National Observational Study of Prescription Dispensing Accuracy and Safety in 50 Pharmacies

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Objectives: To measure dispensing accuracy rates in 50 pharmacies located in 6 cities across the United States and describe the nature and frequency of the errors detected. *Design:* Cross-sectional descriptive study. *Settings:* Chain, independent, and health-system pharmacies (located in hospitals or managed care organizations). *Participants:* Pharmacy staff at randomly selected pharmacies in each city who accepted an invitation to participate. *Intervention:* Observation by a pharmacist in each pharmacy for 1 day, with a goal of inspecting 100 prescriptions for dispensing errors (defined as any deviation from the prescriber's order). *Main Outcome Measure:* Dispensing errors on new and refill prescriptions. *Results:* Data were collected between July 2000 and April 2001. The overall dispensing accuracy rate was 98.3% (77 errors among 4,481 prescriptions; range, 87.2%–100.0%; 95.0% confidence interval, ± 0.4%). Accuracy rates did not differ significantly by pharmacy type or city. Of the 77 identified errors, 5 (6.5%) were judged to be clinically important. *Conclusion:* Dispensing errors are a problem on a national level, at a rate of about 4 errors per day in a pharmacy filling 250 prescriptions daily. An estimated 51.5 million errors occur during the filling of 3 billion prescriptions each year.

J Am Pharm Assoc. 2003;43:191–200.

The national awakening of health care professionals to medication safety issues is evidenced by the reaction to the Institute of Medicine's report *To Err Is Human*.[1] This report stimulated discussion of the fundamental questions "Is there a dispensing error problem?" and "If so, what is its nature and magnitude?" Answering these questions is important for identifying needed interventions (e.g., automation, training) and justifying their associated expense. Case studies using observation in outpatient pharmacies have detected error rates ranging from 0.2% to 10%.[2–9] Using conservative estimates of a 1% dispensing error rate and an annual total of 3 billion dispensed prescriptions, a projected 30 million errors would occur each year in United States.[10]

A measure of the national dispensing error rate should be of immediate interest to not only consumers and pharmacists but also to groups, such as the National Committee for Quality Assurance and state boards of pharmacy, that are interested in setting a standard of quality for prescription filling operations. Although no standard exists for prescription dispensing errors in the ambulatory setting, a national standard has been established for medication administration errors in nursing homes: An error rate exceeding 5% can result in withholding of reimbursement by the federal Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration).[11]

The drug distribution system in the ambulatory care setting consists of the processes of prescribing, prescription fulfillment, patient self-administration, and follow-up monitoring. In this study we focused on errors in the prescription fulfillment process in chain, independent, and health-system (hospital and managed care) pharmacies.

We used direct observation to detect errors because it is recognized as the most accurate method, detecting many more errors than voluntary self-reports in hospitals and long-term care facilities.[12–18] Observation has a number of advantages when used to study the sensitive subject of medication errors:[12]

- Knowledge of the error by the person involved is not required (they are often not aware that an error has been made).
- Willingness to report the error is not a factor (there is no threat of disciplinary action as a result of recording the error using observation).
- Remembering to report errors is not required.
- Ability to communicate errors is not required.
- Selective perception of the nurse or pharmacist is not involved

Received September 17, 2002, and in revised form December 17, 2002. Accepted for publication January 8, 2003.

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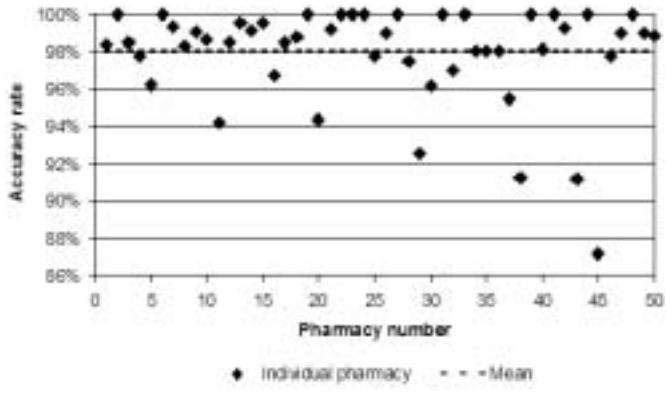
(they may only believe it is necessary to report serious errors).

Observation has been used to detect medication administration errors in studies in hospitals and nursing homes for more than 40 years.[19–39]

Objectives

The primary objective of this study was to describe the nature and frequency of dispensing errors in prescription filling operations, differentiating among three different types of pharmacies (chain, independent, and health system) in six large cities in the United States. In addition, a comprehensive list of error prevention techniques used in pharmacies was constructed. Factors in pharmacy work systems and the work environment associated with errors were explored, and these are the subject of a separate report.[40]

Figure 1. Accuracy Rates for 50 Study Pharmacies



Methods

Study Design and Study Units

In this descriptive study we assessed dispensing errors detected during 1 day of observation of prescription filling in 50 pharmacies in 6 large cities. The unit of analysis was a filled prescription, new or refill, processed on the day of the study. Each medication ordered on one prescription form was considered a separate prescription (e.g., if five medications were ordered on one form, five prescriptions were counted). The goal was to observe and evaluate 100 prescriptions for errors in the order in which they were filled by the pharmacy staff while the observer was present.

This study was deemed exempt from review by the Auburn University Institutional Review Board.

Definitions

For new prescriptions, a dispensing error was defined as a discrepancy between the prescriber's interpretable written order and the filled prescription (including written modifications made by the pharmacist pursuant to contact with the prescriber or in compliance with pharmacy policy). For refill prescriptions, an error was defined as any deviation between the contents of the filled prescription and the contents described on the pharmacy-generated prescription label.

