Medication Management Transactions and Errors in Family Medicine Offices: A Pilot Study

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Abstract

Objective: The objective of this study was to determine the feasibility of detecting medication errors by self-observation of office transactions related to medication management. **Methods:** Primary care physicians (N = 14) and office staff (N = 18) reported all their medication management transactions during the 4-hour study period. A study coordinator abstracted additional information from patients' charts. **Results:** Participants documented 440 medication management transactions for 246 encounters: 98 office visits, 70 patient refill requests, 34 pharmacy refill requests, 16 nonvisit patient phone questions, 13 encounters initiated by laboratory results, and 15 others. Errors were identified in 84 of the cases (34.1 percent). Error types included medication not listed on the chronic medication list (59); medication not listed anywhere in the chart (7); wrong dose prescribed (6); prescription incorrectly written (5); failure to implement medication across care settings (3); contraindicated medication prescribed (1); and other (3). None of these errors would have been detected by chart review alone. **Conclusion:** Self-reporting followed by chart review is feasible in primary care practices and discovers medication errors that might not have been detected by either method alone.

Introduction

Few studies have examined medication-related errors associated with medication management transactions occurring in primary care practices. Investigators have examined malpractice claims,¹ medical records,² and medication orders^{3, 4} to determine the rates and nature of medication errors in ambulatory care. Gandhi, et al.,² and Blendon, et al.,⁵ found that the most common primary care medication errors are related to monitoring the effects of medications and responding to reported symptoms. Among a sample of elderly patients, Gurwitz, et al.,⁶ found that many adverse drug events were due to prescribing errors. Physician handwriting^{3, 7, 8} and the general quality of prescription orders⁴ are also sources of medication errors. When post-visit interviews with patients who received prescriptions are combined with chart review data, errors have been found to occur in as many as one of every four patients.²

No studies were found, however, that identify specific primary care office processes that are associated with medication errors. In busy primary care offices, the office staff is intimately involved in medication management transactions. For example, receptionists take messages about medication refills; nurses and medical assistants call or fax prescriptions to pharmacies based on practitioners' orders; and patients leave messages requesting refills on office voicemail. These communications are inherently complex, involve inter-professional communications, and are susceptible to human error. Many medication management transactions are handled by phone, fax, and e-mail and involve written communications and hand-offs to several practice staff members. No investigator has explored the extent to which office processes contribute to medication errors.

The hypothesis of the present study was that physicians and staff may be able to identify and report in real time the errors they observe during routine medication management transactions, and that these observations might ultimately identify office processes requiring improvement. A pilot study was designed and implemented to investigate this notion.

Methods

The primary objective of the pilot study was to determine the feasibility of physicians and office staff to detect and report medication management transaction errors during the course of their routine work. A secondary objective was to determine the frequency of medication errors associated with specific factors. The following factors were examined:

- The role of the individual(s) handling the medication management transaction.
- The number of individuals involved in the medication management transaction.
- The method of communicating the medication management transaction (i.e., telephone, fax, e-mail).
- The type of medication (e.g., acute, new chronic, existing chronic).
- The type of medication management transaction.
- The number of medications involved.
- The prescribing method (electronic vs. paper).

The study defined error as "anything that happens in your own practice that should not have happened or did not happen that should have happened," a definition used in other primary care error-reporting studies.⁹ Error categories were taken from the International Taxonomy of Errors in Primary Care – Version 2,¹⁰ with additional detail for the "other" category. No attempt was made to classify outcomes or harm to patients.

The participants in the pilot study included the entire staff (14 physicians and 18 office staff) of three primary care family medicine offices located in Connecticut, who volunteered to participate. None of the sites in the study used an electronic medical record. However, one practitioner did supplement the paper chart with a handheld PDA to electronically support prescription management.

The primary care practice sites followed their own usual office practices for medication orders, refills, and responses to phone, fax, and e-mail questions from patients and pharmacies. Typically, after making a diagnosis, physicians, advance practice nurse practitioners (APRNs), and physician assistants (PAs) write medication orders on paper prescription pads, document the orders in the patient's paper chart, hand the prescription to the patient, and provide brief instructions about the medication. Faxed refill requests from a pharmacy are paper-clipped to the chart for response by the practitioner. Refill messages left by phone are transcribed onto an

adhesive-backed form approximately 2" by 5" in size. These are then paper-clipped to the chart for completion of drug dosage and amount to be refilled, which is completed by a physician, APRN, or PA. Nurses, medical assistants (MAs), and licensed practical nurses (LPNs) do not help write any prescriptions but will enter medications onto the medication list.

