Medication Safety

How Many Hospital Pharmacy Medication Dispensing Errors Go Undetected?

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Medication errors are common and often preventable.[1,2] The hospital pharmacy's medication dispensing process is a source of medication errors and potential adverse drug events (ADEs).[2,3] Hospital pharmacies in the United States each dispense hundreds of thousands to millions of medication doses annually, and therefore even low dispensing error rates can generate many errors. Previous research also indicates that nurses only intercept 33% of serious medication dispensing errors before medication administration, so many of these errors could reach patients.[3] Hospitalized patients are often critically ill, and many are susceptible to harm from these types of errors.[4]

Many previous studies of dispensing error rates reflect pharmacy dispensing patterns before the widespread use of automated dispensing cabinets,[5–9] which are now commonly deployed by central hospital pharmacies to better control the distribution of frequently used medications on patient care units. Previous studies have also reported conflicting rates of pharmacy dispensing errors, ranging from 0.0041% to 3.6%.[2,6–7,11] One of these studies relied on self-reporting to detect dispensing errors and likely underestimated the incidence of these errors.[11] Other studies evaluated dispensing errors in atypical settings. For example, in most pharmacies, dispensing currently occurs in a two-step process where technicians fill medication orders and pharmacists verify.[5] However, three studies evaluated the dispensing

Article-at-a-Glance

Background: Hospital pharmacies dispense large numbers of medication doses for hospitalized patients. A study was conducted at an academic tertiary care hospital to characterize the incidence and severity of medication dispensing errors in a hospital pharmacy.

Methods: Direct observation of dispensing processes was undertaken to determine presence of errors with review by a physician panel to determine severity.

Results: A total of 140,755 medication doses filled by pharmacy technicians were observed during a seven-month period, and 3.6% (5,075) contained errors. The hospital pharmacist detected only 79% of these errors during routine verification; thus, 0.75% of doses filled would have left the pharmacy with undetected errors. Overall, 23.5% of undetected errors were potential adverse drug events (ADEs), of which 28% were serious and 0.8% were life threatening. The most common potential ADEs were incorrect medications (36%), incorrect strength (35%), and incorrect dosage form (21%).

Discussion: Given the volume of medications dispensed, even a low rate of drug distribution process translates into a large number of errors with potential to harm patients. Pharmacy distribution systems require further process redesign to achieve the highest possible level of safety and reliability.

process with pharmacy technicians or nurses performing both the filling and the verification steps.[6–7,10]

Two of these studies were also performed in a highly controlled environment with simulated errors that may not reflect routine hospital pharmacy practice.[7,10] Moreover, previous studies did not evaluate the severity and potential for patient harm from dispensing errors. Therefore, the clinical implications of medication dispensing errors remain uncertain.

To address these gaps in our understanding of dispensing errors, we conducted a direct observational study to determine the incidence of pharmacy generated dispensing errors, categorize the types of errors, and evaluate their potential to cause patient harm.

Methods

We performed the study in a 725-bed tertiary academic medical center during a seven-month period (February–August 2003). Approximately six million doses of medications are dispensed on an annual basis from its centralized inpatient pharmacy. The study was limited to pharmacy dispensing activities between 7 A.M. and 3 P.M., when the majority of medications are dispensed. Each dispensing process evaluated consists of a two-step dispensing protocol used in approximately 76% of hospitals in the United States.[5] Step 1—*filling*—requires a pharmacy technician to select medications from the pharmacy inventory. Step 2—*verification*—requires a pharmacist to verify the accuracy of the medications filled by the pharmacy technician before delivery to the patient care areas.

Dispensing Errors

We defined a dispensing error as follows:

- Any discrepancy between dispensed medications and physician orders (for patient-specific doses) or replenishment reports (for automated dispensing cabinets)
- Any deviation from standard pharmacy policies.

If a hospital pharmacist discovers a technician's filling error during the routine verification step, we defined that error as a *detected dispensing error*. We also introduced a trained pharmacist observer who visually inspected medications that had already undergone the usual two-step dispensing process. If the pharmacist did not detect a technician filling error during the normal pharmacist verification step but the research observer intercepted it, we defined that error as an *undetected dispensing error*.

We further classified detected and undetected dispensing errors by error type. Each independent human error (such as picking an incorrect medication) made by the pharmacy technician could reach multiple patients if not intercepted. Therefore, errors were primarily expressed in terms of the number of doses with errors, as this measure highlights the number of opportunities for patients to be harmed. To illustrate the number of opportunities for patient safety interventions to prevent errors, we also calculated the number of independent human errors committed by the pharmacy technicians.