Will call prescriptions had been filled previously and were waiting to be picked up by the patient or his or her representative. (As discussed later in this article, the accuracy of these prescriptions provided a measure of any impact of the observer because they were filled at a time when the observer was not present.) Errors on will call prescriptions were defined in the same way as refill prescriptions.

Error categories, defined in detail in Appendix 1, were wrong drug, wrong strength, wrong dosage form (correct drug), wrong quantity, wrong prescription label information (excluding instructions), wrong label instructions, omission, wrong time, and deteriorated drug.

Table 1. Accuracy Rates by Pharmacy and Prescription Type

	Pharmacy Type			
Prescription Type	Chain	Health System	Independent	Totals
No. of pharmacies	26	9	15	50
% pharmacies	52.0	18.0	30.0	100
No. of new prescription errors	31	18	14	63
No. of new prescriptions filled	1,043	343	575	1,961
% accuracy, new prescriptions	97.0	94.8	97.6	96.8
No. of refill prescription errors	3	1	7	11
No. of refill prescriptions filled	739	315	623	1,677
% accuracy rate, refill prescriptions	99.6	99.7	98.9	99.3
No. of uncategorized prescription errors	3	0	0	3
No. of uncategorized prescriptions filled	553	118	172	843
% accuracy, uncategorized prescriptions	99.5	100	100	99.6
Total no. of prescription errors	37	19	21	77
Total no. of prescriptions filled	2,335	776	1,370	4,481
% accuracy, overall	98.4	97.6	98.5	98.3

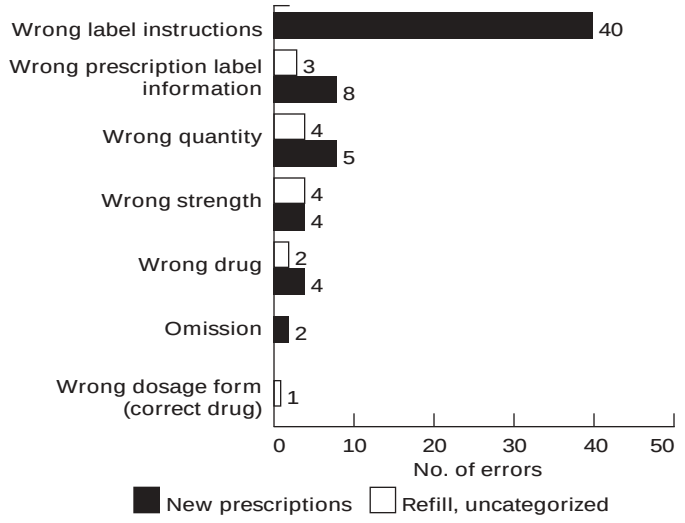
Sample Selection and Recruitment

Six large metropolitan statistical areas were selected as representative locations for pharmacy practice in the United States based on consultation with organizational leaders from the American Pharmaceutical Association, the National Community Pharmacists Association, and the National Association of Chain Drug Stores. The cities were (population rank in 2000 is noted in parentheses): Chicago (3), Dallas–Fort Worth (9), Los Angeles (2), Philadelphia (6), Seattle (13), and Tampa–St. Petersburg–Clearwater (21).[41] All four U.S Census Bureau regions were represented (Midwest, Northeast, South, and West). Nine pharmacies were randomly selected in each city from the *1998 Phone Search USA* version 5.0, Delorme (Yarmouth, Maine), along with five backup pharmacies for each of the original nine. If an initially contacted pharmacy declined the invitation to participate, the next backup pharmacy was contacted until a total of 50 pharmacies agreed. Pharmacies in Chicago were identified by using Netscape Yellow Pages (http://yp.netscape.com) because of a large discrepancy in the numbers of pharmacies identified by the two sources. The goal was to have 50% of the pharmacies in the chain store category (which included food stores and mass merchandisers), 25% in the independent pharmacy category, and 25% in the health-system category (outpatient pharmacy, clinic, or managed care pharmacy). These percentages approximate the relative prescription volume filled by each type of pharmacy.[10]

Letters of invitation to participate sent to the managers of independent and health-system pharmacies produced no responses. Therefore, in five of the cities, a local area coordinator was recruited from the faculty of a pharmacy school in or near the city to assist with pharmacy recruitment on a personal, one-to-one basis. In Dallas–Fort Worth, we engaged the pharmacies directly by telephone and fax because no local coordinator was needed. The pharmacy managers were offered a $500 honorarium in return for their participation. A combination of personal visits, faxes, and telephone requests was used successfully to complete the recruitment process.

Chain pharmacy recruitment involved an additional step before pharmacies were contacted: identifying the appropriate manager at the chain's headquarters (vice president level, typically) to obtain permission to contact pharmacy managers at pharmacies that had been selected at random. The pharmacy managers at the store level were then given the opportunity to accept or decline participation.

Figure 2. Frequency of Error Categories, by Type of Prescription[a]



[a]See definitions in Appendix 1.