The study design involved two, 2-hour prospective self-observation time slots at the three family medicine offices. During the study period, physicians and staff documented on a Medication Transaction Study Form every transaction involving the management of a medication.^a Physician and staff self-reported if they thought the medication management transaction involved an error. At a subsequent date, a nurse reviewer abstracted study variables from the office paper medical record for each patient involved in the medication management transactions. Because the study was a pilot, the team was not concerned about obtaining representative time slots to account for annual, monthly, daily, or hourly patterns. The categories on the data collection form included:

- Patient's name, date of birth, and study ID.
- Communication method (in person/phone/fax/e-mail, etc.).
- Names of medications and whether they were prescribed by a non-study physician.
- Reason for transaction (e.g., new diagnosis, renewals, medication change due to a lab result).
- Type of medication (new chronic, chronic, acute).
- Method of prescribing (electronic, other).
- Role of individual(s) involved in the medication management transaction (MD/PA/APRN, nursing staff, other clinical staff, medical record staff, or front desk).
- Description of any suspected error detected in the execution of the medication management transaction by any of the office staff.

To make completion easier than open-ended reporting, the data collection form included a set of responses to most questions. The second page of the data collection form, which was completed by the chart reviewer, included:

- Patient demographics (year of birth, ethnicity, insurance provider).
- Confirmation that each medication involved in the transaction was noted in the patient chart.
- Confirmation that each chronic medication involved in each transaction was noted on the chronic medication list.
- Number of chronic medications listed on the medication list.
- Confirmation of allergy listed in chart.
- Reviewer's comments as to possible error.

A third page of the data collection form was designed for the study coordinator and physician reviewers to record their comments about the transaction, make a final determination about any error, and provide a checklist for the type of error detected.

^a The data collection form can be obtained from the corresponding author upon request.

Prior to rollout of the study, all physicians and staff at the three sites participated in a training session. At the training session, the study coordinator reviewed the study protocol, including how to complete the transaction data collection form. Staff and physicians were instructed to attach the form to every medication-related phone message, fax, e-mail, or actual prescription that came into or left the office during the data collection period. For those patients scheduled to see the physician during the data collection period, a data collection form was attached to the medical chart prior to the patient being seen by a physician.

During the study, all staff and physicians at the three sites recorded all process interactions concerning medications during a 2-hour period on 2 different days (4 hours per site) on the data collection forms. The time slots were not preselected based on patient volume or other criteria suspected to be associated with errors. Time slots were at the convenience of each practice site.

During each study period, each medication management transaction was tracked from its inception to completion. Medication management transactions might begin with a call or fax from a patient or a pharmacy, a new prescription written for an acute problem, or a routine medication continuation initiated by a clinician during an office visit. The first individual to handle the medication management transaction attached a data collection form to the chart or medication request note and documented the patient's name, method of communication with the office, name of medication(s), reason for the medication management transaction, whether it was a new or existing medication, and whether the prescription was for an acute or chronic medical condition. For transactions that involved more than one medication, only one data collection form was used. As the transaction moved through the practice, each person who handled the transaction indicated his/her involvement with a check-off in a designated section of the data collection form and flagged potential errors. In addition, the study coordinator was onsite during the data collection period to respond to any questions. At the end of each 2-hour data collection period, the study coordinator collected all data collection forms.

At a later date, an independent nurse reviewer brought the data collection forms to each office site and abstracted patient charts associated with the medication management transactions being studied. The nurse reviewer collected basic demographic information for the patient, including year of birth, race/ethnicity, and insurance provider. The nurse reviewer noted whether the chart contained a notation regarding medication allergies and a medication list; whether the medication management transaction was noted on the medication list for a chronic medication or elsewhere in the chart for acute medications; and the total number of chronic medications listed for the patient. The nurse reviewer did not abstract any information about transactions leading up to or occurring after the transaction noted on the data collection form. After completion, the data collection forms were returned to the study coordinator.