Dispensing Processes Studied

To ensure that our findings would reflect the different dispensing processes used in a hospital pharmacy, we studied the following four dispensing processes:

1. Automated dispensing cabinets fill. Automated dispensing cabinets are medication storage units for commonly used medications. Nurses may only remove medications for a specific patient with a pharmacist-approved physician order. During automated-dispensing cabinet fill, pharmacy technicians obtain an inventory stock replenishment report that identifies medications that need restocking in each cabinet.

2. Controlled substances fill. Controlled substances are stocked in the automated dispensing cabinets on the patient care units. Similar to the automated dispensing cabinet fill, pharmacy technicians in this process use inventory stock replenishment reports to identify controlled substances that need to be restocked in cabinets located in patient care areas. However, controlled substance fill occurs separately from automated dispensing cabinets fill in a tightly regulated environment with daily inventory counts.

3. First dose fill. During first dose fill, the pharmacy dispenses the first dose of newly ordered patient-specific medications that are not routinely stored in the automated dispensing cabinets (because they are less commonly used). Before the dispensing process, orders for patient specific medications are reviewed and approved by a clinical pharmacist.

4. Cart fill. Cart fill dispensing involves the delivery of a 24-hour supply of patient-specific medications after

order review and approval by the clinical pharmacist. Cart fill dispensing errors were identified through a comparison of the pharmacist approved physician order and a computerized cart fill list. These medications are not stored in the automated dispensing cabinets, but rather in a separate medication cart with individual patient drawers. Cart fill doses are typically used after doses filled by the first dose process have been administered.

We observed a representative sample of doses dispensed for automated dispensing cabinet fill, cart fill, and controlled substances fill each for one month, and first dose for two months. To obtain the relative proportions of doses dispensed by each of the four processes, we reviewed the dispensing logs on a representative day.

Review and Scoring of Errors

Two board-certified internists (from a panel of three [T.K.G., J.M.R., E.G.P.]) each independently reviewed and scored the severity of all detected and undetected dispensing errors. Physician reviewers were blinded to whether the error was intercepted by the pharmacist or the observer. A pharmacist provided the physician panel with supplemental information regarding dispensing policies, package sizes, and other pharmacy-specific information when required.

Each physician reviewer determined whether the patient could have suffered an injury if the dispensing error was not intercepted prior to medication administration to the patient. We defined errors with potential to harm patients as potential ADEs. The level of potential harm, if present, was further classified as significant, serious, or life threatening. This classification scheme has been used in several other patient safety studies.[12,13] Differences between reviewers were reconciled by consensus. To assess reviewer agreement on the classification of dispensing errors as potential ADEs, kappa scores were calculated for each reviewer pair (based on results of the initial independent reviews) and summarized with a weighted average. There were two pairs of physician reviewers, with overall kappa score of 0.87, indicating excellent agreement in classifying errors as potential ADEs.

Error data were managed using database software, and statistical analyses were performed using a commercially available statistical package. Institutional Review Board approval was obtained at the study institution.

Results

During the study period, a total of 140,755 medication doses were observed across the four dispensing processes. We found an overall unweighted pharmacy dispensing error rate of 3.6% (5,075), of which 2.9% (4, 016) were detected errors and 0.75% (1,059) were undetected errors (Table 1, page 76).

Technician medication filling accuracy was 96.4% (135,680 out of 140,755 doses filled correctly). However, the hospital pharmacists' accuracy in verifying medications was much lower. Pharmacists failed to detect 20.9% (1,059) of all technician-filling errors (5,075) during the verification process. Error rates (detected and undetected combined) for individual processes were: cart fill 6.0%, automated dispensing cabinet fill 4.2%, first dose fill 2.9%, and controlled substances fill 0.9%. Adjusting for the percent of doses dispensed by each of the four processes, the weighted pharmacy dispensing error rate was 3.7%, very similar to the unweighted error rate (Table 1).

For all four dispensing processes, 22.8% (1,159) of the overall errors had potential to cause harm and were thus classified as potential ADEs. Of these 1,159 potential ADEs, 63.8% (740) were significant, 33.9% (393) serious, and 2.2% (26) life threatening (Table 2, page 77). The panel was unable to determine the potential for harm for 2.7% (136) of errors, mostly due to incomplete data collection. Pharmacists intercepted 78.5% (910) of the 1,159 potential ADEs during the routine verification process. The research observer intercepted the remaining 21.5% (249) potential ADEs, which normally would have escaped detection by the verification processes in the pharmacy. Of these 249 undetected errors that were potential ADEs, 177 (71.1%) were significant, 70 (28.1%) serious, and 2 (0.8%) life threatening. The proportion of errors classified as potential ADEs was similar between detected and undetected errors (detected errors: 22.7%; undetected errors: 23.5%). Of the 1,610 independent human errors, 401 (24.9%) had the potential for harm; of these, 275 (17.1%) were significant, 119 (7.4%) were serious, and 7 (0.4%) were life threatening.

