

Unit-based clinical pharmacists' prevention of serious medication errors in pediatric inpatients

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In 1999, the Institute of Medicine (IOM) report *To Err Is Human* estimated that 44,000–98,000 people die each year at least in part because of medical error.¹ This galvanized the patient safety movement in the United States, although a number of previous studies had documented the frequency and serious consequences of medication errors.^{2–6} Errors occur in about 5% of medication orders for adult patients; approximately 1 out of 7 of these errors has significant potential for harm.⁷ Less is known about the frequency of errors in pediatric patients, but children may be at even greater risk. Medication error rates in pediatric inpatients have been reported to be as high as 1 in every 6.4 orders.⁸ In a previous study in pediatric inpatients, we found that although medication error and preventable adverse drug event (ADE) rates were similar to those in adults, the rate of potentially harmful errors (potential ADEs or near misses) was almost three times higher in children.⁹

Most current efforts to reduce medication error rates focus on

Purpose. Rates of serious medication errors in three pediatric inpatient units (intensive care, general medical, and general surgical) were measured before and after introduction of unit-based clinical pharmacists.

Methods. Error rates on the study units and similar patient care units in the same hospital that served as controls were determined during six- to eight-week baseline periods and three-month periods after the introduction of unit-based clinical pharmacists (full-time in the intensive care unit [ICU] and mornings only on the general units). Nurses trained by the investigators reviewed medication orders, medication administration records, and patient charts daily to detect errors, near misses, and adverse drug events (ADEs) and determine whether near misses were intercepted. Two physicians independently reviewed and rated all data collected by the nurses. Serious medication errors were defined

as preventable ADEs and nonintercepted near misses.

Results. The baseline rates of serious medication errors per 1000 patient days were 29 for the ICU, 8 for the general medical unit, and 7 for the general surgical unit. With unit-based clinical pharmacists, the ICU rate dropped to 6 per 1000 patient days. In the general care units, there was no reduction from baseline in the rates of serious medication errors.

Conclusion. A full-time unit-based clinical pharmacist substantially decreased the rate of serious medication errors in a pediatric ICU, but a part-time pharmacist was not as effective in decreasing errors in pediatric general care units.

Index terms: Clinical pharmacists; Clinical pharmacy; Errors, medication; Hospitals; Interventions; Pediatrics; Pharmaceutical services

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information technology (IT)-based interventions. Computerized prescriber order entry (CPOE) has received the greatest publicity, largely because of its strong theoretical rationale and early studies showing

notable reductions in errors.^{10–13} For example, CPOE reduced nonintercepted serious medication errors by 86% from baseline in a large tertiary-care hospital.¹⁴ CPOE decreased medication errors by 40% in a tertiary-

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care pediatric hospital; ADEs were reduced by 41% in a pediatric critical care unit.^{15,16} More recently, studies have suggested that CPOE, like any intervention, can lead to new types of errors, especially during the early phase of technology deployment and dissemination.¹⁷ Furthermore, CPOE is expensive to install and update.

It is important, therefore, to evaluate other, non-IT approaches to reducing medical error. For example, standardized protocols, education programs, and initiatives that address institutional culture may be efficacious in reducing medication error rates, although the evidence base for these interventions is quite limited.^{18,19} The use of unit-based clinical pharmacists is perhaps the most promising non-IT-based intervention. Leape et al.²⁰ found that having a clinical pharmacist participate on physician rounds in an adult intensive care unit (ICU) decreased preventable ADEs at the prescription-writing stage by 66%, while Kucukarslan et al.²¹ found that unit-based clinical pharmacists reduced preventable ADEs at the same stage by 78%. These studies, conducted on adult units in single institutions, focused primarily on errors in ordering medications. Few studies have focused on errors at all stages of the medication-use process in children.

We hypothesized that unit-based clinical pharmacists might be able to reduce rates of serious medication errors in pediatric inpatients in both ICU and general care unit settings. Our study was designed to test this hypothesis in pediatric inpatient units of an academic medical center.

Methods

Study site. The prospective cohort study was conducted at a freestanding pediatric teaching hospital located in an urban area with a socioeconomically diverse patient population. Fewer than 5% of the patients treated

are adults, most of whom have complex long-term medical and surgical conditions. At the time of this study, physicians wrote orders on paper charts. Copies were sent to the pharmacy, and nurses transcribed orders into the medication administration record (MAR). Before the study intervention, dispensing pharmacists sent ready-to-administer doses to the patient care units but participated only intermittently in unit-based rounds.

