Reporting of Adverse Drug Events: Examination of a Hospital Incident Reporting System

Radhika Desikan, Melissa J. Krauss, W. Claiborne Dunagan, Erin Christensen Rachmiel, Thomas Bailey, Victoria J. Fraser

Abstract

Background: Voluntary hospital reporting systems are potentially valuable sources of information about medical errors and adverse events. This study examined the extent and variation in the reporting of medication errors and adverse drug events in a voluntary hospital incident reporting system. **Methods:** A retrospective analysis of received incident reports of potential and preventable adverse drug events over a 22-month period was conducted at a 1,300-bed, university-affiliated, tertiary care hospital. Reporting of adverse drug events into the hospital's online Risk Management Event/Incident Entry System (RMEES), which is mainly used by nurses, was compared to reporting by pharmacists into a pharmacy reporting system (PHRED). **Results:** During the study period, the reported preventable and potential adverse drug event rates were 0.47 and 1.85 per 1,000 patient days, respectively, for RMEES-reported events compared with rates of 0.08 and 41.5 per 1,000 patient days for PHRED-reported events. Significant differences by service ($P < 0.001$) were present for potential adverse drug event rates in both RMEES and PHRED, but preventable adverse drug event rates did not differ significantly ($P > 0.05$) by service. A modest relationship ($R^2 = 0.27$) between potential and preventable adverse drug event rates reported to RMEES was present. The median ratio of potential to preventable adverse drug events in RMEES was 4.5 (range = 0 to 16). The median ratio of PHRED to RMEES reports was 7.8, but varied markedly among individual nursing units (range = 0 to 157). **Conclusions:** Compared with rates reported in the literature, voluntary incident reporting yielded a much lower reporting rate of adverse drug events with considerable variation in reporting among units and service areas. Voluntary reporting of medical errors and adverse events is unlikely to yield reliable estimates of event rates.

Introduction

Hospitals and health care providers strive to deliver the safest care possible. Nevertheless adverse drug events are common,[1–4] often preventable,[5–9] and costly.[10–15] Preventable adverse drug events occur due to medication errors, which include errors in the process of ordering or delivering a medication and errors of omission (e.g., failing to administer a drug as prescribed). Bates et al.[16, 17] estimated that approximately 1 percent of medication errors result in adverse drug events. Minimizing or eliminating medication errors is vital to improve patient

safety and the quality of hospital care. Medication error reporting is an essential component of achieving these goals.

Several national voluntary and mandatory reporting systems exist for medication errors, adverse events, and medical device problems in the United States.[8–22] The Institute of Medicine called for national mandatory reporting to State departments of health of events that result in death or serious harm, and voluntary reporting within health care organizations of less serious events.[19, 23–27] The Institute for Safe Medical Practices, however, has endorsed voluntary reporting of adverse drug events.[23, 24, 26] Although the debate regarding the need for voluntary or mandatory reporting systems continues,[23–25, 28–32] voluntary reporting systems are more appealing to institutions and are potentially valuable sources of information that hospitals could use for systemwide improvements.[33]

Previous research on voluntary incident reporting involved examining reports on a restricted number of patient care units for limited time periods, typically less than 1 year.[34–39] To better understand how to enhance incident reporting, it is essential to examine the existing state of reporting, particularly voluntary systems. This study analyzed a hospitalwide voluntary incident reporting system at an academic teaching hospital during a 22-month time period. Specifically, this study aimed to determine the extent and variation in the reporting of potential and preventable adverse drug events by comparing incident reporting with other information sources, such as pharmacist reporting of events.

Methods

Setting

Barnes–Jewish Hospital (BJH) is an urban, 1,300-bed, tertiary care referral center affiliated with Washington University School of Medicine in St. Louis, Missouri, and a member of BJC HealthCare. In 2001, BJH had 49,927 inpatient admissions and 81,792 emergency department visits. We examined medication events that led to patient harm (adverse drug events) and potential adverse drug events (errors that caused no harm or were intercepted before they reached the patient) captured by BJH's online Risk Management Event/Incident Entry System (RMEES) from May 2000 to March 2002.

Definitions

An *adverse drug event* is an injury related to medication use. Adverse drug events can be preventable or nonpreventable. *Preventable* adverse drug events arise from medication errors that may occur in the process of ordering, transcribing, dispensing, or administering a drug. *Potential* adverse drug events are errors that have the capacity to cause injury, but fail to do so either by chance or because they are intercepted.[40]

Data sources

Risk Management Event/Incident Entry System (RMEES)

BJH's online RMEES is an event/incident reporting and tracking system. This system includes an easily accessible, confidential, Web-based reporting application for reporting patient-related incidents that may have led to adverse outcomes. The system has been in use for over 10 years at BJH, and over 14,000 events of many different types, including medication-related events, have been recorded in the database since its inception. Nurses are the primary users of this system, but other allied staff such as patient care technicians and respiratory technicians can also report into this system. However, they typically report incidents to nurses who enter the information. During nursing orientation, risk management education introduces staff to the theory of the RMEES and informs them of the types of events that should be reported. Clinical information systems education shows the staff nurses, unit secretaries, and patient care technicians the actual application and how to fill out the online forms. Physicians do not report directly into this system, but they may ask nurses or other health care workers to report incidents into the system. Pharmacists use the Pharmacy Resource Directory (PHRED), a separate reporting system, to document medication errors and adverse drug events.