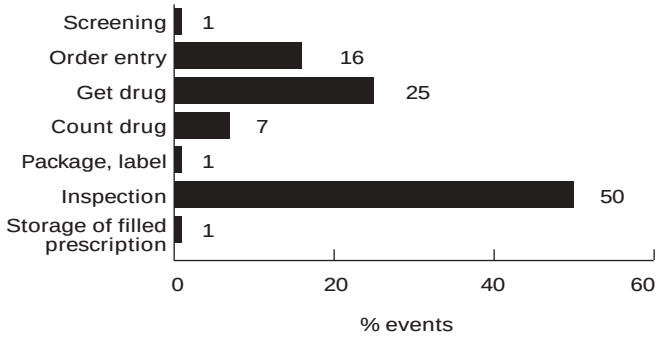
Data Collection Techniques

Direct, undisguised observation was used to inspect prescriptions as they were filled or after they were filled.[4,6,42] The observer recorded data when doing so would be least intrusive without delaying the provision of the prescription to waiting patients. To minimize their effects on the pharmacy staff, the observers were specially trained to be unobtrusive and nonjudgmental. The observers were licensed pharmacists with experience checking prescriptions in busy pharmacies. In addition, each pharmacist observer had a PhD degree in a pharmacy-related field that included research methods training. One of the coprincipal investigators (EAF) refined the observation method and other data collection techniques, conducted all but 8 observation days, and trained the other two pharmacist observers, evaluating their competency during practice observations at a study pharmacy.

Table 2. Accuracy Rate by City

	No. of Pharmacies	% All Prescriptions	No. of Errors	No. of Prescriptions	% Accuracy
Chicago	7	18	10	801	98.8
Dallas–Fort Worth	9	16	18	720	97.5
Los Angeles	8	14	13	610	97.9
Philadelphia	9	19	13	835	98.4
Seattle	8	11	10	505	98.0
Tampa–St. Petersburg–Clearwater	9	22	13	1,010	98.7
Overall	50	100	77	4,481	98.3

Figure 3. Origination of Errors, Based on Percentage of 77 Dispensing Errors and 74 Process Deviations



As the staff filled prescriptions, the observer recorded the drug name, strength, form, type of packaging, source of drug, label instructions, type of prescription (new, refill, or renewal), and time of filling. Information recorded was tailored to each site and was sufficient to allow a determination of whether an error had occurred. The information on the prescription or label was compared with the information used to fill the prescription—the drug product and strength could usually be verified against the stock bottle; if the stock bottle was unavailable, the tablet/capsule imprint code was recorded.

Correction of Errors

If a difference between the contents of a filled prescription container and the prescription order or label was observed at the time that the pharmacy staff was finished processing the prescription, but before it was dispensed to the patient, the observer alerted the pharmacist. This gave the pharmacist the opportunity to explain why there was a difference or to confirm the error and correct it. Interventions to correct errors were performed tactfully and in a low-key, nonthreatening manner so as not to embarrass any pharmacy staff or alert patients to a problem. Labels for new prescriptions were sometimes evaluated after the observation period when it was not possible to assess them during the filling process (copies of the labels were sometimes attached to the back of the original prescriptions or could be reviewed in the computer system). Label errors were brought to the attention of the pharmacist to enable him or her to correct the discrepancy, which sometimes required contacting the patient if the prescription had already been picked up.

Will Call Prescription Evaluation

Will call prescriptions were checked by comparing the contents of the prescription container with the pharmacy-generated label; drug, strength, dosage form, and quantity were assessed. Wrong label errors were not evaluated for will call or refill prescriptions because of the additional time that would have been required to retrieve the original prescription order from the pharmacy's files.

Clinical Importance of Errors

Clinically important errors were those judged to have the potential for causing patient harm or discomfort and a high likelihood of causing such harm. A panel of four practicing pharmacists evaluated and discussed each error detected, assigned a score of 1 (important) to 5 (not important) for patient harm potential as well as a score of 1 (very likely) to 5 (very unlikely) for the likelihood of patient harm actually occurring. The scores were assigned based on consensus of the panelists and added together (importance plus likelihood). An error with a score of 6 or less was deemed clinically important.

Effect of Observer

A post hoc analysis of the accuracy rate on will call prescriptions was used to check for an effect of two of the three observers on the accuracy rate. Because will call prescriptions were filled when the observer was not present, a significant difference between the accuracy rate for prescriptions filled while the observer was conducting the study and those filled just before the study and present in the will call area might indicate that the observer influenced the accuracy rate.

Table 3. Examples of Errors Detected for Selected Error Types

Error Type	Prescription	Error
Wrong drug	Carisoprodol 350 mg	Filled with chlordiazepoxide 10 mg
Wrong label instructions	Doxepin 25 mg, 1 capsule by mouth every night at bedtime	Labeled as "take 1 half teaspoon"[a]
Wrong quantity	Filgrastim injection (Neupogen—Amgen) 480 mcg, 7 vials	14 vials dispensed
Wrong quantity	Oxycodone and acetaminophen (Roxicet—Roxane), 240 tablets ordered	340 tablets dispensed
Wrong strength	Ortho Tri-Cyclen (Ortho-McNeil)	Filled with Ortho Cyclen (Ortho-McNeil)
Wrong strength	PremPhase 0.625 mg/5 mg (Wyeth)	Filled with PremPro 0.625 mg/5 mg (Wyeth)
Wrong time	Clonazepam 0.5 mg, one-half tablet every morning, 2 at bedtime	Tablets placed in evening bubble instead of bedtime bubble on blister card

[a]No other instructions were placed on the label.

The post hoc analysis of will call prescriptions was added to the study design to check for an effect of the observer, starting with the 12th pharmacy in the study and performed where possible. Will call items were checked in 28 of the remaining 38 pharmacies because of time constraints at some sites. Therefore, the results of the comparison between will call accuracy rates and prescriptions filled on the study day are limited to the 28 pharmacies with data for will call prescriptions and for two of the three observers. Will call prescriptions were studied at 62% of chain pharmacies, 40% of independent pharmacies, and 67% of health-system pharmacies.

For this comparison, the accuracy rate for prescriptions filled during the study day excluded wrong label information and wrong label instruction errors because these types of errors were not assessed on will call prescriptions. Ideally, the prescriptions in the will call area would have been filled by the same people who filled the prescriptions on the study day. However, this direct comparison was not possible, and, consequently, the accuracy rates were calculated as a measure of the entire prescription filling system without regard for who filled the prescriptions.