We studied the error rates before and after pharmacist intervention in two general medical units, two general surgical units, the pediatric ICU, and the cardiac ICU. The pairs of general units were selected because of their similar characteristics and patient populations. The ICUs, however, had differences in case mix; whereas the cardiac ICU served primarily patients with heart diseases, the pediatric ICU had patients from the general surgery, neurosurgery, orthopedic, craniofacial reconstruction, otolaryngology, and medicine services. One of the medical units and one of the surgical units were randomly selected as experimental groups, and the others served as controls. The pediatric ICU was randomly selected as an experimental group; the cardiac ICU served as its control. Despite the differences between cardiac ICU patients and pediatric ICU patients, these were the most similar patient populations in terms of severity and complexity of disease. The hospital's human subjects research committee approved the study protocol.

Definitions. We used IOM definitions for the study.¹ Medication errors were defined as errors in drug ordering, transcribing, dispensing, administering, or monitoring. Medication errors with significant potential for injuring patients were defined as near misses or potential ADEs. Near misses were further subdivided into intercepted and nonintercepted potential ADEs. Whereas intercepted near misses were corrected before the

medication reached the patient, non-intercepted near misses were administered but did not cause any harm. ADEs were defined as injuries that resulted from the use of a drug.²² An ADE was considered preventable if it was associated with a medication error and nonpreventable if it was not. For example, a rash due to penicillin in a known penicillin-allergic patient was considered a preventable ADE, whereas a penicillin-related rash in a patient with no known allergies was a nonpreventable ADE. Serious medication errors were defined as preventable ADEs and nonintercepted near misses. An effective patient safety intervention should decrease serious medication error rates, but it may increase rates of intercepted near misses. These same definitions have been used in previous studies.^{13,14}

We used the term "unit-based clinical pharmacist" to describe a pharmacist whose duties include making rounds with physicians as well as monitoring drug dispensing, storage, and administration. The unit-based clinical pharmacists all had earned the Doctor of Pharmacy degree and had comparable skill levels. In contrast, the primary role of "dispensing pharmacists" at our institution is to dispense medications.

Data collection. Before collecting data, we enlisted the support of staff members and educated them on the study's purpose and methods. We trained nurse data collectors for two weeks to develop a comprehensive, uniform approach to error detection. Interrater reliability was verified in the month before formal data collection and again every other month during the study period.

Baseline data were collected for six to eight weeks in each unit during a six-month period from March to August 2000. After the introduction of unit-based clinical pharmacists, data were collected concurrently in each intervention and control ICU or general unit pair

for three months between June and November 2000.

Medication errors, near misses, and ADEs were identified through detailed review of all medication orders, MARs, and patient charts by a nurse data collector randomly assigned to each study unit on a daily basis. These reviews were performed each weekday and on Mondays for the previous weekend. To compile as complete a list as possible, we also solicited reports of errors from house officers, nurses, and pharmacists. Reporting a medication error did not trigger a review of clinical data; rather, all clinical data were reviewed daily for all patients enrolled in the study. All reported errors had previously been identified in the review process.

Data collected for each error, near miss, or ADE included the drug name, dose, route, and category; the point in the system at which the error occurred; the type of error; medical teams involved; and additional work resulting from the error. The data collectors evaluated whether near misses had been intercepted. Data on the complexity of individual drug regimens, including number and types of drugs, were recorded. Clinical and demographic data were collected from patient records and institutional administrative databases. Morbidity and disability data were collected until discharge for all patients with an ADE.

Two physicians independently reviewed each suspected ADE and near miss and classified them as ADEs, near misses, or medication errors. The reviewers were blinded to the time period (i.e., before or after intervention) and the unit location of events in order to minimize potential bias. The reviewers used a four-point Likert scale to rate the severity of injury for ADEs and near misses. Preventability of ADEs was rated on a five-point Likert scale, and attribution (i.e., the likelihood that an incident was due to the specific

drug) was rated with the algorithm of Naranjo et al.²³ Disagreements between reviewers were resolved through discussion and consensus.

