mean 3.89) to each pharmacy to obtain individual child pharmacy data.

### 3.4. Concordance of Medicaid pharmacy data and pharmacy record data

There was complete agreement between the Medicaid pharmacy data and pharmacy record data on the number of pharmacy claims in a 12-month period for 26% ( $n=42$ ) of subjects. Within each drug class, the concordance between pharmacy record data and Medicaid pharmacy data ranged from 44% to 78% of subjects depending on the drug class

Table 1

Concordance of Medicaid pharmacy claims data and pharmacy record data for each subject ( $N=159$ ) by drug class: inhaled corticosteroids (ICS), leukotriene modifiers (LTM), short-acting beta agonist (SABA) and oral corticosteroids (OCS)

Medication	Concordance % ( $N$ )	Source of discordance			
		Pharmacy record		Medicaid record	
		# Subjects	Discrepancy	# Subjects	Discrepancy
ICS	57.2% (91)	20	Missed 1 claim	11	Missed 1 claim
		27	Missed $\geq 2$ claims (range 2–9)	10	Missed $\geq 2$ claims (range 2–9)
LTM	78.0% (124)	8	Missed 1 claim	5	Missed 1 claim
		13	Missed $\geq 2$ claims (range 2–12)	9	Missed $\geq 2$ claims (range 2–11)
SABA	44.0% (70)	37	Missed 1 claim	10	Missed 1 claim
		28	Missed $\geq 2$ claims (range 2–13)	14	Missed $\geq 2$ claims (range 2–6)
OCS	68.5% (109)	32	Missed 1 claim	9	Missed 1 claim
		6	Missed $\geq 2$ claims (range 2–3)	3	Missed $\geq 2$ claims (range 2–3)

Table 2

Discordance between Medicaid pharmacy claims data and pharmacy records data for number of pharmacy claims within each drug class: inhaled corticosteroids (ICS), leukotriene modifiers (LTM), short-acting beta agonist (SABA) and oral corticosteroids (OCS)

Medication	Total # of pharmacy claims captured by Medicaid	Total # of pharmacy claims missed by Medicaid	Total # of pharmacy claims captured by pharmacy records	Total # of pharmacy claims missed by pharmacy records
		% (N)		% (N)
ICS	536	8.7% (51)	470	21.0% (125)
LTM	375	9.6% (40)	354	14.7% (61)
SABA	735	5.3% (41)	621	18.2% (138)
OCS	212	7.4% (17)	182	20.5% (47)
Total	1858	149	1627	371

(Table 1). For example, of the 159 subjects, the pharmacy records data and Medicaid data agreed on the total number of ICS claims filled over the 12-month study period for 91 (57.2%) of the subjects. For the other 68 subjects, either the pharmacy record did not include 1 (20 subjects) or more (27 subjects) claims that appeared in the Medicaid record, or the Medicaid record did not include 1 (11 subjects) or more (10 subjects) that were included in the pharmacy records. Pharmacy record data accounted for the majority of the discordance in that more subjects had 1 or more claims that were captured by the Medicaid pharmacy data and missed by the pharmacy records data.

Discordance between the number of pharmacy claims captured and missed by either the Medicaid pharmacy data or the Pharmacy record data is shown in Table 2. A total of 1858 claims were captured by the Medicaid pharmacy data. The majority of the total number of claims that was missed by the Medicaid pharmacy data was ICS medications. Medicaid pharmacy data failed to capture even a single pharmacy claim on 4.4% ( $n=7$ ) of subjects who had pharmacy claims captured by the pharmacy record data.

The pharmacy record data captured a total of 1627 pharmacy claims with similar distribution as compared to the Medicaid pharmacy data. However, the majority of the claims missed by the pharmacy records data were SABA medications. Pharmacy record data failed to capture a single pharmacy claim in 1.9% ( $n=3$ ) of subjects who had pharmacy claims captured by the Medicaid pharmacy data.

#### 4. Discussion

There are few published studies evaluating the accuracy of pharmacy data obtained outside of large health care organization or national datasets. Sherman et al. compared pharmacy refill information to Medicaid claims records and determined that pharmacy refill histories were 92% accurate [22]. Evaluation of integrated claims datasets such as those used by health plans and Medicaid has received more attention in the literature. In an evaluation of data loss in Maryland Medicaid data, Stuart et al. estimated that while up to 1/3 of encounter data were lost, the group had “high confidence” in claims data, which include the pharmacy data [23]. The confidence in the pharmacy claims data is related to the fact that reimbursement is dependent on accurate reporting and billing by the pharmacies whereas encounter data are not [17]. Our results indicate that there was significant overlap between the pharmacy data captured by the Medicaid pharmacy dataset and pharmacy record dataset, yet the overall concordance between the two data collection methods was low. The concordance improved if the level of tolerance was set at  $>1$  claim missed, but even at that level the agreement between the two data collection methods was modest.

There were certain benefits to each data collection method. Using pharmacy record data allowed for data to be collected on more subjects. Of the 221 subjects enrolled in the original study, pharmacy data were available on 96.8% ( $n=214$ ) of subjects. Medicaid pharmacy data were available for only 72.8% ( $n=161$ ) of the subjects enrolled either because subjects refused to consent to have their Medicaid records reviewed ( $n=13$ ) or more importantly because the subjects were not enrolled in Medicaid for the entire data collection period ( $n=47$ ). On the other hand, for those subjects in the Medicaid system, the Medicaid pharmacy data captured more pharmacy claims than the pharmacy records data accounting for fewer sources of discrepancy.

There were also limitations to both methods of data collection. Obviously, the data obtained were only as good as the data entered and both data collection methods had potential for error in capturing the pharmacy claims. In addition, both data collection methods required front-end coordination to collect consent and authorization forms. The pharmacy records data collection method we employed was dependent on the caregiver’s report of all of the pharmacies used

during the data collection period. There were wide variations in interpretation of HIPAA requirements among the individual pharmacies with some pharmacy chains requiring records be requested from a corporate office, some requiring that a family member request and retrieve the pharmacy records and one chain that refused to supply medication records despite signed consents and HIPAA forms. Many of these issues resolved as pharmacy corporate policies evolved to reflect newly implemented HIPAA regulations. Limitations of Medicaid claims data include the effort to request permission from appropriate agencies to release Medicaid data, expenditure for data extraction, and need for an experienced programmer who understands Medicaid data to clean and validate the data. In addition, Medicaid data are only available for subjects who use Medicaid insurance to fill their prescriptions. Medications purchased with cash or commercial insurance are not captured.

Regardless of data collection method, pharmacy claims data only determine whether or not a medication is available for use. Pharmacy data do not address the practice of sampling, sharing of medications among household members or pharmacy assistance programs that supply medications to patients directly. Even if a medication is filled at the pharmacy, there is no guarantee that the subject actually administered the medication at the correct time, in the correct dose or used the appropriate administration technique.

In spite of the differences in the methods used to collect data, pharmacy fill records are a rich source of data with both clinical and research applications. Our data suggest that pharmacy records collected directly from the pharmacy can include data on more subjects and that pharmacy data culled from Medicaid claims may be more likely to capture more total number of claims. One could assume that other integrated datasets would vary in quality in comparison with Medicaid pharmacy data, depending on the methods of claim data collection. In addition, our decision to exclude subjects with incomplete data means that our results are not directly applicable to a broad population spectrum. For instance, subjects who did not receive Medicaid were not part of the concordance analysis. However, the methods described here are applicable to other diseases and other claims datasets. Clinicians and researchers must weigh the potential benefits and limitations described here to determine the most appropriate method to collect pharmacy data.

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