The Association Between Pharmacist Support and Voluntary Reporting of Medication Errors: An Analysis of MEDMARX® Data

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Abstract

Objective: We used MEDMARX®, the national medication error-reporting program, to compare medication errors reported by critical access hospitals (CAHs) to those reported by non-Federal, general community hospitals. **Methods:** We used the availability of pharmacist support to represent the structure and process of medication use and within-cluster resampling to account for the correlation of error reports within hospitals. **Results:** CAHs with 15 or fewer hours of pharmacist support per week were significantly less likely to report "near miss" errors—a characteristic of high-reliability organizations—than general community hospitals with 24-hour pharmacist support. **Conclusion:** The severity of voluntarily reported medication errors is associated with the structure and process of medication use as indicated by the availability of pharmacist support. MEDMARX is a potential data source for patient safety organizations (PSO). PSOs must consider varying structure and process within reporting organizations and account for the correlation of data within clusters.

Introduction

The Risk from Medication Errors

Medication errors are the most common source of risk to hospitalized patients.[1] On average, a hospitalized patient experiences one medication error per day.[2] This lack of reliability in hospitals' medication use practices results in 400,000 preventable medication-related injuries costing $3.5 billion annually.[2] The Institute of Medicine's (IOM) publication, *Preventing Medication Errors*, summarizes research and the work of the Joint Commission and the National Quality Forum to establish an action agenda for health care organizations to systemically improve the safety of medication use.[2] This agenda includes actions for prescribers, pharmacists, and nurses. Furthermore, the agenda identifies evidence-based safe medication practices, including dispensing medications in unit-dose or unit-of-use form, using standardized abbreviations, identifying "high alert" drugs, reading back verbal orders, standardizing labeling, and integrating pharmacists throughout the medication use process.

The Role of Voluntary Reporting and Patient Safety Organizations in Medication Safety

The IOM recommends mandatory reporting of adverse events and voluntary reporting of nonharmful errors to facilitate learning about and preventing systems-level sources of errors.[1] Successful voluntary reporting programs allow organizations to learn from their experience by providing independent, expert analysis focused on systems rather than on individuals.[3] Reporting programs—whether mandatory or voluntary—do not determine the actual incidence of errors and adverse events.[4, 5, 6] Estimating the incidence of errors requires a multimodal approach, including voluntary reporting, direct observation, and chart review.[7] The Patient Safety and Quality Improvement Act of 2005 calls for the creation of patient safety organizations (PSOs) that collect, aggregate, and analyze confidential reports of errors and near misses from multiple organizations in a standard format. The ultimate goal of PSOs is to identify patterns of system failures and to recommend measures that will mitigate the risks and hazards patients encounter in the health care system.[8]

MEDMARX®, the Nation's first Internet-accessible and largest voluntary medication error reporting program,[9] was established in 1998 by the United States Pharmacopeia (USP), affirming safe medication use as a national priority. MEDMARX is an anonymous medication error-reporting program that subscribing hospitals and health care systems participate in as part of their ongoing quality improvement initiatives. Nationally, data from MEDMARX contribute to knowledge about the causes and prevention of medication errors. Over 870 hospitals and health care systems have submitted reports of more than 1.3 million medication errors to MEDMARX. Analyses of voluntary medication error records from large patient safety databases, such as MEDMARX, can identify system sources of error and lead to the establishment of safe medication practices.

The Agency for Healthcare Research and Quality (AHRQ) has had an important role in patient safety and medication error reporting. In July 2005, the University of Nebraska Medical Center (UNMC) received one of 17 Partnerships in Implementing Patient Safety (PIPS) grants from AHRQ to fund the project, *Implementing a Program of Patient Safety in Small Rural Hospitals.* The primary aim of this project was to develop the organizational infrastructure for voluntarily reporting and analyzing medication errors in small rural hospitals that is necessary for identifying system sources of error. Given the limited technologic and human resources in these hospitals, UNMC used MEDMARX as the tool for 35 small rural hospitals to report and analyze medication errors in a standardized format. In March 2007, with funding from AHRQ, USP sponsored a conference for users of MEDMARX and other reporting programs. Participants shared successful strategies for reporting and learning from medication errors, a process consistent with the objectives of a PSO.

Structure and Process as Determinants of Medication Safety

Analyses from large patient safety databases typically aggregate reports from all hospitals, regardless of differences in structure or process. Structure refers to the capacity for work and encompasses the human resources, the equipment, and the environment in which care is provided. Process refers to the health care activities—i.e., what was done with the structure. The causal relationship between structure, process, and outcome must be established by scientific

evidence.[10, 11] Hospitals that lack the structures of computerized medication administration records, automated dispensing devices, barcoding technology, or pharmacist review of medication orders are likely to have different latent system sources of error than hospitals with these structures and processes. Medication error reporting is also likely to differ based on the structure and process of medication use within hospitals. Little has been published regarding the effect of medication use structure and process on voluntary medication error reporting.