The study coordinator reviewed each data collection form, categorized the transaction as involving error or no error, and categorized the error according to the International Taxonomy of Errors in Primary Care – Version 2,¹⁰ with additional details for "other" categorization.

In the final step, one of the physician investigators reviewed all of the data collection forms, made a final classification about error, and noted the rationale. For the purposes of this study,

medication management transactions were classified into two categories: "no error" and "error." The second physician investigator then reviewed the data collection forms, noted agreement or disagreement with the first physician's opinion, and the rationale. If there was a disagreement, the data collection form was re-reviewed by both physicians. Only when both physicians agreed about the result was the final assignment of the error status considered complete. All information gathered on the data collection forms was then entered into a database for statistical analysis.

In dissecting the anatomy of an error for purposes of quality improvement, it was important to analyze medication management processes. The term "transaction" was used to define any unique process, where a different person participated in the medication management process. Examples include a receptionist answering or returning a patient's phone call, nursing staff recording the medication in the chart, or a physician writing a prescription. Thus, there could be multiple transactions in a single "encounter." We also recognized that medication management has a life cycle and could include an "episode" of multiple encounters, during which prescribing, dispensing, recording, administering, and monitoring take place. Each encounter could include multiple individual transactions. An error could occur during any of the transactions during any of the encounters making up the medication management episode.

Not all errors result in harm to a patient; some errors are discovered before harm takes place. Therefore, a mitigation transaction was defined as a transaction where such discovery takes place. As with error, a mitigation transaction could take place during any of the multiple encounters making up the medication management episode. During analysis of the results, it was important to distinguish between encounters during which there was an error transaction and encounters during which there was a mitigation transaction. Although the mitigation transaction/encounter was an opportunity to identify an error, the transaction processes surrounding the mitigation (e.g., person handling, type of transaction) were not considered appropriate processes to be associated with causes of the actual error for quality improvement. Thus, when analysis was performed on a variable that reflected office processes surrounding a mitigation transaction (who handled the transaction, number of times the transaction was handled, and communication method), that (mitigation) transaction was excluded from the analysis. If the variable being analyzed reflected the underlying patient or medication being managed (e.g., type of medication, number of medications, insurance provider), the mitigation transactions/encounters were included in the analysis.

Because of the pilot nature and small size of this study, the data analysis was primarily descriptive in nature. Summary statistics appropriate to the distributional characteristics of the variables of interest were computed. Bivariate relationships between number and percent of errors were explored for the role of the individual handling the medication management transaction, number of individual(s) involved in the medication management transaction, communication method, type of medication, type of medication management transaction, number of medications prescribed, and prescribing method.

Results

After eliminating one record for insufficient data, the 12 hours of observation yielded 440 medication management transactions involving 246 patient encounters and 337 medications. The

demographics of the 246 patient encounters were as follows: mean age, 52 years (range, newborn to 99 years); 93 percent Caucasian (Connecticut's population is 89.3 percent Caucasian); 4 percent African American (Connecticut's population is 8.7 percent African American); and 3 percent other races (Connecticut's population is 2.0 percent other races). Although the highest error rates were documented for middle-aged patients (aged 26-65 years), no significant trends were noted for any of the demographic variables.

Several study variables did not lend themselves to analysis. Too many unique medications were involved in the transactions to associate errors with detailed medication names. There were only four transactions where the medication was "prescribed by another physician." There were only eight transactions where the list of allergies was not present in the chart. Of these eight, two had medication documentation errors. Because of the methodologies used, no transactions reflecting the adverse events/patient harm were identified.

The types and frequency of errors identified are summarized in Table 1. Errors were identified for 84 of the medication management encounters (34.1 percent); 67 errors (80 percent) were chart documentation errors. The physicians and staff identified 18 errors during the study periods, an error rate of 7.3 percent per medication management encounter. The chart review identified 66 additional errors, mostly documentation errors; 16 of the errors (19.1 percent) were discovered during mitigation encounters.