Process Deviations

Corrections to prescriptions made by pharmacy staff during the filling process were recorded as process deviations (sometimes referred to as "near errors" or "near misses") and were interpreted as an indicator of the system's ability to prevent errors. For example, if the wrong drug or strength was retrieved from a shelf, but the error was corrected before the filling process was completed, a process deviation was noted with details about how the discrepancy was detected. The stage of the prescription filling process during which each deviation occurred was noted. A summary of the relative frequency of noted deviations was developed to help identify areas for process improvement.

Statistical Hypotheses and Tests

Two separate one-way analyses of variance were used to test the following hypotheses:

- Accuracy rates for chain, independent, and health-system pharmacies were not different.
- Accuracy rates in the six study cities were not different.

The possible effect of the observer on the observed pharmacy staff was assessed using a *t* test for related measures,[43] error rates on prescriptions filled during the study day (new and refill) were compared with will call error rates (excluding label-related errors for all prescriptions). We hypothesized that a lack of difference between the error rates would indicate the absence of a significant effect of the observer on the dependent variable, error rates.

The accuracy rates detected by each observer were compared as an indicator of interobserver reliability using analysis of variance.

The α level for all statistical tests was preset at .05. The data analysis tools in Microsoft Excel 97 (Microsoft; Redmond, Wash.) were employed for the analyses.

Results

Data were collected in the 50 pharmacies that agreed to participate over a 10-month period between July 2000 and April 2001. Corporate executives from one chain pharmacy declined to participate. Among the chains that accepted, 12 individual pharmacies declined participation in the study. Sixty independent or health-system pharmacies declined the invitation to participate as one of the 30 observation sites available for these types of pharmacies. An additional 30 randomly selected independent and health-system pharmacies were excluded because they were no longer in

Figure 4. Effectiveness of the Inspection Process at Detecting Errors Based on the Task Where the Error Originated

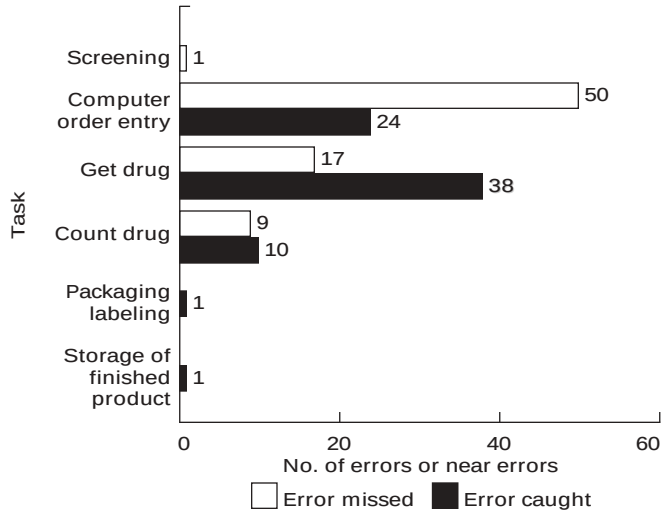


Table 4. Errors Judged to Be Potentially Clinically Important

Error Type	Prescription Order
Wrong dosage form	
Disopyramide sustained action (Norpace CR—Pharmacia) 100 mg	Disopyramide (Norpace—Pharmacia) 100 mg
Wrong label information	
Clindamycin 150 mg, labeled for wife of patient	Ordered for husband
Budesonide (Rhinocort—AstraZeneca) inhaler, 4 refills	No refills
Wrong label instructions	
Ipratropium bromide inhaler (Atrovent—Boehringer Ingelheim), said every other day	Four times daily
Promethazine with codeine, 1 teaspoonful by mouth every 4 hours as needed for cough	1 teaspoonful by mouth every 8 hours as needed for cough

operation or did not have a prescription filling operation (for example, a hospital might not have had an outpatient pharmacy).

Of the observed prescriptions, 52% (2,335) were filled in 26 chain pharmacies, 31% (1,370) were filled in 15 independent pharmacies, and 17% (776) were filled in 9 health-system pharmacies. Observers were not able to interpret 1 prescription of the 1,962 new prescriptions evaluated (0.05%). This prescription was excluded from the study, making the total new prescriptions equal to 1,961. This is comparable with a previously identified uninterpretable rate in a hospital and nursing home study of 0.2%.[13]

Accuracy Rates and Error Types

The overall dispensing accuracy rate was 98.3% (77 errors among 4,481 prescriptions; range, 87.2%–100%; 95% confidence interval, ± 0.4%). Accuracy rates for all 50 pharmacies are displayed in Figure 1. Table 1 is a summary of accuracy rates by pharmacy type and prescription type. There was no significant difference in accuracy rates between the pharmacy types ($F_{2,47} = 0.259$, $P = .773$). Uncategorized prescriptions were not identified as new or refill by the observer. This information was either not determinable during the observation or not collected by the observer (due to the fast pace of some operations, for example). The accuracy rates for uncategorized prescriptions was 99.6% (840 correct out of 843 prescriptions). Accuracy rates for all pharmacies combined in each of the six cities are displayed in Table 2 (no significant differences detected; $F_{(5,44)} = 0.801$, $P = .555$). The dispensing accuracy rate for new prescriptions was 96.8%, or 63 of 1,961 (all characteristics of the filled prescription were checked).

The frequency of errors detected on new prescriptions is shown in Figure 2. Label instruction errors occurred most frequently. Refill prescriptions had a 99.3% accuracy rate (11 errors among 1,677 prescriptions). Error types for refill and uncategorized prescriptions are also shown in Figure 2. Examples of each type of error detected are provided in Table 3.