Differences in hospital structure and process are evident in a comparison of Critical Access Hospitals (CAHs) with larger hospitals. CAHs are a category of limited-service hospitals created in 1997 as part of the Balanced Budget Act to maintain access to care in rural areas by providing cost-based reimbursement. CAHs, the Nation's smallest hospitals,[12] are limited to 25 inpatient beds for acute care and have an average inpatient length of stay of 96 hours. As of May 2007, there were 1,283 CAHs,[13] representing approximately one-fourth of the general community hospitals in the Nation.[14]

A primary difference in medication use between CAHs and larger hospitals is the amount of pharmacist support. Survey research suggests that approximately 40 percent of CAHs have a pharmacist available for fewer than 20 hours per week.[15] When integrated into the medication use process, pharmacists are available to consult with prescribers, to review and interpret medication orders, and to prepare, dispense, and monitor medications.

Pharmacists who regularly review medication orders are, by training, able to identify, intercept, and report medication errors that originate during prescribing or dispensing. The limited availability of pharmacists in CAHs limits pharmacists' ability to intercept medication errors before reaching the patient (e.g., near-miss errors); it also limits their participation in the medication error-reporting process.[16] While research has shown that limited financial resources, low patient volume, and lack of accreditation by the Joint Commission are all associated with having limited pharmacist support in small rural hospitals,[15, 16] little has been published comparing error-reporting patterns of the Nation's smallest community hospitals to those of larger hospitals and health care systems.[16]

The structure and process of a hospital's medication use system is responsible for latent system sources of error. The purpose of voluntary medication error reporting is to identify these sources of error. Consequently, it may be particularly useful for a hospital to review and learn from error reports submitted by organizations with similar structures and processes, in addition to reviewing all aggregated reports. The purpose of this study was to compare the medication errors reported by the 35 CAHs that participated in our patient safety project to those reported by non-Federal community hospitals (NFCHs) with 24-hour pharmacist support.

The amount of pharmacist support was used as an indicator of differences in the structure and process of the medication use system. We sought to determine whether the proportion of errors classified as near misses was associated with the structures and process of medication use as represented by the amount of pharmacist support. We used reporting of near misses as our dependent variable of interest because reporting and analyzing near misses is a characteristic of high-reliability organizations (HROs) that are preoccupied with failure. HROs include nuclear power plants, aircraft carriers, and air traffic control operations, all of which have complex, tightly coupled operations with the potential for catastrophic failure and yet have fewer accidents

than expected. HROs pay attention to near misses as small failures that provide free lessons about sources of poor system reliability.[17]

Methods

Study Design and Population

We identified medication error report variables and hospital characteristics from the 35 CAHs, which had varying levels of pharmacist support, and from 147 NFCHs with 24-hour pharmacist support. We used the query-building functions of Crystal Reports, Ver. 9 (Crystal Decisions, Inc., San Jose, CA), to connect to the MEDMARX Oracle database with open database connectivity drivers. These software drivers allowed the Crystal Reports application to access the data stored within the various data tables (regardless of the underlying database management system). We identified and exported two data sets (CAH and NFCH) in worksheet format that contained all reported medication errors from these two groups of hospitals (Table 1). Next, we imported these data sets into SAS® Ver. 9.1 (SAS Institute, Cary, NC).

Hospital Characteristics

MEDMARX subscribers receive a unique, anonymous, identification number, known as a facility ID number (FID). Each subscriber completes a facility profile that describes the type of facility, owner, size, and level of pharmacist support. The facility profile also contains variables that describe the extent of implementation of structures that support safe medication use. These variables describe the use of computerized prescriber order entry, automated dispensing devices, and computer-generated medication administration records. We used the FID to link each medication error report to the hospital submitting the record.

Medication Error Report Data

The MEDMARX program assigns a unique record number to each error report, which includes information about the severity, phase of the medication use process in which the error originated, type, and cause of error. The MEDMARX program uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) *Index for Categorizing Medication Errors* to assess the severity of the error.[18] The NCC MERP scale assigns an alphabetical category, A through I, to describe the severity of the error based on the outcome for the patient (Table 2). The index has a reported kappa value of $\kappa = 0.62$.[19] Category B errors are actual errors that were intercepted before they reached the patient and are frequently referred to as "near misses."

The phase of the medication use process refers to the steps required to process a medication order. The process begins when the medication is procured by an organization. Next, a licensed prescriber orders the medication. This order is transcribed from the patient's medical record for processing. Next, a pharmacist reviews the order and dispenses the medication for use by another health care professional (typically a nurse). This health care professional administers and monitors the medication's effects on the patient.[9] The type of error is the basic description,