The RMEES database contains the following information: event date, floor, event number, event description, and medical record number of the affected patient. This information is provided by the person reporting the event. After pharmacy staff receives adverse drug event data from RMEES, they further categorize the event by severity level, error source, and event reason. Potential adverse drug events are categorized at severity levels A and B. Level A events have the potential to do harm but do not reach the patient. Level B events have potential for harm and reach the patient, but cause no harm. Preventable adverse drug events are categorized at severity level C. Events at this level reach the patient and either lead to harm or require an increase in monitoring. Level C excludes drug-related injuries that are not the result of error. Seven categories are used to describe the reasons for the event. These include medication administration errors due to slip or memory lapse, device use error, intravenous error, transcription error, prescribing error, charting error, and a miscellaneous "other" category. In order to make coding consistent, one person (investigator RD) performed the data cleaning. For this study, medications involved in preventable adverse drug events were coded according to the American Hospital Formulary Service pharmacologic-therapeutic classification system published by the American Society of Health-System Pharmacy.

Pharmacy Resource Directory

PHRED is a comprehensive online medication event reporting system that is available to all pharmacy personnel at BJH, including all staff pharmacists (who are primarily involved in dispensing medications) and clinical and unit-based pharmacists assigned to individual floors. Besides reporting potential and

preventable adverse drug events, PHRED contains useful resources for pharmacists such as drug information links and hospital policies and procedures. Adverse drug event categories reported in PHRED are similar to those captured in RMEES. Pharmacy staff further categorizes the reported events in a manner analogous to that described for RMEES.

Alerts from pharmacy expert systems

We also reviewed computerized alerts generated by two pharmacy expert systems: Dose Checker and PharmADE. These expert systems are capable of real-time detection of prescribing errors, thereby helping physicians and pharmacists reduce medication errors. DoseChecker routinely screens approximately 50 drugs that are either potentially toxic or typically eliminated through the kidneys for appropriate dosing, generating alerts to pharmacists when the drug dose falls outside locally developed dosing guidelines.[41] PharmADE screens drug orders for more than 130 contraindicated drug combinations and generates alerts when it detects potentially serious drug interactions.[42] After validating the alerts, pharmacists contact physicians for possible changes to drug orders. Physician- and pharmacist-confirmed alerts generated during the 22-month time period provided an objective source of information on medication events.

Other data sources

Demographic data on patients involved in preventable adverse drug events was obtained from the hospital's billing department. Data on patient days was obtained from the hospital's admissions office.

Analysis

Individual patient care units were classified into services including medicine, surgery, obstetrics, psychiatry, and rehabilitation, based on the predominant type of patients admitted to those patient units. Specific criteria were applied in the calculation of patient days as follows:

- For units that closed during the study period and did not reopen, patient days were calculated only for the time period the unit was open.
- For units that closed during the study period, but reopened subsequently as the same unit or a different unit within the same service, patient days were calculated by summing the numbers for the original and newly reopened unit.

Adverse drug events reported from areas outside of patient care areas (e.g., pharmacy, pheresis, pain management center) were classified as "other." Information on patient days was not available for these areas.

Rates for both potential and preventable adverse drug events per 1,000 patient days were determined for all hospital units and for the various service areas. The total pharmacy alert rate was calculated as the total number of physician- and

pharmacist-confirmed alerts per 1,000 patient days. Data was analyzed using SPSS® version 11.0 for Windows® (SPSS, Chicago, IL). Comparisons of the reported rates of adverse drug events were performed using the chi-square procedure, stratified by service and unit type. Results were considered significant if two-tailed *P* values were ≤ 0.05. The Bonferroni correction was used to control for type 1 error for pair-wise comparisons.

Results

Overall reporting of events in RMEES and PHRED

There were 94,445 admissions and 483,845 patient days during the 22-month study period. A total of 228 preventable adverse drug events and 898 potential adverse drug events were reported into RMEES during this time. There were 51 unique units (six ICUs, four observation units, and 41 nursing divisions) that reported potential and/or preventable adverse drug events into RMEES. Among the 51 units, one (2 percent) reported no potential adverse drug events, while four (7.8 percent) reported no preventable adverse drug events. Radiology accounted for 31 out of 43 preventable adverse drug events (72 percent) that occurred outside of patient care areas and were classified as "other."