Clinical Importance of Errors

Of the 77 errors detected, 5 (6.5%) were judged to be potentially clinically important, and these are described in Table 4. This represents 0.1% of the 4,481 prescriptions evaluated in this study.

Potential Sources of Error

During the study, 74 process deviations were recorded. Examples of the deviations are shown in Table 5. Note that all process deviations were corrected and may or may not have resulted in negative outcomes or errors. One instance involved a pharmacist who, working alone because the technician scheduled for that work period was ill, retrieved rofecoxib (Vioxx—Merck) and tamoxifen, counted rofecoxib, was interrupted by a telephone call, returned to the counter and saw the label for the rofecoxib on top, and counted another vial of rofecoxib. The first rofecoxib vial was labeled with the rofecoxib label, while the second was labeled with the tamoxifen label. The pharmacist caught the error during inspection by opening each vial and comparing the contents to what the label said should be in the vial.

Where did the detected errors originate? Figure 3 presents the percentage of process deviations and actual errors occurring at each stage of the prescription filling process. The task being performed when a process deviation occurred was used as the basis for identifying a possible point of origin for errors. The task most often associated with actual dispensing errors (errors that were not caught by the pharmacy staff) was the inspection process. Inspection missed 76 actual errors and caught 74 process deviations. The remaining actual error was a screening error. Figure 4 elaborates on the effectiveness of the inspection process, comparing errors caught by inspection with errors missed based on the task during which the error probably originated.

Error-Prevention Techniques and Technology Loopholes

A list of 20 error prevention techniques used in one or more of

Table 5. Examples of Process Deviations

Process Deviation	Prescription	Filled With
Near wrong drug	Cefuroxime (Ceftin—GlaxoSmithKline)	Cefprozil (Cefzil—Bristol-Myers Squibb)
Near wrong drug	Diltiazem (Tiazac—Biovail)	Label said hydrochlorothiazide
Near wrong drug	Tamoxifen (Nolvadex—AstraZeneca)	Rofecoxib (Vioxx—Merck)
Near wrong strength	Amoxicillin 250 mg/5 mL	125 mg/5 mL
Near wrong strength	Isosorbide mononitrate (ISMO—Wyeth) 20 mg	60 mg
Near wrong strength	Irbesartan and hydrochlorothiazide (Avalide—Sanofi Synthélabo), 300 mg/12.5 mg	150 mg/12.5 mg
Near wrong strength	Terazosin 10 mg	Terazosin 1 mg
Near wrong label instructions	Chlorhexidine (Peridex—Zila) 15 cc swish and spit	Label said 0.5 cc swish and spit
Near wrong label instructions	Amoxicillin 500 mg, 2 twice daily	Label said 1 twice daily

Table 6. Error Prevention Techniques Observed in One or More Study Pharmacies

Work procedures enhancing organization, simplification
Work on one patient's prescriptions at a time, and keep the prescriptions in a bin to separate from other patients' prescriptions
Return drug stock bottles to shelves immediately after filling the prescription to avoid overcrowding on work counter
Use a bin system for drug stock bottle up above filling counter: one bin for drug stock bottles to be filled, second bin for those in process, then put in third bin after filling
Circle number of tablets in a bottle if different from 100 to avoid dispensing incorrect quantity
Manage interruptions—tell patient, "I'll be right with you"—and then finish work before helping patient
Put drug stock bottle on counter upside down after filling to prevent mixups
Inspection processes
"Smell check" for oral liquid products and some oral solid tablets
Counseling: show and tell, review filled prescription with patient
Bar code double-check of drug product using the NDC on the drug stock bottle compared with label (should avoid entering drug in computer using drug stock bottle; select from list instead to realize benefit of bar code checking system)
Write middle NDC numbers on back of prescription, then compare with NDC printed on label
Circle middle NDC numbers on labels
Seven-check system: compare seven items on new prescriptions with what is printed on vial label—patient name, drug name, strength, instructions, quantity, number of refills, prescriber name—and check off each item after checking
Have magnifying glass available to inspect tablet/capsule identification codes that are very small (e.g., lorazepam tablets)
Double-check drug product by reviewing tablet/capsule identification code and comparing with drug in stock bottle or with computer system photograph
Try to have two different staff members check prescription
Use yellow or pink highlighting of drug name, drug strength, and patient name on preprinted prescription vial labels
Facility design, work environment
Additional lighting over filling and inspection areas
Antifatigue floormats, chairs available
Modification of drug container
Magic Marker highlighting on drug bottle labels or caps to indicate unusual strengths or brand-name equivalents
Memory aid
Take label to shelf to get drug—this serves as a memory aid and efficiency aid.

NDC = National Drug Code.

the participating pharmacies is provided in Table 6. Observers recorded information about some of the methods indicating that the systems were not always effective. For example, the prescription check-off system—in which seven label characteristics are compared with the original prescription—failed to catch a wrong label instruction (label read "three times daily" instead of "four times daily"). A loophole in a bar code checking system was described by an observer at one of these sites as follows: When a clerk scanned the receipt's bar code at the cash register in preparation to dispense a prescription, an error message told the clerk that a pharmacist had not yet verified the prescription; the clerk took the bag and receipt to the pharmacist verification area, scanned the bar code on the receipt and then entered the National Drug Code number for the drug from the receipt (instead of the drug stock bottle used to fill the prescription), thus bypassing the safety system.