Table 1. Characteristics of hospitals by pharmacist availability

Hospital characteristics	Pharm available 0 – 15 hrs/wk N (%)	Pharm available 32 – 76 hrs/wk N (%)	Pharm available 24 hr/day, 7 days/wk N (%)
Type of hospital			
Critical Access	18 (100.0)	16 (100.0)	0
General community	0	0	143 (100.0)
Average occupied bed size			
1 – 10	13 (72.2)	4 (25.0)	0
11 – 24	5 (27.8)	12 (75.0)	0
25 – 49	0	0	1 (0.7)
50 – 99	0	0	3 (2.1)
100 – 199	0	0	31 (21.7)
200 – 299	0	0	51 (35.7)
300 – 399	0	0	28 (19.6)
400 – 499	0	0	12 (8.4)
>500	0	0	17 (11.9)
Owner/operator of facility			
Government, non-Federal (State/city/county)	12 (66.7)	2 (12.5)	13 (9.1)
Nongovernment, nonprofit	6 (33.3)	14 (87.5)	130 (90.9)
Average doses dispensed per month			
<9,999	17 (94.4)	13 (81.2)	2 (1.4)
10,000 – 19,999	1 (5.6)	2 (12.5)	3 (2.1)
20,000 – 29,999	0	1 (6.2)	0
30,000 – 99,999	0	0	42 (29.4)
100,000 – 149,999	0	0	36 (25.2)
150,000 – 199,999	0	0	22 (15.4)
≥200,000	0	0	38 (26.6)
Computerized prescriber order entry			
Used in all clinical areas	0	1 (6.2)	11 (7.7)
Used in some clinical areas	0	4 (25.0)	9 (6.3)
Not in use	18 (100.0)	11 (68.8)	123 (86.0)
Computer-generated medical administration record	2 (11.1)	7 (43.8)	129 (90.8)
Automated dispensing system in use			
Centralized + decentralized system	0	2 (12.5)	68 (47.6)
Centralized system	2 (11.1)	1 (6.2)	12 (8.4)
Decentralized system	0	3 (18.8)	58 (40.6)
Not in use	16 (88.9)	10 (62.5)	5 (3.5)
Pharmacist primarily prepares inpatient IV admixture products & solutions	0	8 (50.0)	140 (97.9)

Note: No facilities had a pharmacist available 16 - 31 hrs/wk.

Table 2. Comparison of medication error reports by pharmacist availability

Severity category all error reports		% Pharm available 0 – 15 hrs/wk (N = 2,586)	% Pharm available 32 – 76 hrs/wk (N = 5,501)	% Pharm available 24 hr/day, 7 days/wk (N = 159,519)
A	Circumstances or events that have the capacity to cause error	28.4	22.6	6.0
B	Error occurred but it did not reach the patient	14.9	23.9	40.9
C	Error occurred that reached the patient but did not cause harm	53.6	49.8	43.4
D	Error occurred that reached the patient and required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm	2.7	3.4	8.0
E	Error occurred that might have contributed to or resulted in temporary harm to the patient and required Intervention	0.4	0.2	1.4
F	Error occurred that might have contributed to or resulted in temporary harm or required initial or prolonged hospitalization	0.0	0.1	0.3
G	Error occurred that might have contributed to or resulted in permanent patient harm	0.0	0.0	0.0
H	Error occurred that required intervention necessary to sustain life	0.0	0.0	0.0
I	Error occurred that might have contributed to or resulted in patient's death	0.0	0.0	0.0
Characteristics of actual error reports by severity (Categories B - I)		**% (N = 1,851)**	**% (N = 4,260)**	**% (N = 149,978)**
	B (near miss)	20.8	30.8	43.5
	C - D (reached the patient, no harm)	78.6	68.7	54.7
	E - I (harm)	0.6	0.5	1.8
Phase of medication use process		**% (N = 1,851)**	**% (N = 4,260)**	**% (N = 149,978)**
	Prescribing	5.8	8.8	18.0
	Documenting	29.1	29.5	25.6
	Dispensing	6.4	10.1	21.2
	Administering	57.3	50.2	33.5
	Monitoring	0.6	0.9	1.3
	Procurement	0.8	0.6	0.3

Table 2. Comparison of medication error reports by pharmacist availability (continued)

Error types	Pharm available 0 – 15 hrs/wk N = 2,002[a] (%)	Pharm available 32 – 76 hrs/wk N = 4,652[a] (%)	Pharm available 24 hr/day, 7 days/wk N = 158,812[a] (%)
Omission	35.8	32.4	29.4
Improper dose/quantity	19.5	21.1	18.4
Prescribing error	3.8	6.2	13.3
Unauthorized/wrong drug	10.8	15.3	13.2
Wrong time	11.4	8.1	7.7
Extra dose	8.4	7.6	6.1
Wrong patient	1.5	1.8	4.3
Wrong route	2.0	1.5	1.6
Wrong administration technique	1.5	1.3	1.6
Drug prepared incorrectly	0.9	1.2	1.3
Wrong dosage form	2.7	1.8	1.3
Mislabeling	1.2	1.5	1.1
Expired product	0.4	0.2	0.4
Deteriorated product	0.0	0.1	0.2

Note: No facilities had a pharmacist available 16-31 hours per week.

a The number of error types exceeds the number of reports for severity Categories B – I because error type is a multi-select field in MEDMARX; each error report may be categorized as more than one error type.

regardless of the cause, that characterizes an error within the medication use process. There are 14 types of errors within the MEDMARX program (Table 2).[9]

Statistical Analyses

We excluded from this analysis hospitals submitting fewer than 10 reports during the data collection period of 2005 through 2006. We divided the data into three groups based on the hours of pharmacist support available within a hospital each week: (1) CAH with a pharmacist available for ≤15 hours/week, (2) CAH with a pharmacist available >32 hours/week but not available 24 hours/day, and (3) NFCH with a pharmacist available 24 hours/day. No CAHs had a pharmacist available 16 to 31 hours/week. We used descriptive statistics to compare hospital characteristics and medication error report data across the three groups of hospitals. We used logistic regression to evaluate the association between the likelihood of reporting Category B errors (dependent variable) and the three levels of pharmacist support (independent variable). NFCHs with 24-hour pharmacist support served as the reference group.