Only 21 units reported preventable adverse drug events into PHRED during the study period. Approximately 6 percent of events (1,196) did not specify a nursing unit; all of these involved potential adverse drug events. Of the 51 units, two (3.8 percent) reported no potential adverse drug events, while 58 percent of the units reported no preventable adverse drug events into PHRED.

Table 1. Overall reporting of adverse drug events at Barnes–Jewish Hospital: rates per 1,000 patient days

Adverse drug events	RMEES number of events (rate*)	PHRED number of events (rate*)	Total number of events (rate*)
Preventable	228 (0.47)	40 (0.08)	268 (0.55)
Potential	898 (1.85)	20,115 (41.5)	21,013 (43.43)
Total (potential + preventable)	1,126 (2.32)	20,155 (41.6)	21,281 (43.9)

* Rate per 1,000 patient days

Table 1 describes the total preventable and potential adverse drug event reporting rates per 1,000 patient days at BJH from both RMEES and PHRED. There were no common preventable adverse drug events between RMEES and PHRED, implying that the two systems capture uniquely independent events. Consequently, the total preventable adverse drug event rate (0.55) reflects the total rate from both systems. On the other hand, potential adverse drug events were not examined to identify common events between the two systems. Based on

the presumption that there is minimal overlap in the events reported in RMEES and PHRED, the best upper-limit estimate (in case there were no common events) of the potential adverse drug event rate is the total potential adverse drug event rate of 43.4 per 1,000 patient days, with the lower limit of this estimate (in case all events were common) being the PHRED rate (41.5 per 1,000 patient days). Total potential adverse drug event rates from both RMEES and PHRED were noticeably higher than preventable adverse drug event rates. RMEES had a considerably lower total adverse drug event (potential + preventable) reporting rate per 1,000 patient days than PHRED.

Demographics

Complete demographic information was available for 215 patients involved in 223 preventable adverse drug events (98 percent). Five events (2 percent) had invalid medical record numbers, precluding any linkage to demographic data. The mean age of patients involved in preventable adverse drug events was 58.6 years (Standard deviation [SD] = 17.95 years) and differed significantly from the mean age (50.3 years) of all inpatients at BJH during the study period ($P < 0.01$). Ages of patients involved in the preventable adverse drug events ranged from 1 day to 96 years. More than one-third of the patients were 80 years or older. Fifty-two percent were female, a percentage which did not differ significantly from that of all inpatients during the study period (57 percent). Approximately 45 percent were covered by Medicare. Their median length of stay was 7 days, with a range of 1 to 95 days. Most patients (64.7 percent) had a length of stay of 10 days or less.

Description of preventable adverse drug events in RMEES and PHRED

Table 2 describes the most frequent preventable adverse drug events reported in RMEES and PHRED. Similar proportions of events were reported in the two reporting systems for most drug classes, event types, and event reasons. No single drug class or event type was predominantly reported in either RMEES or PHRED. In both RMEES and PHRED, medication administration errors due to slip or memory lapse were among the most common reasons for the events.

In RMEES, the drugs most frequently reported involving preventable adverse drug events were heparin, insulin, vancomycin, and morphine (all from the top four drug classes of RMEES), while the drugs most frequently involved in PHRED events were diltiazem, heparin, and propofol (from the top three drug classes of PHRED). Insulin was not reported in any of the PHRED events. More than 50 percent of the preventable adverse drug events in RMEES were associated with just 14 drugs, while no such pattern was noted for the drugs involved in PHRED events. Events involving cardiovascular agents were more common in PHRED events. No PHRED reports involved IV infiltrations from radiologic contrast dyes or other medications. Overall, almost one-third (30 percent) of the preventable adverse drug events reported by nurses in RMEES were related to medication administration errors, while the majority of pharmacist-reported PHRED events were associated with transcription errors.

Table 2. Description of the most frequently reported preventable adverse drug events in RMEES and PHRED