Observer Evaluation

Was there an effect of the observer on the pharmacy staff? A *t* test for related measures found no significant difference between the error rates for prescriptions filled (or refilled) on the observation day and will call prescriptions filled before the study day (t = 0.252, df = 27, P = .803) when no observer was present. Fourteen errors were detected on 1,299 will call prescriptions checked at 28 study pharmacies by 2 observers. Content errors (drug and strength) were compared for the two groups of prescriptions (wrong label information and wrong label instruction errors were excluded from this analysis because the accuracy of the label was not evaluated for will call prescriptions).

The ability of observers to collect adequate data was also evaluated. Observers missed or did not record adequate data to evaluate the accuracy of 5 of 5,790 (0.1%) filled prescriptions reviewed. This is in addition to the one prescription that was deemed uninterpretable.

There was no significant difference among the accuracy rates detected by the three pharmacist researchers ($F_{2,47}$ = 1.108, P = .339). One pharmacist observed in 42 pharmacies, while the other two pharmacists completed observations in 4 pharmacies each.

Discussion

Four errors occur each day in pharmacies filling 250 prescriptions per day. This finding is comparable with results of some previous observational studies that used comparable error definitions,[4–6] but lower than others that identified error rates of 6% and 10%.[3,7] We believe that the two pharmacies involved in the 6% and 10% error rate studies may have had higher error rates because they were conducting research as a result of suspected error problems.

The finding that there was not a significant difference in accuracy rates between cities may indicate that our results are representative of a national dispensing accuracy rate and can be generalized to pharmacies willing to participate in such studies.

Wrong label information and instructions were the most common types of errors. Importantly, this indicates that errors in the computer order entry process used to create the label occur most frequently. These types of errors must not be ignored by pharmacists who might tend to focus on the less frequent, but often more dangerous, wrong drug errors (the target of bar code checking).

Figures 3 and 4 reveal that inspection is the weakest part of the prescription fulfillment process. Efforts to improve accuracy should focus on helping pharmacists perform inspections more accurately. The ability to keep the original prescription (or an electronic representation of it) with the product and label throughout the filling process is important; one study used the original prescription during the counseling and double-check processes and found that this helped detect errors.[45] Lighting levels of 146 footcandles,[4] elimination or minimization of interruptions and distractions,[46] and addressing noise issues[47] can also help improve pharmacists' inspection accuracy.

Implications for Practice

The typical pharmacist fills about 13,000 prescriptions annually, according to *Consumer Reports*.[47] Assuming a 40-hour work week with time off for vacations and holidays and 220 workdays during which those 13,000 prescriptions are filled, pharmacists have a workload of about 60 prescriptions per day. Hypothetically, if those 60 prescriptions are all new, the error rate detected in this study for new prescriptions (3.2%) suggests that, every day, the typical pharmacist fills two new prescriptions incorrectly, in one or more ways. These two daily errors most often involve giving the wrong instructions for use but may also include dispensing the wrong drug, wrong strength, or wrong quantity (such that the patient may run out of medication or have extra doses).

To the patient, this means that the chances of receiving an incorrectly filled new prescription are about 1 in 30. The chances are 1 in 1,000 that a patient will receive a prescription with a potentially clinically important error. Grasha "estimate[s] that for every 1 million prescriptions filled, only about 30 will contain a clinically significant mistake that goes unnoticed by the pharmacist or patient" (1 in 33,000 ratio).[48] However, the method of error detection used by Grasha in his research, which was cited in *Consumer Reports*, was not clear. The errors detected in our study using direct observation indicate that 1,115 potentially important errors occur in every 1 million prescriptions, producing an estimate of 3.3 million potentially important errors among the 3 billion prescriptions filled annually in the United States.[10]

Clinically important errors were defined as those having the potential to lead to patient harm or discomfort. True clinical importance on a case-by-case basis has never been studied because it is so difficult to evaluate—follow-up by a medical team would be needed for each ambulatory patient for the initial fill and all refills of each prescription or medication order. A central problem is that safe therapy for one patient may be dangerous for another, depending upon the patient's illness and physical condition. We believe that all prescriptions—and, therefore, all problems—should be considered to be clinically important because the medications were important enough for the physician to order and for the pharmacy to charge the patient (even placebos, though none were observed in the present study). However, researchers in hospitals have attempted to go further and distinguish a "potentially more dangerous class" of error based on the pharmacologic category of the medication involved.[21,38] For such purposes, we provide information about errors involving all of these more dangerous drugs so that readers can make their own judgments about the errors detected in this study (see Table 4).

Limitations

Pharmacists who agreed to have their pharmacies participate in this study may have been more likely to do so because they believed they did not have an error problem—the results may, therefore, overestimate the national accuracy rate. The accuracy of labels was not verified for refill and will call prescriptions, and our results for those types of prescriptions likely overestimate the true dispensing accuracy rate.

The effect of the observer on the observed is always a concern in studies of this type. However, evidence comparing study day prescription accuracy with accuracy of prescriptions filled before the observer's arrival suggests that the observers did not affect the accuracy rates. (Note that this comparison did not include the third observer, but because the accuracy rates detected by the observers did not differ significantly, lack of effect of the third observer is suggested.)

Conclusion

Dispensing errors are a problem on a national level, at a rate of 4 errors per day in a pharmacy filling 250 prescriptions daily. The rate of errors on new prescriptions (3.2%) is less than the only comparable standard of 5% set by the federal government for the nursing home industry.[11] Based on these findings, an estimated

51.5 million errors occur during the filling of 3 billion prescriptions each year. This figure includes 3.3 million errors of potential clinical importance.

The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, stock holdings, gifts, or honoraria.

This study was funded by an unrestricted contract from ScriptPro LLC of Kansas City, Kans.

Invited paper presented at the Sesquicentennial Stepping Stones Summit—Summit One: The Best Use of Technology in Pharmacy Practice; February 26–27, 2002; Baltimore, Md.