Reports submitted to MEDMARX are clustered by hospital, which means that the reports submitted by each hospital are correlated and cannot be treated as independent outcomes. Generalized estimating equations (GEE) are typically used to account for the correlation of data within clusters. However, the GEE methods assume that cluster size is not related to the outcomes of interest.[20] In our analysis, cluster size was the number of reports submitted by a hospital; cluster size was significantly associated with our outcome of interest—i.e., reporting

near misses. Specifically, the volume of medication errors reported by the hospitals was positively associated with reporting errors of severity Category B ($P < 0.0001$). Because CAHs tended to submit fewer error reports than the NFCHs, we could not ignore the differences in cluster size in our analysis. To achieve a valid estimate of the standard error in the presence of this difference in cluster size, we used a within-cluster resampling method to account for the nesting of error reports within hospitals. This method remains valid when cluster size is informative.[20, 21] One error report was randomly drawn from each of the 177 hospitals included in the analysis. Because the 177 error reports from each sample were independent, a logistic regression was used to estimate the association between pharmacist support and the likelihood of reporting Category B errors. This sampling procedure was repeated 1,000 times with replacement, and logistic regression was conducted for each sample. The odds ratio and 95 percent confidence interval for the odds ratio were estimated from the results of the 1,000 samples using the method provided by Hoffman.[21]

Results

Sample Characteristics

The 35 CAHs from the UNMC PIPS grant and the 147 NFCHs reported 167,632 medication errors to MEDMARX during the calendar years 2005 and 2006. After excluding the five hospitals that reported 10 or fewer errors during this period, there were 34 CAHs that reported 8,087 medication errors and 143 NFCHs that reported 159,519 errors (Table 2). The number of error reports submitted by the 177 hospitals varied from 11 to 8,309. There were varying levels of pharmacist support among the CAHs: 18 (53 percent) had a pharmacist available ≤15 hours/week and reported 2,586 medication errors. The remaining 16 CAHs (47 percent) had a pharmacist available 32 to 76 hours per week and reported 5,501 medication errors

The hospital groups differed in structures other than pharmacist availability (i.e., bed size, ownership, and volume of doses dispensed) that could also influence the medication use process (Table 1). They also differed in the prevalence of other technologically based structures and processes that support safe medication use. Only five CAHs with a pharmacist available 32 to 76 hours per week and 20 NFCHs with 24-hour pharmacist support used computerized prescriber order entry (CPOE) in any area. The two categories of CAHs without 24-hour pharmacist support were less likely to use a computer-generated medication administration record (11 percent and 44 percent vs. 91 percent) or automated dispensing systems (11 percent and 37 percent vs. 96 percent) than the NFCHs. The CAHs were far less likely to report that intravenous solutions were prepared primarily by a pharmacist than were the NFCHs (0 percent and 50 percent vs. 98 percent).

Medication Error Severity

The severity of medication errors varied by the availability of pharmacist support (Table 2). Specifically, the CAHs reported a higher proportion of circumstances that had the capacity to cause an error (Category A) than did the NFCHs (28 percent and 23 percent vs. 6 percent). When considering actual medication errors (Categories B - I), the CAHs reported a lower proportion of near misses (Category B) (21 percent and 31 percent vs. 44 percent) and a higher proportion of

errors that reached the patient but did not cause harm (Categories C or D) (79 percent and 69 percent vs. 55 percent) than did the NFCHs. Harmful errors (Categories E - I) accounted for approximately 2 percent of reported errors from the NFCHs and <1 percent of reported errors from the CAHs. Only the NFCHs reported fatal medication errors during the 2005 to 2006 reporting period.

After accounting for the clustering of error reports within a hospital by using the within-cluster resampling technique, we found that CAHs with ≤15 hours of pharmacist support were significantly less likely to report Category B errors than were hospitals with 24-hour pharmacist support [odds ratio (OR) 0.64; $P = 0.048$, 2-tailed test] (Table 3). No significant difference in the likelihood of reporting near misses was found between CAHs with 32 to 76 hours of pharmacist support and NFCHs (OR 0.98; $P = 0.91$).

Table 3. Association between pharmacy support and the likelihood of reporting Category B errors

Pharmacist support	OR	95% CI	*P*-value[a]
Available 0-15 hr/wk[b]	0.64	0.42 - 0.9978	0.048
Available 32-76 hr/wk[b]	0.98	0.70 -1.39	0.91

Note: No facilities had a pharmacist available 16-31 hours a week.

a 2- tailed z-test.

b The reference category is pharmacist available 24 hours a day.