Table 1. Distribution of Medication Errors

	Automated Cabinets	Controlled Substances	Cart Fill	First Dose	Total	Overall Rate*
Proportion of doses dispensed by process	64%	17%	10%	9%	100%	—
Number of doses filled by pharmacy technician	81,698	25,591	13,720	19,746	140,755	—
Number of correctly filled doses (% of doses filled correctly)	78,267 (95.8%)	25,351 (99.1%)	12,893 (93.4%)	19,169 (97.1%)	135,680 (96.4%)	96.4%
Number of detected errors† (% of filled doses with detected errors)	2,802 (3.4%)	204 (0.8%)	614 (4.5%)	396 (2.0%)	4,016 (2.9%)	2.9%
Number of undetected errors‡ (% of filled doses with undetected errors)	629 (0.77%)	36 (0.14%)	213 (1.6%)	181 (0.92%)	1,059 (0.75%)	0.75%
Total errors§ (% of filled doses with detected or undetected errors)	3,431 (4.2%)	240 (0.94%)	827 (6.0%)	577 (2.9%)	5,075 (3.6%)	3.7%

* Weighted by the proportion of doses dispensed by each of the four processes.

† Errors intercepted by pharmacist during routine verification.

‡ Errors intercepted by research observer.

§ Detected error + undetected error.

The physician panel deemed 26 medication dispensing errors to be potentially life threatening (Table 3, page 78). Five occurrences involved the dispensing of latex containing vials to a patient with a documented latex allergy. Another involved adult dosage strengths dispensed to the neonatal intensive care unit. Incorrect medication errors included an event where nesiritide was filled instead of the ordered nitroprusside, and dopamine vials were filled instead of dobutamine vials.

Of the 5,075 dispensing errors, the most common error type was incorrect quantity dispensed (n = 2,970, 59%) followed by incorrect strength (n = 571, 11%), incorrect medication (n = 554, 11%), and incorrect dosage form (n = 443, 9%). Of the 1,159 potential ADEs, incorrect medication was the most common (n = 423, 36%), followed by incorrect strength (n = 402, 35%) and incorrect dosage form (n = 245, 21%; Table 4, page 79). Comparison of the types of errors intercepted by pharmacists and research observers revealed that incorrect quantity errors were more often caught by pharmacists, whereas incorrect strength errors, incorrect dosage forms errors and expired medication errors were more often caught by research observers (Table 4).

Discussion

This study yielded a weighted dispensing medication error rate of almost 4%, which is on the higher end of the range of errors reported in previous studies, demonstrating that direct observation methods are superior to self-reporting for the detection of dispensing errors. Although the pharmacy technicians accurately filled more than 96% of the medication doses, the pharmacist was able to intercept only approximately 80% of the errors committed by the pharmacy technicians. As a result, 0.75% of the medication doses that entered the pharmacy distribution process would have left the pharmacy with undetected errors. In addition, nearly 25% of these undetected errors had the potential to cause patient harm and are thus potential ADEs. At the study hospital, where 6 million medication doses are dispensed annually, these error rates translate to about 45,000 dispensing errors leaving the pharmacy undetected, of which about 10,600 have potential for harm and are thus potential ADEs.

Several factors may explain the presence of errors in the dispensing process. First, a dispensing process that relies exclusively on repetitive human inspection is subject to human fatigue.[14] Second, human beings are not proficient at catching rare events. This might explain the

Table 2. Classification of Medication Dispensing Errors with Potential to Cause Harm

Severity Classification	Example	Overall Independent Human Errors*	Detected Errors in Dispensed Medications†	Undetected Errors in Dispensed Medications‡	Overall Errors in Dispensed Medications§
No potential for harm	Expired levofloxacin pill dispensed.	1,130 (70.2%)	2,980 (74.2%)	800 (75.5%)	3,780 (74.5%)
Potential for harm (Potential ADE)		401 (24.9%)	910 (22.7%)	249 (23.5%)	1,159 (22.8%)
Significant	4,000 units of erythropoietin ordered, but 40,000 units dispensed.	275 (17.1%)	563 (61.9%‖)	177 (71.1%‖)	740 (63.8%‖)
Serious	Hydroxyzine ordered, but hydralazine dispensed.	119 (7.4%)	323 (35.5%‖)	70 (28.1%‖)	393 (33.9%‖)
Life Threatening	Nitropress (nitroprusside) ordered, but Natrecor (nesiritide) dispensed.	7 (0.4%)	24 (2.6%‖)	2 (0.8%‖)	26 (2.2%‖)
Unable to Determine	—	79 (4.9%)	126 (3.1%)	10 (0.9%)	136 (2.7%)
Total Errors	—	1,610 (100%)	4,016 (100%)	1,059 (100%)	5,075 (100%)

* Independent human errors (both detected and undetected) committed by pharmacy technician. Each of these errors might lead to multiple doses that were dispensed in error.