Acknowledgments: Kem P. Krueger, Bill G. Felkey, Renée Noel Arbet, Bob Shapiro, Teresa A. O'Sullivan, Jan D. Maiuro, Avery L. Spunt, Tony Sorrentino, Randell E. Doty, Nathan T. Dorris, Grady T. Holman.

References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Washington DC: National Academy Press; 1999.
2. McGhan WF, Smith WE, Adams DW. A randomized trial comparing pharmacists and technicians as dispensers of prescriptions for ambulatory patients. *Med Care*. 1983;21:445–53.
3. Guernsey BG, Ingrim NB, Hokanson JA, et al. Pharmacists' dispensing accuracy in a high-volume outpatient pharmacy service: focus on risk management. *Drug Intell Clin Pharm*. 1983;17:742–6.
4. Buchanan TL, Barker KN, Gibson JT, et al. Illumination and errors in dispensing. *Am J Hosp Pharm*. 1991;48:2137–45.
5. Spader TJ. Hatfield GM, Hanson EC. Dispensing errors and detection at an outpatient pharmacy. Paper presented at: Annual Meeting of the American Society of Health-System Pharmacists; June 3–8 1995; Philadelphia, Pa.
6. Allan EL. *Relationships Among Facility Design Variables and Medication Errors in a Pharmacy* [dissertation]. Auburn University, Ala: Auburn University; 1994.
7. Kistner UA, Keith MR, Sergeant KA, Hokanson JA. Accuracy of dispensing in a high-volume, hospital-based outpatient pharmacy. *Am J Hosp Pharm.* 1994;51:2793–7.
8. Grasha AF. Into the abyss: seven principles for identifying the causes of and preventing human error in complex systems. *Am J Health Syst Pharm*. 2000;57:554–64.
9. Carper J. Effect of automation on errors. Paper presented at: American Society of Health-System Pharmacists Midyear Clinical Meeting; December 5, 2000; Las Vegas, Nev.
10. Ukens C. Manufacturer Rx sales top $120 billion, IMS reports. *Drug Topics*. March 20, 2000:34.
11. Appendix N—Surveyor procedures for pharmaceutical service requirements in long-term care facilities. In: *State Operations Manual*. Baltimore, Md: Centers for Medicare & Medicaid; 2002:281. Available at: http://cms.hhs.gov/manuals/pub07pdf/AP-J-N.pdf. Accessed September 3, 2002.
12. Barker KN, McConnell WE. The problems of detecting medication errors in hospitals. *Am J Hosp Pharm*. 1962;19:360–9.
13. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm*. 2002;59:436–46.
14. Shannon RC, De Muth JE. Comparison of medication-error detection methods in the long term care facility. *Consult Pharm*. 1987; 2(March/April):148–51.
15. Borel JM, Rascati KL. Effects of an automated, nursing unit-based drug-dispensing device on medication errors. *Am J Health Syst Pharm*. 1995;52:1875–9.
16. Bond CA, Raehl CL. Pharmacists' assessment of dispensing errors: risk factors, practice sites, professional functions, and satisfaction. *Pharmacotherapy*. 2001;21:614–26.
17. Baker HM. Rules outside the rules for administration of medication: a study in New South Wales, Australia. *Image J Nurs Sch*. 1997;29:155–8.
18. Dean BS, Barber ND. Validity and reliability of observational methods for studying medication administration errors. *Am J Health Syst Pharm.* 2001;58:54–9.
19. Flynn EA, Barker KN. Medication error research. In: Cohen MR, ed. *Medication Errors: Causes, Prevention, and Risk Management*. Washington, DC: American Pharmaceutical Association; 1999:6.1-6.30.
20. Barker KN, Harris JA, Webster DB, et al. Consultant evaluation of a hospital medication system: analysis of the existing system. *Am J Hosp Pharm*. 1984;41:2009–16.
21. Schnell BR. A study of unit dose drug distribution in four Canadian hospitals. *Can J Hosp Pharm*. 1976;29:85–90.
22. Barker KN, Heller WM, Brennan JJ, et al. The development of a centralized unit dose dispensing system. Part six: the pilot study—medication errors and drug losses. *Am J Hosp Pharm*. 1964;21:609–25.
23. Jozefczyk KG, Schneider PJ, Pathak DS. Medication errors in a pharmacy-coordinated drug administration program. *Am J Hosp Pharm*. 1986;43:2464–7.
24. Barker KN, Allan EL. Research on drug-use-system errors. *Am J Health Syst Pharm*. 1995;52:400–3.
25. Barker KN, Pearson RE, Hepler CD, et al. Effect of an automated bedside dispensing machine on medication errors. *Am J Hosp Pharm*. 1984;41:1352–8.
26. *A Study of Patient Care Involving a Unit Dose System. Final Report*. Iowa City, Iowa: University of Iowa; 1967. United States Public Health Service grant HM-00328-01.
27. Barker KN. The effects of an experimental medication system on medication errors and costs. Part one: introduction and errors study. *Am J Hosp Pharm*. 1969;26:324–33.
28. Crawley HK, Eckel FM, McLeod DC. Comparison of a traditional and unit dose drug distribution system in a nursing home. *Drug Intell Clin Pharm*. 1971;5:166–71.
29. Shultz SM, White SJ, Latiolais CJ. Medication errors reduced by unit-dose. *Hospitals*. 1973;47(6):106–12.
30. Means BJ, Derewicz HJ, Lamy PP. Medication errors in a multidose and a computer-based unit dose drug distribution system. *Am J Hosp Pharm*. 1975;32:186–91.
31. Brown WM, Blount CW, Harley GD. *Quality of Pharmaceutical Care in Small Hospitals*. Kansas City, Mo: Missouri Regional Medical Program; 1976.
32. Barker KN, Mikeal RL, Pearson RE, et al. Medication errors in nursing homes and small hospitals. *Am J Hosp Pharm*. 1982;39:987–91.
33. Reitberg DP, Miller RJ, Bennes JF. Evaluation of two concurrent drug-delivery systems in a skilled-nursing facility. *Am J Hosp Pharm*. 1982;39:1316–20.
34. O'Brodovich M, Rappaport P. A study pre and post unit dose conversion in a pediatric hospital. *Can J Hosp Pharm*. 1991;44:5–15, 50.
35. Cooper S, Zaske D, Hadsall R, et al. Automated medication packaging for long-term care facilities: evaluation. *Consult Pharm.* 1994;9:58–70.
36. Ruffin DM, Hodge FJ. Pharmacists' impact on medication administration errors in long-term care facilities. *Consult Pharm*. 1995;10:1025–32.
37. Dean BS, Allan EL, Barber ND, et al. Comparison of medication errors in an American and a British hospital. *Am J Health Syst Pharm*. 1995;52:2543–9.
38. Barker KN, Kimbrough WW, Heller WM. *A Study of Medication Errors in a Hospital*. Fayetteville, Ark: University of Arkansas; 1966.
39. Hynniman CE, Conrad WF, Urch WA, et al. A comparison of medication errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. *Am J Hosp Pharm*. 1970;27:802–14.
40. Flynn E, Barker K, Carnahan B. Observational study of factors associated with prescription dispensing errors in 50 pharmacies. Abstract presented at: American Pharmaceutical Association Annual Meeting; March 29, 2003; New Orleans, La.
41. U.S. Census Bureau. *Metropolitan Area Rankings by Population Size and Percent Change for July 1, 1998 to July 1, 1999 and April 1, 1990 to July 1, 1999*. Washington, DC: Population Estimates Program, Population Division, U.S. Census Bureau; 2000. Available at: http://eire.census.gov/popest/archives/metro/ma99-04.txt. Accessed January 28, 2003.
42. Barker KN. Data collection techniques: observation. *Am J Hosp Pharm.* 1980;37:1235–43.
43. Bruning JL, Kintz BL. *Computational Handbook of Statistics.* 3rd ed. Glenview, Ill: HarperCollins; 1987.