Role of individual handling the medication management transaction. Before excluding mitigation transactions, the transactions were handled a total of 440 times by front desk staff, nursing staff, APRNs, PAs, other medical staff, and other nonmedical staff. Physicians, PAs, and APRNs handled the prescription(s) most frequently (N = 210), followed by nursing staff (N = 97), medical record staff (N = 60), clinical staff (N = 51), and finally the front desk (N = 22). After excluding mitigation transactions, the error rate was higher for front desk staff, but there was no statistically significant difference (Table 2).

Number of people involved in the medication management encounter. Before excluding mitigation encounters, the number of staff handling the transactions were: one person (N = 113); two people (N = 50); three people (N = 69); four people (N = 10); five people (N = 3); and six people (N = 1). After excluding mitigation encounters, the error rate increased significantly (P < 0.01) as the number of personnel involved in the transaction increased (Table 3). Error rates increased from 25 percent to 100 percent as the number of people handling the medication management transaction increased from one to four or more people. The 16 mitigation encounters that were excluded were handled 41 times, reflecting the burden of mitigating the error but not processes associated with the error itself.

Method of communicating the medication management transaction. All but one error associated with mitigation encounters were associated with phone or fax communications. In these cases, it was the phone or fax that was responsible for mitigating the error but not how the error occurred. After excluding mitigation encounters, the error rates were fairly consistent across communication methods, except for online encounters (only two cases), which had a 100 percent error rate (two documentation errors) (Table 3). The method of communicating the medication management transaction showed no statistically significant differences.

Error transactions (N)	Total errors (%)
59	70.2
7	8.3
1	1.2
1	1.2
68	80.9
6	7.1
5	6.0
2	2.4
1	1.2
1	1.2
1	1.2
16	19.1
84	100.0
	59 7 1 1 6 8 6 5 2 1 1 1 1 1 1 1 1 6

Table 1.Frequency of error by type of medication management
and type of error

a Identified during prescribing encounters or chart review.

b Identified during mitigation encounters.

Role of person handling transaction ^a	Transactions with errors	Total transactions	% Error	<i>P</i> -value ^b
Physician/PA/APRN	65	201	32.3	
Nursing	27	86	31.4	
Other clinical staff	17	49	34.7	
Medical records	16	52	30.8	
Front desk	8	15	53.3	
Total	133	403	33.0	0.54

Table 2. Frequency of error by role of person handling transaction

a Excluding mitigation encounters.

b Chi-square.

	Errors	Encounters	% Error	P-value
Number of persons handling	transaction ^a			<0.01
One person	28	112	25.0	
Two people	19	66	28.8	
Three people	17	48	35.4	
Four or more people	4	4	100.0	
Communication method ^a				0.28
In-person appointment	29	101	28.7	
In-person walk-in	2	6	33.3	
Phone call	24	79	30.4	
Fax	11	42	26.2	
Online	2	2	100.0	
Total	68	230	29.6	

Table 3. Frequency of error by number of times transaction was handledand by communication method

a Excluding mitigation encounters.

Type of medication. Error rates varied widely by the type of medication (Table 4). For new chronic medications, errors occurred in 74.2 percent of encounters; for renewal of existing chronic medications, 37.0 percent of encounters; and for acute care medications, 13.8 percent. The difference in errors by type of medication was highly significant (P < 0.00001).

Reason for encounter. Error rates also varied by reason for the encounter (Table 4). Reasons for the encounter included 98 for initial patient diagnosis/treatment, 70 for patient-initiated medication renewal requests, 34 for pharmacy renewal requests, 16 for nonvisit patient questions, 13 for discussion of laboratory results, and 7 for insurance benefit-type medication management transactions.

Although the numbers are small, three reasons for the medication management transaction are worth noting because of their high error rates. Insurance coverage issues were associated with a 71.4 percent error rate; patient medication renewal requests had a 44.3 percent error rate; and transactions related to the results of lab tests initiating medication requests had a 38.5 percent error rate.

Number of medications involved. Of the medication management encounters, 73 percent (180/246) involved a single medication (Table 4). However, the error rate was significantly higher (P = 0.02) when two or more medications were handled in an encounter, compared to one medication: 45.5 percent vs. 30.0 percent, respectively. Although the numbers were small, there was a trend for documentation errors to increase as the number of medications increased. This could have been a byproduct of managing the overall number of medications the patient was taking (not just the transactions recorded during the study). On average, patients were taking 3.81 chronic medications; range, 0 to 17 chronic medications.