Medication Use Process

The CAHs were less likely than the NFCHs to report errors that originated in the prescribing phase (6 percent and 9 percent vs. 18 percent) and dispensing phase (6 percent and 10 percent vs. 21 percent) of the medication use process and more likely to report administering errors (57 percent and 50 percent vs. 34 percent) (Table 2). Analysis of the phase of the medication use process by error severity indicated that CAHs were less likely to report near misses in the prescribing phase (53 percent and 64 percent vs. 82 percent) and dispensing phase (38 percent and 51 percent vs. 58 percent) than were NFCHs (Table 4). The proportions of reported near-miss errors in the administration phase were similar (9 percent and 6 percent vs. 9 percent) (Table 4). The small numbers of monitoring and procurement errors reported by the CAHs prevent meaningful comparisons to those reported by the NFCHs (Table 2).

Type of Error

Omission and improper dose/quantity were the two most frequently reported error types, regardless of the amount of pharmacist support within a hospital (Table 2). The proportions of all reported error types were similar across the three groups of hospitals, with the exception of prescribing errors. Specifically, the CAHs reported a smaller proportion of prescribing errors than did the NFCHs (4 percent and 6 percent vs. 13 percent) (Table 2). With the exception of omission errors, an analysis of the type of error by severity revealed that CAHs with 1 to 15 hours of pharmacist support per week reported the smallest proportion of all types of errors as Category B (Table 5). Prescribing errors were more likely than any other error type to be reported as Category B across the three groups of hospitals.

Table 4. Phase of origination and severity of actual (Categories B - I) medication error reports by pharmacist availability

Phase of medication use process	Pharm available 0 – 15 hrs/wk (N = 1,851)	Pharm available 32 – 76 hrs/wk (N = 4,260)	Pharm available 24 hr/day, 7 days/wk (N = 149,978)
Prescribing reports	(N = 108)	(N = 375)	(N = 26,998)
Severity category:			
B (%)	52.8	63.7	81.6
C - D (%)	46.3	35.5	16.9
E - I (%)	0.9	0.8	1.5
Documenting reports	(N = 539)	(N = 1,256)	(N = 38,473)
Severity category:			
B (%)	34.3	57.4	51.0
C - D (%)	64.9	42.3	47.8
E - I (%)	0.7	0.3	1.2
Dispensing reports	(N = 118)	(N = 430)	(N = 31,748)
Severity category:			
B (%)	38.1	51.4	57.6
C - D (%)	61.0	48.1	41.4
E - I (%)	0.8	0.5	1.1
Administering reports	(N = 1,061)	(N = 2,138)	(N = 50,290)
Severity category:			
B (%)	8.9	5.8	8.8
C - D (%)	90.7	93.7	88.4
E - I (%)	0.5	0.5	2.8
Monitoring reports	(N = 11)	(N = 37)	(N = 1,953)
Severity category:			
B (%)	0.0	10.8	32.0
C - D (%)	90.9	86.5	61.8
E - I (%)	9.1	2.7	6.3
Procurement reports	(N = 14)	(N = 24)	(N = 516)
Severity category:			
B (%)	28.6	25.0	44.4
C - D (%)	71.4	75.0	54.5
E - I (%)	0.0	0.0	1.2

Note: No facilities had a pharmacist available 16-31 hours/week.

Table 5. Type and severity of actual medication error reports (Categories B - I) by pharmacist availability

Type of medication error	Pharm available 0 – 15 hrs/wk (N = 2,002[a])	Pharm available 32 – 76 hrs/wk (N = 4,652[a])	Pharm available 24 hr/day, 7 days/wk (N = 158,812[a])
Omission error reports	(N = 717)	(N = 1,507)	(N = 46,657)
Severity category:			
B (%)	14.5	13.5	29.8
C - D (%)	84.7	86.2	68.5
E - I (%)	0.8	0.3	1.8
Improper dose/quantity reports	(N = 391)	(N = 983)	(N = 29,239)
Severity category:			
B (%)	32.0	42.9	44.7
C - D (%)	67.5	56.4	52.7
E - I (%)	0.5	0.7	2.6
Prescribing error reports	(N = 76)	(N = 286)	(N = 21,102)
Severity category:			
B (%)	55.3	66.1	83.3
C - D (%)	43.4	32.9	15.4
E - I (%)	1.3	1.0	1.3
Unauthorized/wrong drug reports	(N = 217)	(N = 711)	(N = 21,044)
Severity category:			
B (%)	26.3	38.3	44.1
C - D (%)	73.3	61.6	54.0
E - I (%)	0.5	0.1	1.9
Wrong time reports	(N = 229)	(N = 376)	(N = 12,224)
Severity category:			
B (%)	8.3	22.3	29.5
C - D (%)	91.7	77.4	69.5
E - I (%)	0.0	0.3	1.1
Extra dose reports	(N = 169)	(N = 356)	(N = 9,652)
Severity category:			
B (%)	26.6	38.2	32.7
C - D (%)	72.8	61.2	65.5
E - I (%)	0.6	0.6	1.8
Wrong patient reports	(N = 30)	(N = 83)	(N = 6,836)
Severity category:			
B (%)	10.0	56.6	47.5
C - D (%)	90.0	43.4	51.5
E - I (%)	0.0	0.0	1.0