Intervention. After baseline error rates were obtained for all six units, a unit-based clinical pharmacist was added to the team in one medical unit, one surgical unit, and one ICU. These pharmacists' primary role was to provide physicians with timely information and advice on ADEs, drug interactions, and appropriate dosages, dose intervals, and routes of administration. In addition, they facilitated communication between the medical care team and the pharmacy and assisted nurses with drug preparation by providing information on administration and monitoring. They also helped monitor the order transcription process and the medication preparation, storage, and distribution systems. The pharmacist was an integral part of the unit-based continuous quality-improvement (CQI) team, which included a unit nurse administrator, a unit attending physician, a member of the unit nursing staff, a member of the house staff, and one of the study's principal investigators or coinvestigators. The CQI team met bimonthly to review serious medication errors and to design process changes and system improvements to be implemented after the completion of data collection.

In the ICU, the pharmacist was present full-time (40 hours per week) and participated daily in physician rounds. In the general medical and surgical units, the pharmacist was available only on a part-time basis during morning hours. The pharmacist in the general surgical unit often had difficulty attending rounds with surgeons, which occurred in the early morning before the start of daytime pharmacist shifts and before scheduled surgeries. In the general medical unit, the pharmacist tended to leave shortly after physician rounds were completed.

Statistical methods. We report preintervention and postintervention rates of serious medication errors (nonintercepted near misses and preventable ADEs) per 1000 patient days, assuming a Poisson distribution. Measures of interrater reliability (before discussion and consensus) were calculated using the kappa statistic, with moderate-to-excellent levels of agreement (0.75 for incident classification). The a priori level of significance was 0.05.

Results

During the study period, we examined a total of 1249 admissions in the ICUs, 1690 admissions in the general medical units, and 1924 admissions in the general surgical units. Table 1 summarizes patient demographics. Preintervention patients were generally similar to postintervention patients in all studied units, with most variation occurring in age distribution.

Table 2 summarizes serious medication error rates. The ICU with the full-time unit-based clinical pharmacist had a decrease in serious medication errors from 29 per 1000 patient days before the intervention to 6 per 1000 patient days after the intervention ($p < 0.01$). On the other hand, during the intervention period, the rate of intercepted near misses in the intervention ICU increased from 32 to 57 per 1000 patients ($p = 0.08$). There was no significant difference between the two ICUs in the preintervention rates of serious medication errors. There were 33 fewer net serious medication errors per 1000 patient days in the intervention ICU (where the reduction was 23 errors per 1000 patient days) than in the control ICU (where the rate increased by 10 errors per 1000 patient days) ($p < 0.001$). There was no reduction in the rate of serious medication errors with pharmacist participation in the general units. In both ICUs, a majority of detected errors occurred at the drug ordering stage (67–100%).

Table 1.
Demographic Characteristics of Study Patients^a

Characteristic	Intervention Unit		Control Unit	
	Preintervention	Postintervention	Preintervention	Postintervention
<i>Intensive Care Units</i>				
<i>n</i>	209	401	280	359
Mean LOS (days) (95% CI)	5.94 (4.12–7.76)	6.50 (4.80–8.19)	5.45 (4.29–6.62)	6.28 (4.92–7.65)
No. (%) female	79 (38)	179 (45)	128 (46)	169 (47)
Race (no. [%])				
White	129 (62)	253 (63)	190 (68)	221 (62)
Black	18 (9)	36 (9)	17 (6)	19 (5)
Asian	6 (3)	9 (2)	6 (2)	8 (2)
Hispanic	15 (7)	31 (8)	14 (5)	26 (7)
Other	7 (3)	23 (6)	22 (8)	32 (9)
Unknown	34 (16)	49 (12)	31 (11)	53 (15)
Age (no. [%])				
0–1 mo	17 (8)	34 (8)	44 (16)	78 (22)
2 mo–1 yr	39 (19)	81 (20)	64 (23)	100 (28)
2–5 yr	37 (18)	78 (19)	47 (17)	58 (16)
6–12 yr	54 (26)	87 (22)	54 (19)	55 (15)
13–19 yr	52 (25)	86 (21)	55 (20)	35 (10)
>19 yr	10 (5)	35 (9)	16 (6)	33 (9)
No. (%) with Medicaid	51 (24)	83 (21)	52 (19)	85 (24)
<i>General Medical Units</i>				
<i>n</i>	56	296	383	955
Mean LOS (days) (95% CI)	4.49 (3.21–5.77)	5.70 (4.73–6.66)	2.89 (2.47–3.31)	2.88 (2.52–3.24)
No. (%) female	26 (47)	143 (48)	172 (45)	428 (45)
Race (no. [%])				
White	29 (53)	182 (61)	187 (49)	485 (51)
Black	10 (18)	37 (13)	51 (13)	140 (15)
Asian	2 (4)	4 (1)	16 (4)	30 (3)
Hispanic	6 (11)	35 (12)	57 (15)	161 (17)
Other	1 (2)	15 (5)	31 (8)	47 (5)
Unknown	7 (13)	23 (8)	41 (11)	92 (10)
Age (no. [%])				
0–1 mo	2 (4)	20 (7)	56 (15)	187 (20)
2 mo–1 yr	17 (30)	37 (13)	176 (46)	289 (30)
2–5 yr	5 (9)	50 (17)	76 (20)	204 (21)
6–12 yr	18 (32)	96 (32)	58 (15)	168 (18)
13–19 yr	12 (21)	73 (25)	15 (4)	98 (10)
>19 yr	2 (4)	20 (7)	2 (1)	9 (1)
No. (%) with Medicaid	17 (30)	81 (27)	89 (23)	188 (20)
<i>General Surgical Units</i>				
<i>n</i>	369	745	279	531
Mean LOS (days) (95% CI)	3.53 (2.88–4.18)	3.74 (3.33–4.14)	4.46 (3.68–5.24)	6.60 (4.10–9.10)
No. (%) female	188 (51)	370 (50)	112 (40)	223 (42)
Race (no. [%])				
White	286 (78)	557 (75)	195 (70)	388 (73)
Black	16 (4)	48 (6)	18 (6)	36 (7)
Asian	9 (2)	13 (2)	5 (2)	7 (1)
Hispanic	19 (5)	45 (6)	27 (10)	39 (7)
Other	13 (4)	20 (3)	10 (4)	23 (4)
Unknown	26 (7)	62 (8)	24 (9)	38 (7)