	Errors	Encounters	% error	<i>P</i> -value
Type of medication				<0.00001
New chronic medication	23	31	74.2	
Renewal of chronic medication	50	135	37.0	
Acute care medication	11	80	13.8	
Reason for encounter				0.05
Initial patient diagnosis/treatment	26	98	26.5	
Patient-initiated renewal request	31	70	44.3	
Pharmacy-initiated renewal request	9	34	26.5	
Patient followup questions (no visit)	4	16	25.0	
Results of lab-initiated Rx	5	13	38.5	
Insurance coverage issue	5	7	71.4	
Other	4	8	50.0	
Number of medications involved				0.02
One medication	54	180	30.0	
Two or more medications	30	66	45.5	
Insurance provider covering encounter				0.71
Private	54	158	34.2	
Public and private	20	54	37.0	
Public	8	30	26.7	
Self-pay	2	4	50.0	
Total	84	246	34.1	

Table 4. Frequency of error by type of medication, reason for encounter, number of medications involved, and insurance provider

Prescribing method. Although none of the practitioners in the study used an electronic health record, one did supplement the paper charts with a handheld, stand-alone electronic prescribing software package. A total of 14 e-prescription transactions were documented; three (21 percent), resulted in error, compared to 34.9 percent error for all other methods. All three errors were described as "not listed on chronic med sheet."

Discussion

The issue of medication errors or adverse events leading to increased patient morbidity and mortality in the primary care setting has been little explored and is daunting to analyze. Patients receive multiple medications from multiple sources with the potential for interactions and overlapping therapies. Patient confusion concerning the appropriate use of medications and individual idiosyncrasies reflecting biases for or against the use of certain medications all complicate the issue of adequate care. In addition, the complexity of patient communication within the modern medical office further confuses the problem. Intercommunication processes were the focus of the study. When face-to-face encounters, pharmacy-to-physician and physician-to-pharmacy phone calls, patient phone calls, faxed messages, online communication, and after-hours contacts are included, the ability to determine exactly which medication a patient is and/or should be taking is a complex and daunting proposition.

The two, 2-hour time slots in our study yielded only a narrow snapshot of a medication management episode and then only from the primary care office site viewpoint. The time slot did not span all medication management processes (i.e., prescribing, dispensing, recording, administering, and monitoring) associated with complete medication management episodes that might evolve over hours, days, or weeks. The time slot from the primary care viewpoint does not include medication management processes from either the patient's or the pharmacist's viewpoint, other than where they intersect with the primary care office site. Not all medication management transactions and review of patient charts documenting identified transactions—was used retrospectively to look at events leading up to an identified transaction, nor was it used to look past the identified transaction to subsequent mitigation encounters or adverse events arising from identified errors.

Our results show that it is feasible to detect medication errors by self-observation of medication transactions in the office. The study methodology worked very well in identifying transaction errors from the perspective of primary care practices. The study methodology did not address transaction errors from the perspective of either the patient (compliance) or the pharmacy (processes). The methodology also did not address patient harm or other undesirable consequences of transaction errors.

Documentation errors could not have been detected simply by reviewing charts or self-reporting of transactions alone. Most errors were identified only by a gap analysis, comparing chart-abstracted information to self-reported summaries. Both methods were needed to discover the high volume of errors.

When the study detected mitigation transactions, the measures reflected processes occurring when the error was discovered rather than the circumstances at the time that the error occurred. Although the methodology investigated single encounters, it should be revised to track all encounters in the complete medication management episode. When a mitigation event is identified, a retrospective review should track back to the encounter where the error occurred and identify office processes associated with the error. All events should be tracked forward in time to sufficiently identify additional encounters where possible adverse events or recovery transactions are recorded.

The limited time snapshot should be expanded to identify yearly, monthly, weekly, daily, or hourly differences. For example, an after-hours snapshot might reveal an even larger volume of documentation errors, since the practitioner might be covering without benefit of a chart and without a mechanism to record interactions in the chart, possibly leading to increased documentation errors. In the limited context of this study (three individual group practice sites, a finite period of study time within the context of busy practices), the absolute number of both documentation and nondocumentation errors was nonetheless remarkable. Of the 246 encounters, 11 (4.5 percent) were associated with an incorrect prescription written or a wrong dose prescribed. The medications included cardiovascular, antibiotic, and narcotic analgesic medications. Most of the errors involved failure to document medications on the chronic medication list. With inadequate documentation, the likelihood of further mistakes and confusion down the road is greatly increased. Incomplete medical record documentation can pose a serious hazard to the patient.