† Errors intercepted by pharmacist during routine verification, expressed in the number of doses with errors.

‡ Errors intercepted by research observer, expressed in the number of doses with errors.

§ Errors intercepted by both pharmacist and research observer combined, expressed in the number of doses with errors.

‖ Percentages based on potential adverse drug events.

relatively high rate at which pharmacists failed to catch dispensing errors committed by the technicians; since errors are already rare by the time the pharmacist performs the inspection, the pharmacist might find it difficult to keep up the vigilance to detect all of the errors. Third, process workarounds might introduce opportunities for errors. These workarounds develop over time as practices that are dangerous become accepted as normal behavior because no adverse events result from these practices.[15] For example, in dispensing a large quantity of the same medication from the automated dispensing machine, a pharmacist may decide to check only one tablet. If the rare error is not detected and no adverse events occur, the pharmacist may believe that this practice is safe, even though standard practice calls for the checking of every tablet. Another factor that may contribute to the presence of dispensing errors is confusion surrounding look-alike and sound-alike medications, as previous research has reported that name confusion may be involved in 25% of all medication errors.[16]

Of the four dispensing processes evaluated, automated dispensing cabinet fill had the highest number of errors (3,431, 4.2%), whereas the cart fill process had the highest error rate (827, 6.0%). The automated dispensing cabinets accounts for two-thirds of doses dispensed from the pharmacy and the filling and checking of these medications is a high volume and repetitive task. Although this process involves routinely used medications, the high volume of medications filled and verified during this process can lead to a high number of errors. During cart fill, pharmacy staff work with multiple medications that are different for each patient and most often represent medications that are not routinely dispensed. These factors may contribute to the higher error rate associated with cart fill. In contrast, first dose fill and controlled substances fill processes had lower error rates. The smaller volume of medications associated with these two processes may partially explain this finding. Also, the process of controlled substances fill is conducted in a highly regulated environment that includes

Table 3. Potentially Life-Threatening Medication Dispensing Errors

Type of Error	Number of Doses with Errors	Description
Incorrect Dosage Form	5	Filled with latex vials for patient with latex allergy
Incorrect Medication	2	Aminocaproic acid filled with calcium gluconate 1 gm vials
Incorrect Medication	1	Gentamicin (20 mg IV) order for neonate filled with hydralazine (50 mg IV)
Incorrect Medication	1	Nitroprusside filled with nesiritide
Incorrect Strength	15	Potassium chloride 6 meq filled with 20 meq
Incorrect Medication	2	Dobutamine filled with Dopamine
Total	26	

daily inventory counts and verification, which may in turn improve the vigilance of staff involved.

Previous studies have shown that nurses intercept only approximately one-third of serious dispensing errors that reach the patient care areas.[3] Therefore, in the study pharmacy, where approximately 10,600 potentially harmful medication doses are dispensed each year, about 7,000 of these potential ADEs might be expected to reach patients annually. Although many of these potential ADEs will not cause actual harm because of patient characteristics (or luck), undetected dispensing errors and their associated potential ADEs represent a large target area for improving patient safety. Previous work by Leape et al.[3] showed that the dispensing process accounted for only 14% of serious medication errors, but the true impact of dispensing errors might be significantly greater, as the retrospective chart review and stimulated reporting methods used was not as good as direct observation for detecting dispensing errors.[17,18] Our results, as derived from direct observation methods, suggest that dispensing errors represent a significant source of potential ADEs.

Several strategies may reduce pharmacy dispensing error rates. Our results suggest that improvements to the process of automated cabinet fill represent the largest target area of improvement for reducing dispensing error rates. A possible strategy to reduce errors could be a second pharmacist verification step. However, this additional step requires the use of a scarce resource and may delay the delivery of medications to the patient areas. Moreover, our results indicate that pharmacists were only 79% accurate at detecting errors. Even if we assume an equal accuracy rate for the second pharmacy verification step, many dispensing errors would still leave the pharmacy undetected.