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Table 1 (continued)

Characteristic	Intervention Unit		Control Unit	
	Preintervention	Postintervention	Preintervention	Postintervention
Age (no. [%])				
0–1 mo	0	2 (0)	32 (11)	59 (11)
2 mo–1 yr	18 (5)	33 (4)	139 (50)	253 (48)
2–5 yr	46 (13)	72 (10)	93 (33)	155 (29)
6–12 yr	129 (35)	273 (37)	15 (5)	56 (11)
13–19 yr	143 (39)	287 (39)	0	8 (2)
>19 yr	33 (9)	78 (10)	0	0
No. (%) with Medicaid	55 (15)	117 (16)	41 (15)	75 (14)

*Data are reported for preintervention and postintervention periods, although no intervention occurred in the control units. LOS = length of stay, CI = confidence interval.

Interception of errors by unit-based clinical pharmacists occurred at all stages of the medication process, with most intercepted errors (79%) occurring at the physician ordering stage.

The increase in the serious medication error rate in the control ICU was largely attributable to an incorrect preprinted order template for acetaminophen that resulted in the ordering of significant overdoses. After excluding these acetaminophen errors from our data analysis, there would still be a net of 30 fewer serious medication errors per 1000 patient days in the intervention ICU than in the control ICU ($p = 0.01$). The acetaminophen template error was recognized and rectified through review of data by the CQI team.

Discussion

Our results suggest that the introduction of a full-time unit-based clinical pharmacist was associated with a 79% reduction in the serious medication error rate in critically ill pediatric inpatients. However, we found no apparent effect from adding part-time unit-based clinical pharmacists to the general medical and surgical units. Because of the low baseline error rates on these units, the study may have been underpowered to detect a difference associated with the intervention. We speculate, however, that the primary reason for efficacy of the intervention only in

the ICU may have been the full-time presence of the pharmacist in the ICU and only part-time involvement in the general medical and surgical units.

Some patient care units appear to have organizational characteristics that either facilitate or impede collaboration with a clinical pharmacist. For example, rounds in the ICU were conducted with a multidisciplinary team at the bedside, whereas rounds in the general medical and surgical units were often conducted away from the bedside and orders were not entered during rounds. Such procedural differences may have mitigated the ability of the pharmacist to correct errors in real time. In addition, the ICU tends to treat fewer patients, and house staff physicians usually are in or near the unit and easily accessible to staff, including unit-based clinical pharmacists. In the general units, patients are more spread out, and each physician is responsible for more patients, often on multiple floors. In addition, surgeons spend a considerable portion of each day in the operating room; although the surgeons had a covering nurse practitioner, it has been previously demonstrated that opportunities for error increase when decision-making responsibilities are “handed off” from one provider to another.^{24,25}