Event classifications	RMEES (N = 228) n (%)	PHRED (N = 40) n (%)	Total (N=268) n (%)
Drug classes			
CNS agents	47 (22.8)	11 (27.5)	58 (21.6)
Blood formation and coagulation agents	37 (16.2)	7 (17.5)	44 (16.4)
Hormones and synthetics	31 (15.0)	1 (2.5)	32 (11.9)
Radiologic contrast	30 (13.2)	0 (0.0)	30 (11.1)
Anti-infectives	24 (10.5)	4 (10.0)	28 (10.4)
Cardiovascular agents	23 (10.1)	10 (25.0)	33 (12.3)
Other	36 (15.7)	7 (17.5)	43 (16.0)
Type of event			
Wrong dose	37 (15.8)	5 (12.5)	42 (15.6)
Wrong drug	32 (14.0)	8 (20.0)	40 (14.9)
Wrong infusion rate	31 (13.6)	5 (12.5)	36 (13.4)
Extra dose	30 (13.2)	5 (12.5)	35 (13.0)
Missed dose	20 (8.8)	5 (12.5)	25 (9.3)
IV infiltrations	17 (7.5)	0 (0)	17 (6.3)
Wrong patient	16 (7.0)	2 (5.0)	18 (6.7)
Other	46 (20.17)	10 (25.0)	56 (20.9)
Event reason			
Administration	89 (39.0)	8 (20.0)	97 (36.2)
Device use	44 (19.3)	5 (12.5)	49 (18.3)
IV error	17 (7.5)	0 (0)	17 (6.3)
Transcription error	17 (7.5)	10 (25.0)	27 (10.0)
Prescribing error	13 (5.7)	8 (20.0)	21 (7.8)
Charting error	10 (4.4)	5 (12.5)	15 (5.6)
Other	37 (16.2)	4 (10.0)	41 (15.3)

Comparison of drug classes and event types for RMEES- and PHRED-reported events

Table 3 compares the drug classes with the various event types for the events reported in RMEES and PHRED. Dosing errors (wrong dose, extra dose, missed dose) were the predominant types of events reported. Almost half (44.4 percent) of the wrong dose events were related to central nervous system agents, primarily morphine. More than 50 percent of the wrong infusion rate events were associated with heparin. Insulin was associated with multiple types of events and accounted for all of the wrong dose, wrong drug, wrong infusion rate, missed dose, and wrong patient events within the “hormones and synthetics” class.

Extent of reporting in RMEES and PHRED

Table 4 describes the reported rates (per 1,000 patient days) of potential and preventable adverse drug events by service for events reported in RMEES and PHRED and the pharmacy expert systems. There was considerable variation in the reported total adverse drug event rates per 1,000 patient days across the various services in both RMEES and PHRED. In RMEES, significant differences by service were noted for reported potential adverse drug event rates per 1,000 patient days ($P < 0.001$). Surgery had a significantly higher potential adverse drug event rate (2.35) than medicine (1.33) and obstetrics (1.03). Reported rates (per 1,000 patient days) of preventable adverse drug events did not differ significantly by service.

In PHRED, the potential adverse drug event rates per 1,000 patient days for the various units varied from 0 to 158 (median = 15) while the preventable adverse drug event rates per 1,000 patient days among the various units varied from 0 to 0.66 (median = 0). Significant differences by service were noted for reported potential adverse drug event rates per 1,000 patient days ($P < 0.001$). Surgery had a marginally, though statistically significant, higher potential adverse drug event reporting rate per 1,000 patient days (44.7) than medicine (42.7); both services had much higher reporting rates than psychiatry (17.9), rehabilitation services (1.21), and obstetrics (0.47) ($P < 0.001$). Preventable adverse drug event rates per 1,000 patient days did not differ significantly by service in PHRED.

Variation in reporting between potential and preventable adverse drug events in RMEES

Figure 1 depicts the adverse drug event reporting variation among patient care units that use RMEES. There was a modest relationship ($R^2 = 0.27$) between the reported potential and preventable adverse drug rates in RMEES across all services. There was no relationship ($R^2 = 0.002$) between potential and preventable adverse drug event reporting rates in PHRED. The potential adverse drug event rates varied from 0.00 to 13.3 (median = 1.4), while the preventable adverse drug event rates varied from 0.00 to 3.15 (median = 0.37). The ratio of potential adverse drug events to preventable adverse drug events across the various units in RMEES varied from 0 to 16 (median = 4.5).

Units in the medicine service had the highest variation in potential adverse drug event reporting rates per 1,000 patient days (range 0.19 to 13.32), followed by surgery (range 0.67 to 9.46). Four surgery units and one obstetrics unit reported only potential adverse drug events (no preventable adverse drug events). On the other hand, surgical units had the highest variation in preventable adverse drug event reporting rates per 1,000 patient days (range 0.1 to 3.15), followed by medicine (range 0.09 to 2.03). One psychiatry unit reported only preventable adverse drug events (no potential adverse drug events).