44. Humalog [product label]. Indianapolis, Ind: Eli Lilly; 2002. Available at: http://pi.lilly.com/humalog-prescribing.pdf. Accessed September 3, 2002.
45. Kuyper AR. Patient counseling detects prescription errors. *Hosp Pharm.* 1993;28:1180–1, 1184–9.
46. Flynn EA, Barker KN, Gibson JT, et al. Impact of interruptions and distractions on dispensing errors in an ambulatory care pharmacy. *Am J Health Syst Pharm*. 1999;56:1319–25.
47. Flynn EA, Barker KN, Gibson JT, et al. Relationships between ambient sounds and the accuracy of pharmacists' prescription-filling performance. *Hum Factors.* 1996;38:614–22.
48. The ABCs of drugstores. *Consumer Reports*. October 1999;64:39–44.
49. Fink J, ed. *Pharmacy Law Digest 1985*. St. Louis, Mo: Facts and Comparisons; 1985.

Appendix 1. Dispensing Error Category Definitions

1. *Wrong drug:* A medication that is different from what the prescriber wrote on the prescription order or, for refill prescriptions, what is printed on the prescription label.

2. *Wrong strength:* A dosage unit containing an amount of medication that is different from what the prescriber specified is dispensed without an adjustment to the dosing instructions to the patient.

3. *Wrong dosage form (correct drug):* The form of the medication used to fill the prescription is different from what the prescriber wrote on the prescription order. Examples of this type of error include filling a prescription with an enteric-coated tablet when it was not ordered as such and using a sustained-release product when one was not ordered.

4. *Wrong quantity:* The number of dosage units or the volume of a product was different from what the prescriber ordered. Unless the observer could see a difference in the number of solid oral dosage forms without counting on a tray, we assumed that the correct quantity was used. Liquid measures were included if it was possible to observe the volume dispensed. If the quantity or volume of liquid could not be determined, the prescription was classified as "no error" if there were not errors in any other categories.

5. *Wrong prescription label information (excluding instructions):* Defined to include one or more of the following deviations from any one of the federal or state requirements for label contents, whichever was more strict:[49]

- Name and address of dispenser (pharmacy).
- Serial number of prescription.
- Date of prescription or date of filling.
- Name of prescriber.
- Name of patient, if stated in the prescription order.
- Drug name.
- Drug strength (if more than one strength was available).
- Quantity dispensed.
- Expiration date.
- Manufacturer or distributor.

6. *Wrong label instructions:* The directions on the prescription label deviated in one or more ways from what was prescribed, except for changes made based on good pharmaceutical practice. (Note that auxiliary label information included on the package by the pharmacist that was not required by the physician was not evaluated in this study.) For example, if "for 14 days" was added at the end of the directions for an antibiotic that was prescribed to be taken for a complete course of therapy, an error was not counted. However, if the physician wrote "for 14 days" on the prescription order and this was omitted from the label instructions, a wrong label instruction error was counted.

7. *Omission:* Failing to dispense a prescribed medication.

8. *Wrong time:* A medication was packaged in blister pack locations that were different from what was conveyed on the prescription (e.g., a medication was placed in the bubble for bedtime doses instead of the one for dinner doses).

9. *Deteriorated drug:* A medication that had passed its expiration date was used to fill a prescription or a prescription was filled with a medication that was stored in a location not in accordance with the manufacturer's recommendations (e.g., outside a refrigerator).

Source: Adapted from Reference 4.