Table 5. Type and severity of actual medication error reports (Categories B - I) by pharmacist availability (continued)

Type of medication error	Pharm available 0 – 15 hrs/wk (N = 2,002[a])	Pharm available 32 – 76 hrs/wk (N = 4,652[a])	Pharm available 24 hr/day, 7 days/wk (N = 158,812[a])
Wrong dosage form reports	(N = 54)	(N = 86)	(N = 2,038)
Severity category:			
B (%)	24.1	38.4	48.2
C - D (%)	75.9	61.6	50.3
E - I (%)	0.0	0.0	1.5
Other reports	(N = 119)	(N = 264)	(N = 10,020)
Severity category:			
B (%)	21.0	48.1	45.7
C - D (%)	78.2	50.0	51.4
E - I (%)	0.8	1.9	3.0

Note: No facilities had a pharmacist available 16-31 hours/week.

a The number of error types exceeds the number of reports for severity Categories B – I because error type is a multi-select field in MEDMARX; each error report may be categorized as more than one error type.

Reporting of Errors by Pharmacy Personnel

Of the 156,089 actual errors reported (Categories B - I) from the 177 hospitals, information about the level of staff discovering the error was available in 111,622 records. This variable is not a required field in the MEDMARX reporting program. Pharmacy personnel (pharmacist, pharmacy technician, nonspecific pharmacy personnel) reported 36,672 (33 percent) of the 111,622 records.

The participation of pharmacy personnel in medication error reporting varied among the three groups of hospitals: in CAHs with ≤15 hours of pharmacist support per week, pharmacy personnel were identified as the staff discovering the error in 3.3 percent (55/1,658) of submitted reports; in CAHs with 32 to 76 hours of pharmacist support per week, pharmacy personnel were identified as the staff discovering the error in 28.4 percent (1,211/4,088) of submitted reports; and in NFCHs, pharmacy personnel were identified as the staff discovering the error in 31.8 percent (31,168/97,893) of submitted reports.

Of the 32,434 actual errors (Categories B - I) discovered by pharmacy personnel across the 177 hospitals, 55 percent originated in the prescribing phase of the medication use process, 21 percent in documenting, 13 percent in dispensing, 9 percent in administering, 2 percent in monitoring, and 0.5 percent in procurement. However, the phase of origination of reported errors that pharmacy personnel discovered differed among the three groups of hospitals: in CAHs with ≤15 hours of pharmacist support per week, 3.6 percent of errors discovered by pharmacy personnel originated in prescribing, 25.5 percent in documenting, and 65.5 percent in administering. In CAHs with 32 to 76 hours of pharmacist support a week, 17.3 percent of errors discovered by pharmacy personnel originated in prescribing, 40.7 percent in documenting, and 33.9 percent in administering. In NFCHs, 56.6 percent of errors discovered by pharmacy

personnel originated in prescribing, 20.6 percent in documenting, and 7.4 percent in administering.

Finally, the severity of reported errors that pharmacy personnel discovered differed among the three groups of hospitals: in CAHs with ≤15 hours of pharmacist support a week, 16.4 percent of actual errors discovered by pharmacy personnel were Category B; in CAHs with 32 to 76 hours of pharmacist support a week, 47.7 percent were Category B; and in NFCHs, 78.6 percent were Category B.

Discussion

Key Findings

These results illustrate differences in the severity of medication errors voluntarily reported by 177 hospitals to a national medication error-reporting program. These differences were associated with the structure and process of medication use, as represented by the number of hours a pharmacist was available each week. As PSOs develop, they will aggregate and compare data from multiple organizations. However, analysis of aggregated data results in the loss of information and an inflated Type I error rate if the data are correlated within clusters. We used the computationally intensive method of within-cluster resampling to account for this correlation and the important differences in the sizes of our clusters. Future analyses of aggregate PSO data will be more likely to result in meaningful improvements in patient safety if data are clustered by differences in the structure and process of care within hospitals. However, appropriate statistical analyses must be used to account for the likely correlation of the data within these clusters.

Structure is the major determinant of the average quality of care a system is able to offer. The relationship between structure, process, and outcome is linear, such that differences in structure result in differences in process, which in turn, affects the outcome of care.[10, 11] A significant difference between the structure of medication use in CAHs and larger community hospitals is the availability of pharmacist support. Pharmacists affect all phases of the medication use process. These results demonstrate that, after accounting for the correlation of reports within a hospital, those hospitals with ≤15 hours of pharmacist support are significantly less likely to report near-miss errors than are hospitals that have pharmacists available 24 hours per day. This pattern is stable across all phases and types of voluntarily reported medication errors. In addition, the more time a pharmacist is available within a hospital, the more likely it is that he or she will report errors and intercept errors that originate in the prescribing phase. For example, "no 24-hour pharmacy" support was selected as a contributing factor in 3 percent of a 5-year aggregation of all MEMARX reports.[22] In contrast, in a 2-year aggregation of data from all CAHs reporting to MEDMARX, those with 1 to 10 occupied beds selected "no 24-hour pharmacy" as a contributing factor in 20 percent of reported errors (*USP data on file*).