Table 3. Event type versus drug class from RMEES and PHRED

	Drug Class n (%)*							
Event Type	**CNS agents**	**Blood formation & coagulation agents**	**Cardiovascular agents**	**Hormones & synthetics**	**Anti-infectives**	**Electrolyte caloric & water balance**	**Other**	**Total ‡ N (% of total)**
Wrong dose	18 (45)	4 (10)	3 (8)	8 (20)	0 (0)	1 (3)	6 (15)	40 (17)
Wrong drug	11 (28)	1 (3)	6 (15)	6 (15)	5 (13)	6 (15)	5 (12)	40 (17)
Wrong Infusion rate	2 (6)	22 (63)	0 (0)	2 (6)	1 (3)	2 (6)	6 (17)	35 (15)
Extra dose	8 (23)	7 (20)	10 (29)	3 (9)	3 (9)	2 (6)	2 (6)	35 (15)
Missed dose	5 (20)	2 (8)	5 (20)	5 (20)	4 (16)	3 (12)	1 (4)	25 (11)
IV infiltrations	0 (0)	1 (17)	0 (0)	0 (0)	4 (67)	0 (0)	1 (17)	6 (3)
Wrong patient	4 (22)	1 (6)	4 (22)	6 (33)	1 (6)	1 (6)	1 (6)	18 (8)
Wrong Administration mode †	2 (11)	1 (6)	2 (11)	1 (6)	9 (50)	3 (17)	0 (0)	18 (8)
Other	5 (24)	3 (14)	3 (14)	1 (5)	1 (5)	2 (10)	6 (29)	21 (9)
	55 (23)	42 (18)	33 (14)	32 (13)	28 (12)	20 (8)	28 (12)	238 (100)

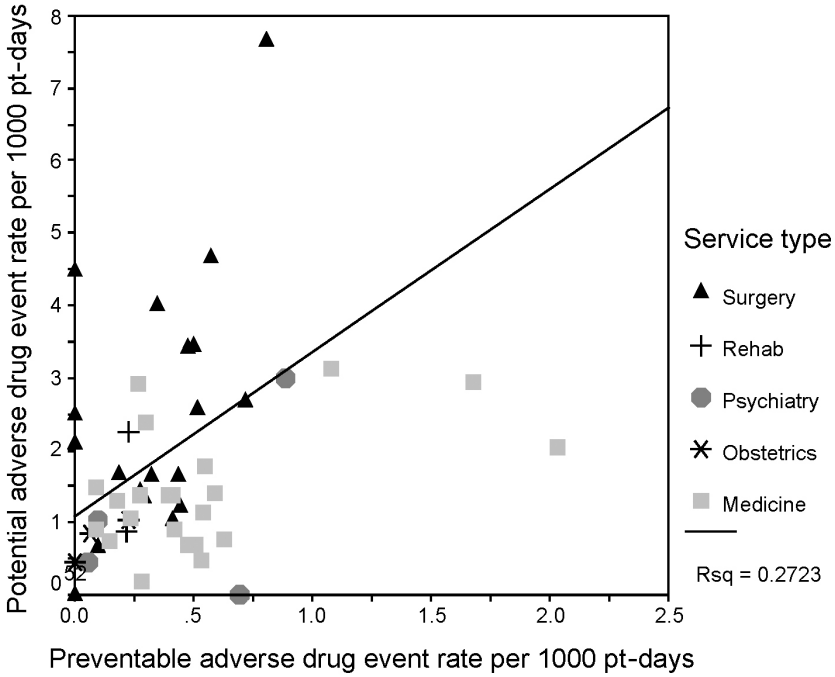
* N (percent of row total). Percentages may not add to 100 due to rounding.
† Wrong administration mode includes wrong time, wrong route, and wrong frequency.
‡ Thirty preventable adverse drug events reported only in the AER system that involved radiologic contrast dyes were not included in the above table. The majority of the events associated with the radiologic contrast dyes were IV infiltrations (36%) and adverse reactions (27%).

Table 4. Reported rates (per 1,000 patient days) of adverse drug events (ADEs) and alerts by service: RMEES and PHRED

	Rate (number of events) by service*				
	Medicine	**Surgery**	**Obstetrics**	**Psychiatry**	**Rehab**
RMEES system					
Potential ADEs	1.33 (342)	2.35 (391)	1.03 (26)	1.64 (46)	1.30 (14)
Preventable ADEs	0.41 (107)	0.37 (62)	0.12 (3)	0.39 (11)	0.18 (2)
Total ADEs	1.74 (449)	0.37 (453)	1.15 (29)	2.04 (57)	1.49 (16)
PHRED					
Potential ADEs	42.79 (10982)	44.64 (7412)	0.47 (12)	17.90 (500)	1.21 (13)
Preventable ADEs	0.09 (24)	0.1 (16)	0	0	0
Total ADEs	42.89 (11006)	44.74 (7428)	0.47 (12)	17.90 (500)	1.21 (13)
Pharmacy Expert System					
Alert rate per 1,000 pt days	7.97 (2046)	6.76 (1123)	0.27 (7)	0.93 (26)	0.84 (9)

* Patient days not available for “other” service category, containing 79 (8.8%) potential adverse drug event reports, 43 (17.9%) preventable adverse drug event reports in the AER system, and 1,197 (6%) PHRED reports.