Other possible strategies for improvement could take advantage of health care information technology. For example, dispensing robots have been used in some hospitals and outpatient pharmacies to reduce dispensing errors, although published data to support their efficacy remain limited.[19,20] Bar-code technology represents another promising solution, with a number of valuable advantages. First, information can be collected at very high speeds with an error rate of less than 1 error per 10 million characters.[21] Second, bar-code technology, when correctly implemented, is easy to use, and operators can master the equipment in a matter of minutes.[21] It is also capable of catching rare events and has significant potential to further improve the relatively high accuracy rate in the pharmacy dispensing process. In addition, it will likely reduce the incidence of incorrect medications, incorrect strength and incorrect dosage form, the three most common causes of potential ADEs found in this study. With the recent Food and Drug Administration regulation requiring bar codes on all prescription drugs used in hospitals, more healthcare institutions are likely to adopt this technology.[22] For example, at our institution, we are implementing this technology throughout the pharmacy dispensing process, so that every medication dose is verified by bar-code scanning during technician filling of medications. Studies to evaluate the impact of this technology on medication dispensing errors are currently underway.

This study's results should be interpreted in light of several limitations. First, it relied on human observers, who might have failed to detect a number of dispensing

Table 4. Types of Pharmacy Dispensing Errors*

Error Type	Severity			Stage of Detection		Total
	Potential to Harm (Potential ADEs)	No Potential to Harm	Unable to Determine	Routine Verification (Detected Errors)	Research Observation (Undetected Errors)	
Incorrect Quantity	25 (2%)†	2,935 (78%)†	10	2471 (62%)‡	499 (47%)‡	2,970 (59%)
Incorrect Strength	402 (35%)†	158 (4%)†	11	419 (10%)‡	152 (14%)‡	571 (11%)
Incorrect Medication	423 (36%)†	109 (3%)†	22	451 (11%)	103 (10%)	554 (11%)
Incorrect Dosage Form	245 (21%)†	192 (5%)†	6	330 (8%)‡	113 (11%)‡	443 (9%)
Label Error	36 (3%)	128 (3%)	40	146 (4%)	58 (5%)	204 (4%)
Order Entry	25 (2%)	110 (3%)	45	152 (4%)	28 (3%)	180 (4%)
Expired	0	141 (4%)	0	41 (1%)‡	100 (9%)‡	141 (3%)
Other	0	6 (<1%)	0	1 (<1%)	5 (<1%)	6 (<1%)
Missing Medication	2 (<1%)	1 (<1%)	0	3 (<1%)	0	3 (<1%)
Reconstitution	1 (<1%)	0	2	2 (<1%)	1 (<1%)	3 (<1%)
Total	1,159 (100%)	3,780 (100%)	136	4,016 (100%)	1,059 (100%)	5,075 (100%)

* Expressed as the number of doses with errors.

† $p < .001$, comparing errors with versus without potential to harm for this error type using the Chi-square test.

‡ $p < .001$, comparing errors caught by routine verification versus research observation for this error type using the Chi-square test.

errors. Second, because the pharmacy technicians and pharmacists were aware of this study, their accuracy rate might have been increased through the Hawthorne effect. Both limitations would tend to underestimate the true rate of dispensing errors. Third, we were not able to conduct observation on all shifts of pharmacy distribution. Although the dispensing processes are essentially the same across all shifts, dispensing error patterns may be different during evening and night shifts. Fourth, we conducted the study in one high-volume academic tertiary care hospital pharmacy, and it is unclear whether these results can be generalized to other pharmacy settings. However, the dispensing processes used at the study hospital are commonly used elsewhere. The underlying root causes of independent human errors (such as why the technician selected the wrong medication or wrong dose) were beyond the scope of this study because we did not directly observe the technicians or pharmacists; however, this would represent an interesting area of focus for future studies to better design prevention interventions.

With 99.25% (0.75% undetected error rate) of medication doses leaving the pharmacy error free, one might conclude that drug distribution processes have high accuracy rates. However, given the high volume of medications dispensed, even a low error rate translates into a large number of errors, many of which have the potential to harm patients. Sole reliance on the vigilance of nurses and pharmacists leaves open many opportunities for errors and adverse events. This study suggests that the dispensing accuracy rate is impressive yet inadequate. We therefore believe that the pharmacy distribution system in hospitals in the United States requires further improvements to minimize errors and patient harm. Because medication dispensing is a well-defined process, very high levels of reliability, with error rates of 10^{-5} to 10^{-6}, should be an achievable goal.[23] High-reliability technologies that follow human factors principles will likely serve as strategy for achieving that goal. J

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