The complexity of medication use requires that pharmacists play a central role in an interdisciplinary system of independent double-checks that places more than one provider between the drug and the patient.[1, 23, 24] When reviewing medication orders, clinical pharmacists verify the appropriateness of the drug and dose as ordered by the prescriber. The importance of this review is reflected by the fact that harmful medication errors are most likely to originate in

the prescribing phase of medication use.[25] When a pharmacist is not present to dispense a medication, the entire responsibility for correct selection of drug, quantity, and dosage form falls on the nursing staff. Specifically, standards of nursing practice require a nurse to verify that the correct drug, quantity, and dosage form is being given to the correct patient, at the correct time, and by the correct route. In a nationally representative sample of CAHs that we surveyed in 2005, 41 percent reported that nurses always or frequently selected and administered a newly ordered medication without an independent double-check by another provider.[26]

Clinical pharmacists also serve an important role in the monitoring and procurement phases of the medication use process. They frequently monitor a patient's response to the prescribed medication regimen for both effectiveness and safety. It is standard practice for clinical pharmacists who work full time at a hospital to manage the procurement phase of medication use and thus control the hospital's formulary. Formulary management is a proven safe medication practice.[23]

Similar to other studies,[15, 16] we found that the structures of computer-generated medication administration records and the presence of automated dispensing systems were more likely to be available in large community hospitals than in CAHs. These technology-based structures affect the process of medication use and reduce the number of opportunities for error. Computer-generated medication administration records minimize the need to manually copy these forms. Automated dispensing systems minimize the need for nurses to enter the pharmacy and limit the number of medications to which they have access. Barcode medication administration (BCMA) is a technology that can intercept medication errors at the point of care.[27]

The MEDMARX facility profile does not identify which hospitals have implemented BCMA. We did not observe differences in the low proportions of near-miss errors intercepted in the administering phase across the three groups of hospitals. It is likely that this costly but effective intervention will become common in large hospitals, but adoption of BCMA is likely to lag in CAHs with limited financial resources. In our 2005 survey of small rural hospitals, 4 percent of CAHs had implemented BCMA.[26]

These results demonstrate that the structure of pharmacist availability is significantly associated with patterns of voluntary medication error reporting. However, a possible argument against aggregating error reports by similarities in structure and process, particularly for CAHs, is that the voluntary reporting system may be insufficient to identify errors and determine system vulnerabilities across all phases of medication use. Specifically, the proportions of errors originating in the prescribing and dispensing phases were much lower in the CAHs than in the NFCHs. Hospitals without the structures and processes to review medication orders are unlikely to identify errors that originate in prescribing. In addition, nurses are not licensed to dispense medications. In those hospitals where pharmacists are not dispensing, errors that originate in the pharmacy as a nurse selects a drug are reported as originating in the administration phase. Hospitals that do not have pharmacists to dispense medications are less likely to identify errors that originate when the drug is selected than hospitals with dispensing pharmacists, simply because an opportunity for an independent double-check is removed. Since prescribing and dispensing errors are under-represented in the voluntary reporting of CAHs, to become high-reliability organizations and intercept errors before they reach the patient these CAHs must learn

from the reporting of other hospitals or implement additional error-detection strategies, such as telepharmacy and BCMA.

Limitations and Strengths

There are several limitations to this analysis. First, the voluntarily reported medication errors in this study come from organizations that self-selected to participate in a national medication error-reporting program. In addition, the 35 CAHs in this analysis were part of an AHRQ-funded patient safety program that emphasized the importance of learning from all errors, especially near misses. Thus, these hospitals might not be representative of all hospitals of similar size or degree of pharmacist support.

Second, errors reported by the NFCHs may be misclassified. We verified the accuracy of error categorizations reported by the CAHs as part of our grant-funded activities. However, no effort was made to verify this accuracy in the NFCHs. While MEDMARX provides a glossary of terms, it is the user who submits the record who must ensure accurate error classification. We do believe, however, that it is unlikely that misclassifications of errors occurred to an extent large enough to explain the differences observed.

A third limitation in this analysis is our use of one characteristic—amount of pharmacist support—to represent differences in the medication use systems across hospitals of different sizes. Other structures, such as CPOE, computer generated Medication Awareness Reporting Systems (MARs), automated dispensing systems and BCMA, significantly influence the medication use process. Data for three of these factors were available for our sample. These additional structural variables were not included in a multivariate analysis due to their collinearity with pharmacist support and the complex resampling methodology. We do not believe that inclusion of additional structure or process variables in the analysis would affect our overall finding that differences in structure and process result in differences in the severity of medication errors that are voluntarily reported by hospitals.

The strength of this analysis is its demonstration that large databases of voluntary error reports generated by future PSOs can be a source of information about hazards to patient safety for hospitals of all sizes. We also demonstrate that hospitals seeking to be high-reliability organizations will need to be able to interpret information provided by PSOs in the context of the structures and processes in use in reporting organizations. Finally, we demonstrate how within-cluster resampling can be used to account for the correlated nature of data that will be reported to PSOs.