Figure 1. Scatter plot of RMEES potential adverse drug event rates versus preventable adverse drug event rates per 1,000 patient days, by service



Note: The reporting rates for two nursing units were outliers (medicine service [x=1, y=13.5] and surgery service [x=3.5, y=9.5]) and were not included in graph due to instability of the estimated rates.

Discussion

Reporting adverse drug events serves as an aid in learning from experience. Our comparisons with literature[3, 5, 7, 16, 17] indicated much lower reporting of preventable adverse drug events and somewhat better, but still considerably low reporting of potential adverse drug events into the voluntary RMEES. These results are similar to other studies involving voluntary incident reporting.[34, 35, 37–39,43] The extent of reporting was much better with PHRED (mainly for potential adverse drug events) in comparison to RMEES. Nevertheless, there was wide variation in reporting patterns among the various service areas, and among the individual hospital units comprising each service in both systems.

Studies of hospitalized patients suggest that adverse drug events are common, although the reported rates have varied depending on the criteria used for defining the events and the mode and intensity in which they were sought.[3, 4, 10, 39, 44–47] Bates et al. found that 1 in 100 medication errors resulted in an adverse drug event.[16] Another report indicated that preventable adverse drug events occur in up to 4 percent of hospitalized patients.[48] Although the true universe of adverse drug events is unknown, extrapolating this to our study we could expect approximately 3,770 preventable adverse drug events (4 percent of 94,445 admissions) during the 22-month time period. However, only preventable adverse drug events were actually reported, which is consistent with other studies that suggest that self-

reporting typically identifies only about 5 percent of actual events.[3] In fact, this problem of significant underreporting with voluntary incident reporting is well documented in the literature.[34, 35, 38, 39] Our study also suggests that in addition to generally poor reporting levels, there is considerable variation in the extent of reporting among various nursing units and services, implying the need for standardized training on adverse drug event reporting.

Although the extent of reporting of total adverse drug events in PHRED was higher than in RMEES, the wide variation in reporting among the individual nursing units and services also supports the notion that to a large extent, voluntary reporting is driven by individual attitudes and behaviors, which in turn are influenced by a complex combination of factors, including reporters' perceptions of the severity and extent of risk that the event poses, reporting culture at the institution, fear of punishment, and liability concerns.[49] Equally compelling is the notion that reporting could reflect the culture on a particular nursing unit. A study of the effects of group- and organizational-level factors on administering drugs to hospitalized patients in different patient care groups suggested that differences in unit properties were associated with differences in error rates.[50] This study suggested that shared perceptions about the consequences of making a mistake within a unit, influenced by leadership behavior, may influence willingness to report mistakes. We noted a modest relationship between the potential and preventable adverse drug event rates among the various services for RMEES reported events, suggesting that nursing units that report numerous potential adverse drug events do not necessarily report many preventable adverse drug events. This further supports the importance of local unit culture and individual attitudes in determining reporting behaviors.

PHRED is a reporting system focused only on medications. Such narrow reporting systems may result in higher levels of reporting than traditional incident reporting as they match the professional expertise to the problems being examined and promote rapid and effective analyses.[19] However, even with PHRED, there was minimal reporting of preventable adverse drug events.

There are several limitations to this study. This analysis depended heavily on the event details provided in the RMEES database, some of which were ambiguous; further evaluation of event types and reasons could not be performed due to lack of access to charts and to persons reporting the incidents. This also precluded our ability to classify the severity level of preventable adverse drug events. Nevertheless, we anticipate that most of the preventable adverse drug events reported in RMEES would be in the significant to serious range, with sentinel event reports being completed for the more serious fatal and life-threatening events. Also, since our study involved only self-reports from RMEES and PHRED, we were unable to make comparisons of the level of incident reporting with more objective measures such as chart reviews, or computerized adverse event detection methods, which would have inherently been better comparison measures.

Incident reporting has played a beneficial role in other high-risk industries such as aviation,[51] and despite its limitations, it will continue to be an important

and relatively inexpensive means of capturing data on errors and adverse events. However, because incident reporting does not capture the true rates of adverse drug events, health care organizations should be cautious in their interpretation of event rates or counts obtained from incident reporting systems and should avoid using them to produce quantitative estimates of harm for quality assessment or comparison purposes. On the other hand, incident reporting provides rich qualitative data concerning the types and patterns of events. Because frontline practitioners most familiar with the event typically generate incident reports, these systems provide unique and valuable information on system-based causes of events, thus facilitating systemwide quality improvement and patient safety.