The analysis of rates of error detected in the study was complicated by the reporting on encounters that included both prescribing and mitigation transactions in the same results. If detected, an error might require additional effort (mitigation transactions) to resolve the error. If undetected, an error might require additional effort to resolve an adverse event. Any efforts expended to resolve mitigation or adverse events become measures of the cost and productivity impact caused by error transactions. One needs to be careful not to associate such additional workflow as a cause of the error.

When the transaction took place during a prescribing encounter, a physician, PA, or APRN was always involved, and the number of people handling the transaction was fewer. When the communication method involved incoming phone calls, faxes, or online interactions, more people were involved.

Errors that were discovered and mitigated by pharmacists or patients typically involved incoming phone calls, faxes, and e-mails that raised the concern and involved staff in multiple roles to receive the question, pull patient charts, and coordinate the response. By their nature, incoming communications involve nonmedical staff to receive the communication, a clinical staff person to triage the communication, and medical record staff to pull the patient's chart for use in the decision. Thus, mitigation events should be excluded from any analysis that attempts to associate the frequency of handling the transaction or the role of the individuals involved in the transaction with a cause of error.

Because phone calls (N = 24), faxes (N = 11), and online communications (N = 2) were associated with 61.9 percent of all errors, quality improvement studies should focus on these modalities to identify cases of error that need to be studied. It is fairly straightforward to identify which incoming communications are mitigation transactions and to use mitigation transactions as a way to identify errors. Although electronic health records (EHRs) might reduce the number of documentation errors, special work flow considerations might be needed to document phone calls, faxes, and other online communications not automatically incorported into an EHR.

Other particular areas needing quality improvement and further study include office processes involving laboratory results that initiate a change in medication; office workflow when multiple people are handling a single transaction; processes involved in new chronic medications; and processes taking place when a chart might not be available, such as incoming patient phone calls and online communications with the patients or pharmacists.

In addition to the microcosmic view of medication-related transaction errors this study provides, we can get a sense of the global impact of errors. For the practitioners and timeframes involved in this study, the error rate averaged 1.5 errors per hour. However, the findings of the study are difficult to generalize because of the limited time of data collection, limited numbers of absolute errors, and the small number of practices involved.

The sheer volume of potential problems related to the prescribing of medications in the primary care setting speaks to the need for a more comprehensive study to validate this study's findings and to propose and test possible office-based solutions to reduce medication errors. One obvious process change/intervention that merits close study is the use of e-prescribing that provides documentation directly into the record. The opportunity to achieve automated documentation and benefit from system prompts that alert the prescribing clinician to potential drug-drug interactions and prescription errors is powerful medicine indeed.

Conclusion

Direct self-observation followed by review of charts and a gap analysis of differences among the findings is feasible in primary care practices and uncovers medication management transaction errors that normally would not be detected by self-reporting or chart reviews alone.

Other methods to track the high probability of error processes might help pinpoint error episodes without engaging practitioners in time-consuming self-observation. Because phone calls, faxes, and online communications were associated with 54.4 percent (37/68) of all the stage-1 errors we detected (Table 3) and most stage-2 mitigation events, quality improvement studies should focus on these communication modalities to identify cases of error for study. Other office processes that demonstrate opportunities for focused improvement include prescribing new chronic medications, medication changes initiated because of laboratory results, and patient requests for medications prior to the point of error discovery and a prospective review of downstream sequellae—might also provide a broader picture of the error episodes.

This pilot study demonstrates that the typical daily medication management transactions that occur in primary care practices using paper records and paper prescriptions provide many opportunities for errors. Many of these errors might not have occurred with electronic prescribing embedded in an electronic medical record. For example, such systems typically automatically update the medication list when a prescription is ordered or modified. Additional larger studies in more venues and studies of transaction errors that occur with ambulatory electronic prescribing mechanisms are needed.

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