Further research is necessary to determine if the addition of a full-time unit-based clinical pharmacist

and increased physician–pharmacist interaction decrease medication errors in the general medical or surgical unit setting. A recent study by Kucukarslan et al.²¹ suggests that pharmacist participation on a general medicine unit may indeed contribute to a significant reduction in preventable ADEs. Our study supports the conclusion that adding pharmacists to medical and surgical rounds is challenging. Altering the shifts of clinical pharmacists so that they are available early for surgeons’ rounds, having them available throughout the day, and having them make rounds with covering nurse practitioners are strategies for improving their effectiveness on general medical or surgical units.

The benefit of unit-based clinical pharmacists in the pediatric ICU in this study is similar to what has been observed in adult ICUs. We found a 79% decrease in the rate of serious medication errors in the pediatric ICU, while Leape et al.,²⁰ using a very similar method, found a 66% decrease in preventable ADEs at the ordering stage in an adult ICU. Our study showed a decrease in serious medication error rates at all stages, whereas Leape et al. were concentrating on errors at the ordering stage.

Like many previous studies, our study documented higher rates of serious medication errors in the pediatric intensive care setting.^{9,22} This is likely the result of greater patient

Table 2.

Occurrence of Serious Medication Errors (SMEs) in Study Units^a

Variable	Intervention Unit		Control Unit	
	Preintervention	Postintervention	Preintervention	Postintervention
<i>Intensive Care Units</i>				
No. patient days	311	835	1062	759
No. SMEs	9	5	21	23
SMEs/1000 patient days	29	6	20 ^b	30 ^c
<i>General Medical Units</i>				
No. patient days	660	1163	604	1319
No. SMEs	5	10	4	10
SMEs/1000 patient days	8	9	7 ^d	8 ^e
<i>General Surgical Units</i>				
No. patient days	573	1109	737	1253
No. SMEs	4	10	6	12
SMEs/1000 patient days	7	9	8 ^f	10 ^g

^aData are reported for preintervention and postintervention periods, although no intervention occurred in the control units.

^b $p = 0.38$ for comparison with intervention unit.

^c $p < 0.01$ for comparison with intervention unit.

^d $p = 0.84$ for comparison with intervention unit.

^e $p = 0.78$ for comparison with intervention unit.

^f $p = 0.81$ for comparison with intervention unit.

^g $p = 0.89$ for comparison with intervention unit.

morbidity and medication complexity. Implementing error prevention strategies such as the use of unit-based clinical pharmacists in ICUs is particularly efficacious because of these higher baseline error rates.

Despite a growing body of data demonstrating the potential of unit-based clinical pharmacists to decrease medication errors, only 30% of hospitals nationwide have pharmacists participating in physician rounds.²⁶ Pharmacists actively participating in rounds provide real-time advice to physicians in the same way that CPOE systems provide real-time computerized decision support. Studies have demonstrated that physicians are much more amenable to changing therapeutic direction when advice is given before rather than after order completion.²⁷ Since about 80% of near misses in pediatric inpatients occur during medication ordering,⁹ unit-based clinical pharmacists can intercept errors and inform clinical choices before orders are finalized. They can also intercept other types of medication errors by independently monitoring the transcription, drug preparation, storage, and dispensing of medications.

In addition to being effective, unit-based clinical pharmacists are practical and financially justifiable. Both adult and pediatric ICUs have shown significant cost savings from implementation of a unit-based clinical pharmacist program.^{28,29} Unit-based clinical pharmacists are generally less expensive than most IT-based patient safety interventions, which can cost millions of dollars to implement and maintain.³⁰ By restructuring existing pharmacist resources from centralized to unit-based positions, hospitals can quickly decrease errors and, perhaps, the overall cost of care.

Our study has several limitations. First, it was performed in a single, freestanding academic pediatric hospital, which limits its generalizability. Ideally, unit-based clinical pharmacists would have been present full-time on all study units, but this was not achieved. It also seems likely that the individual attributes of clinical pharmacists have an important impact on their efficacy in reducing error rates. However, given the single-institution design of this study, we were unable to assess such factors.

Conclusion

A full-time unit-based clinical pharmacist substantially decreased the serious medication error rate in the pediatric intensive care setting, but a part-time pharmacist was not as effective in general care pediatric units.

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