Incident reporting also generates new knowledge of events that may have never occurred before. The potential adverse drug events, which are reported more frequently, may suggest a trend that could help in identifying processes that have the potential for serious harm. We believe that voluntary incident reporting will assume greater importance as the use of information technology in health care increases with the widespread introduction of bar coding and computerized prescriber order entry systems. These safeguards will lead to further decreases in the frequency of commonly occurring and more easily recognizable adverse drug events. Consequently, the ability of incident reporting to uncover unique occurrences will assume greater relative importance. Also, de-identified information of rare events obtained from incident reporting can be collated with similar reports from other institutions, thereby increasing the analytic power for detection of rare events.

Conclusion

Our analysis shows the variability in adverse drug event reporting across nursing units and across systems at different points in the medication delivery process. Perhaps hospitals should provide standardized education to all frontline staff in order to minimize the variation in error reporting. Reporting systems that focus on certain types of events and that are aligned with reporters' expertise may yield increased reporting. We anticipate that with greater use of information technology, the utility of voluntary reporting systems may improve, but voluntary systems cannot be relied upon for quantitative determination of error rates or harm. Future studies should examine the barriers to reporting, and evaluate various strategies to enhance reporting.

Acknowledgments

Support for this work came from Grant # U18 HS1189801 from the Agency for Healthcare Research and Quality.

Author affiliations

Department of Medicine, Washington University School of Medicine (RD, MK, WCD, TB, VF). BJC HealthCare, St. Louis, MO (WCD, EC, TB, and VF).

Address correspondence to: Melissa J. Krauss, M.P.H.; Division of Infectious Diseases, Washington University School of Medicine; Campus Box 8051, 660 S. Euclid Avenue, St. Louis, MO 63110. Phone: 314-454-8570; e-mail: mkrauss@im.wustl.edu.

References

1. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients–results of the Harvard Medical Practice Study II. N Engl J Med 1991324: 377–84.
2. Brennan TA, Leape LL, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients– results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324:370–6.
3. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events– Implications for prevention. JAMA 1995;274(1):29–34.
4. Classen DC, Pestotnik SL, Evans RC, et al. Computerized surveillance of adverse drug events in hospital patients. JAMA 1991;266(20):2847–-51.
5. Bates DW, Leape LL, Petrycki S. Incidence and preventability of adverse drug events in hospitalized adults. J Gen Intern Med 1993;8:289–94.
6. Leape LL, Lawthers AG, Brennan TA, et al. Preventing medical injury. Qual Rev Bull May 1993;146–9.
7. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. Br Med J 2000;320:741-4.
8. Cullen DJ, Sweitzer BJ, Bates DW, et al. Preventable adverse drug events in hospitalized patients: a comparative study of intensive care and general care units. Crit Care Med 1997;25(8):1289–97.
9. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. JAMA 1995; 274(1):35–43.
10. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. JAMA 1997;277(4):307–11.
11. Classen DC, Pestotnik SL, Evans RC, et al. Adverse drug events in hospitalized patients – excess length of stay, extra costs, and attributable mortality. JAMA 1997;277(4):301–06.
12. Senst BL, Achusim LE, Genest RP, et al. Practical approach to determining costs and frequency of adverse drug events in a health care network. Am J Health Syst Pharm 2001;58(12):1126–32.
13. Schneider PJ, Gift MG, Lee Y, et al. Cost of medication-related problems at a university hospital. Am J Syst Pharm 1995;52(21):2415–8.
14. Johnson JA, Bootman LJ. Drug-related morbidity and mortality: a cost-of-illness model. Arch Intern Med 1995;155(18):1949–56.
15. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients–a meta–analysis of prospective studies. JAMA 1998;279(15):1200–5.
16. 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.
17. Bates DW. Medication errors: how common are they and what can be done to prevent them? Drug Safety 1996;15(5):303–10.
18. Leape LL. Reporting of adverse events. N Engl J Med 2002;347(20):1633–38.
19. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. A report of the Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC: National Academy Press; 2000.
20. Continuing Education for Pharmacy Technicians. Current error reporting systems. Available from: http://www.continuingeducation.com/pharmtech/errorreporting/systems.html.
21. Kaiser Permanente. Existing reporting systems. Available from: http://www.kaiserpermanente.org/medicine/ihp/pdfs/exist_error_rep.pdf.
22. Cousins DD. Developing a uniform reporting system for preventable adverse drug events. Clin Ther 1998;20:C45–C58.
23. David U. Medication error reporting systems: problems and solutions. New Medicine 2001;1(2):61–5.
24. Institute for Safe Medical Practices. Discussion paper on adverse event and error reporting in healthcare. January 24, 2000. Available from: http://www.ismp.org/Pages/IOM.html.

25. Continuing Education for Pharmacy Technicians. Mandatory versus voluntary reporting. Available from: http://www.continuingeducation.com/pharmtech/errorreporting/reportingtypes.html.

26. Landis NT. ADE rate uncertain, reporting systems inadequate, GAO tells legislators. Am J Health Syst Pharm 2000;57(6):515–6, 519.