Conclusion

These results demonstrate that after accounting for the correlation of reports within a hospital, CAHs with ≤15 hours of pharmacist support per week were significantly less likely to report intercepting medication errors before they reached patients than were hospitals that have pharmacists available 24 hours per day. The differences in reporting patterns observed between hospitals across the phases and types of voluntarily reported medication errors were associated with their differences in structure, as indicated by the availability of pharmacist support.

Knowledge of the variation in the structure and process of care in organizations that report to PSOs will enhance an understanding of how this variation contributes to error and will, thus, improve the likelihood that recommended changes to the structure and processes of care will improve patient safety. If PSOs are to appropriately analyze data from reporting organizations, they must be able to account for the correlation of the data within these hospital clusters. If appropriate statistical methods that account for the correlation are not used, the variance of mean summary statistics will be underestimated in the presence of positive correlation. This underestimation may result in false positive reporting (i.e., the reporting of differences that do not exist). Finally, as PSOs develop and disseminate recommendations to improve patient safety based on aggregated data analysis, future research must examine the impact of their recommendations on patient outcomes.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.
2. Institute of Medicine. Preventing medication errors. Washington, DC: National Academies Press; 2007.
3. Leape LL. Reporting of adverse events. N Engl J Med 2002; 347: 1633-1638.
4. Ashish K, Kuperman GJ, Teich JM, et al. Identifying adverse drug events: Development of a computer-based monitor and comparison with chart review and stimulated voluntary report. JAMA 1998; 5: 305-314.
5. Bates DW, Boyle DL, Vander Vliet MB, et al. Relationship between medication errors and adverse drug events. J Gen Intern Med 1995; 10: 199-205.

6. Classen DC, Pestotnik SL, Evans RS, et al. Computerized surveillance of adverse drug events in hospital patients. JAMA 1991; 27: 2847-2851.

7. 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: 436-446.

8. The patient safety and quality improvement act of 2005. Available at: www.ahrq.gov/qual/psoact.htm. Accessed April 29, 2008.

9. Stevenson JG. Medication errors: Experience of the United States Pharmacopeia. Jt Comm J Qual Saf 2005; 31: 106-111.

10. Donabedian A. Evaluating the quality of medical care. Milbank Q 1966; 44: 166-206.

11. Donabedian A. An introduction to quality assurance in health care. New York: Oxford University Press; 2003.

12. Mueller KJ. The Medicare prescription drug, improvement, and modernization act of 2003 (P.L. 108-173): A summary of provisions important to rural health care delivery. Omaha. RUPRI Center for Rural Health Policy Analysis; 2004. Policy Paper P2004-1.

13. Flex Monitoring Team Site. A complete list of Critical Access Hospitals. Available at: www.flexmonitoring.org/documents/CAH_LIST_08_06_07.xls. Accessed April 29, 2008.

14. American Hospital Association. AHA hospital statistics. Chicago: Health Forum, LLC; 2006.

15. Casey MM, Moscovice IS, Davidson G. Pharmacist staffing, technology use, and implementation of medication safety practices in rural hospitals. J Rural Health 2006; 22: 321-329.

16. Jones KJ, Cochran G, Hicks RW, et al. Translating research into practice: Voluntary reporting of medication errors in critical access hospitals. J Rural Health 2004; 20: 335-343.

17. Weick KE, Sutcliffe KM. Managing the unexpected: Assuring high performance in an age of complexity. San Francisco: John Wiley & Sons; 2001.

18. Index for categorizing medication errors. National Coordinating Council for Medication Error Reporting and Prevention; 2001. Available at: www.nccmerp.org/pdf/indexBW2001-06-12.pdf. Accessed June 10, 2008.

19. Forrey RA, Pedersen CA, Schneider PJ. Interrater agreement with a standard scheme for classifying medication errors. Am J Health Syst Pharm 2007; 64: 175-181.

20. Follmann D, Proschan M, Leifer E. Multiple outputation: Inference for complex clustered data by averaging analyses from independent data. Biometrika 2003; 59: 420-429.

21. Hoffman EB, Sen PK, Weinberg CR. Within-cluster resampling. Biometrika 2001; 88: 1121-1134.

22. Hicks RW, Becker SC, Cousins DD. MEDMARX data report. A chartbook of medication error findings from the perioperative settings from 1998-2005. Rockville, MD: USP Center for the Advancement of Patient Safety; 2006.

23. Cohen MR. Medication errors: Causes, prevention, and risk management. Sudbury, MA: Jones and Bartlett Publishers; 2000.

24. Shojania KG, Duncan BW, McDonald KM, et al. Making health care safer. A critical analysis of patient safety practices. Evidence report/technology assessment no. 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001. Available at: www.ahrq.gov/clinic/ptsafety/pdf/front.pdf. Accessed May 2, 2008.

25. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274: 29-34.

26. Cochran, GL, Jones KJ, Xu L, Mueller K. Prevalence of evidence-based safe medication practices in small rural hospitals. Omaha. Nebraska Center for Rural Health Research; April 2008. Brief No. 2008-1. Available at: http://www.unmc.edu/ruprihealth/Pubs/IssueBrief2008-1.pdf. Accessed July 17, 2008.

27. Heinen MG, Coyle GA, Hamilton AV. Barcoding makes it mark on daily practice. Nurs Manag 2003: 18-20.