27. James B, Lawrence DM, Leape L, et al. The Institute of Medicine report on medical errors: Misunderstanding can do harm. Quality of Health Care in America Committee. MedGenMed 2000;2(3):E42.

28. Quality Interagency Coordination Task Force. Doing what counts for patient safety: Federal actions to reduce medical errors and their impact. Rockville, MD: Agency for Healthcare Research and Quality, 2000. Available from: http://www.quic.gov/reports/errors6.pdf

29. Meyer G, Heigel FJ, Flink E. Error reporting systems. In: Beyond State reporting: Medical errors and patient safety issues. Proceedings of the workshop for State patient safety teams; 2001 June 6–8; Nashville, TN. Rockville, MD: Agency for Healthcare Research and Quality; 2000. Available from: http://www.ahcpr.gov/news/ulp/ptsafety/ptsafety.htm.

30. ASHP Statement on Reporting Medical Errors [ASHP Reports]. Am J Health Syst Pharm 2000;57(16):1531–2.

31. National Health Policy Forum. Improving quality and preventing error in medical practice [Issue Brief No. 753], Washington, DC: George Washington University, March 15, 2000. Available from: http://www.nhpf.org/pdfs_ib/IB753_Quality&Error_3-15-2000.pdf

32. Barach P, Small S. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. Br Med J 2000;320:759–63.

33. Cohen M. Why error reporting systems should be voluntary. Br Med J 2000;320:728–9.

34. Bennett B, Lipman A. Comparative study of prospective surveillance and voluntary reporting in determining the incidence of adverse drug reactions. Am J Hosp Pharm 1977;34:931–6.

35. Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: a problem for quality improvement. Jt Comm J Qual Improv 1995;21(10):541–8.

36. Keith MR, Bellanger-McCleery RA, Fuchs JE. Multidisciplinary program for detecting and evaluating drug reactions. Am J Hosp Pharm 1989;46:1809–12.

37. Berry LL, Segal R, Sherrin TP, et al. Sensitivity and specificity of three methods of detecting adverse drug reactions. Am J Hosp Pharm 1988;45:1534–9.

38. Hartwig SC, Denger SD, Schneider PJ. Severity-indexed, incident report-based medication error-reporting program. Am J Hosp Pharm 1991;48:2611–6.

39. Jha AK, Kuperman GJ, Teich JM, et al. Identifying adverse drug events: developments of a computer-based monitor and comparison with chart review and stimulated voluntary report. JAMIA 1998;5(3):305–14.

40. Leape LL. Understanding and preventing drug misadventures: preventing adverse drug events. Am J Health Syst Pharm 1995;52(4):379–82.

41. McMullin TS, Reichley RM, Kahn MG, et al. Automated system for identifying potential dosage problems at a large university hospital. Am J Health Syst Pharm. 1997; 54(5): 545–49.

42. Bailey TC. Real-time notification of medication errors. Health Manag Technol. 2000 Jun: 21(6):24–6.

43. Barker KN, Allan EL. Understanding and preventing drug misadventures: research on drug-use-system errors. Am J Health Syst Pharm 1995;52(4): 400–3.

44. Wald H, Shojania KG. Incident reporting. In: Shojania KG, Duncan BW, McDonald KM, Wachter RM. Making health care safer: a critical analysis of patient safety practices. Evidence Report/Technology Assessment Number 43. AHRQ Publication No. 01-E058. Rockville, MD: Agency for Healthcare Research and Quality; July 2001. Available from: http://www.ahcpr.gov/clinic/ptsafety/chap4.htm.

45. 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(5):436–46.

46. Shannon RC, De Muth JE. Comparison of medication-error detection methods in the long term care facility. The Consultant Pharmacist March/April 1987:148–51.

47. Barker KN, Flynn EA, Pepper GA, et al. Medication errors observed in 36 health care facilities. Arch Intern Med 2002;162(16):1897–903.

48. Winterstein AG, Hatton RC, Gonzalez-Rothi R, et al. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. Am J Health-Syst Pharm 2002;59:1742–9.

49. Atherton T. Description and outcomes of the Doctor Quality incident reporting system used at Baylor Medical Center at Grapevine. BUMC Proceedings 2002;15:203–8.

50. Edmonson AC. Learning from mistakes is easier said than done: group and organizational influences on the detection and correction of human error. J Appl Behav Sci 1996;32:5–28.

51. Billings C. Incident reporting systems in medicine and experience with the aviation safety reporting system. In: Cook RI, Woods DD, Miller C, editors. A tale of two stories: contrasting views of patient safety. Report from a workshop on assembling the scientific basis for progress on patient safety. McLean, VA: National Patient Safety Foundation at the AMA; 1998 Available from: http://www.npsf.org/exec/billings.html.