

# Assessing medication prescribing errors in pediatric intensive care units\*

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**Objective:** To evaluate a matrix for determining the predominant type, cause category, and rate of medication prescribing errors, and to explore the effectiveness of hospital-based improvement initiatives among pediatric intensive care units (PICUs).

**Design:** This study involved the prospective identification of medication errors for categorization and evaluation by using a matrix methodology. A pretest-posttest design without a control group was used to explore the impact of initiatives employed to reduce medication error rates and severity.

**Setting:** PICUs in nine freestanding, collaborating tertiary care children's hospitals that participated in both baseline and postintervention analyses.

**Methods:** We evaluated 12,026 PICU medication orders at baseline and 9,187 orders postintervention for prescribing errors, excluding resuscitation orders. A standardized tool and process captured error type, cause category, and severity for 2 wks before and after intervention. Three levels of error detection were used and included pharmacy order entry, PICU nurse order transcription, and team-based overview. Site-specific interventions were implemented, which included predominantly provider education as well as informational (47%) and dosing "assists" via preprinted orders, forcing functions, or prompts (39%).

**Results:** Of baseline orders, 11.1% had at least one prescribing error. The interception of prescribing errors improved 30.9% (1.6% of all orders at baseline, 2.0% post intervention). Preventable adverse drug events were uncommon (0.6% of all medication errors) and of low severity at baseline; most were wrong dose errors. The implementation of improvement initiatives, specific for each facility, resulted in a 31.6% reduction in prescribing errors from 11.1% to 7.6%. However, site results varied considerably.

**Conclusions:** A benchmark for medication prescribing errors in the PICU was identified among nine children's hospitals. The methodology was successful in accounting for site-specific differences with regard to identifying and documenting errors as well as reporting results of improvement initiatives. Furthermore, the methodology employed was generalizable in the identification of predominant prescribing error types, which helped to track individual hospital improvement initiative development and implementation. Overall improvement in prescribing error rates was noted; however, considerable variation in the success of improvement initiatives was noted and bears further attention. (*Pediatr Crit Care Med* 2004; 5:124-132)

In 2000, the release of the Institute of Medicine's report on medical errors (1) galvanized the attention of health care providers, regulators, and policymakers alike. In 1998, the Committee on Drugs and Committee on Hospital Care of the American Academy of Pediatrics identified medication error and safety as priorities for practitioners caring for children (2). Also in 1998, the Child Health Accountability Initiative (CHAI) was formed as a 12-hospital collaborative, and its first project used their

pediatric intensive care units (PICUs) to study medication errors in children.

Although adverse events command our attention, understanding patterns of more ubiquitous "near miss" potential errors (3-8) may provide data to evaluate meaningful system change. The ADE Prevention Study Group (3-5, 9), which has advanced the understanding of medication safety with adults, reported 6.5 adverse drug events (ADEs) and 5.5 potential ADEs per 100 nonobstetric admissions. In intensive care unit (ICU) settings, the rate of preventable and potential ADEs was twice as high. However, when adjusted for the number of drugs ordered, the rates were similar (5). Twenty-eight percent of all ADEs were judged preventable (3).

The pediatric population is at even greater risk of adverse drug event occurrences since dose, medication safety, and efficacy are difficult issues in young patients (10-14). Pediatric medication error rates have been identified in a small

number of studies in which error rate reports varied widely, although comparison is limited due to methodological differences. A recent report, using an observational approach in a tertiary children's hospital, identified a potential ADE rate that was three times that of a previous adult hospital study (1.1% of 10,778 medication orders), whereas the preventable ADE rate was similar (15).

As an initial step to develop both a methodology and a benchmark, CHAI members identified medication prescribing errors in the PICU as the priority for focus. Physician members of CHAI advocated a concentration of efforts on the prescribing phase because they believe that a) prescribing errors were grossly underreported via spontaneous incident reports; b) physicians have control at this phase of the medication usage process; c) prescribing errors were likely to result in ADEs; and d) lack of information about both the drug and patient was a proximal cause of errors in published reports (3).

**\*See also p. 000.**

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Therefore, the purposes of this study were as follows:

1. Establish a methodology, generalizable across a broad range of settings, for identifying, documenting, analyzing, and reporting prescribing errors.
2. Determine the overall rate of prescribing errors (i.e., benchmark) among participating pediatric hospital PICUs.
3. Report the relative effectiveness of a variety of hospital-specific, self-selected interventions in reducing medication errors and ADEs in PICUs.

## METHODS

### Collaborative Arrangements

The participating CHAI hospitals were tertiary centers, and all but one were freestanding children's hospitals. PICUs ranged in size from 6 to 24 beds. CHAI collaborative hospitals agreed on a set of standard definitions for the project. Definitions of medication errors, adverse drug events (preventable and nonpreventable adverse drug reactions), actual and potential errors, medication error cause category (e.g., prescribing), medication error type (e.g., incorrect dose), and adverse drug event severity score were standardized (see Appendix A). One site was designated to manage the entire project, acting as a resource regarding standardization once the project was initiated. Each site designated its own site coordinator to manage the project locally, and each site obtained appropriate internal review board approval per their local policies and procedures. A standardized medication error survey form was adopted (see Appendix B) that required completion within 72 hrs of the medication error, thus capturing prescribing errors as completely as possible. Excluded from review were uses of medications for resuscitation, which do not follow routine processes.

Standardized identification of medication errors used three levels of surveillance. These included a) the pharmacy order review for errors and computer order entry step; b) the PICU nurse order transcription and review for errors step; and c) an oversight team check. The anticipated variability among institutions as to the effectiveness of pharmacy and nursing checks for errors was overcome by the oversight team approach. The oversight teams at each institution were similar in composition and functioned with close collaborative supervision. A member of the oversight team from each site participated in the collaborative standardization process involving the development of the standardized definitions, error identification, and reporting process for this project. The oversight team served as a final step in the project process to ensure as com-

plete and consistent identification and reporting as possible, given the potential for variability among participating hospitals in medication error identification and reporting proficiency, hospital-specific medication error definitions, organizational cultures, predominant errors, medication use systems, and pre-existing process changes designed to reduce medication errors. Efforts to support adherence with and understanding of the collaborative standardized process were enhanced through conference calls and communication with the project management site to troubleshoot procedures and interpret events. Some minor variations remained in how sites staffed their oversight team and who served as site coordinator; however, as much standardization as possible was instituted to minimize surveillance bias.

The pharmacy and nursing surveillance levels used processes already available at each site to identify and then reconcile medication errors with the prescriber: The type of error, use of floor stock, and a brief narrative were recorded. The oversight team was responsible for the review of all orders, correct identification of errors, and completion of the standardized survey form. Each error was classified as actual or potential. Adverse events were identified and given a severity score. The oversight team coordinated discussion of each error as needed.

### Data Collection

*Procedures.* A pretest-posttest design without control group was used. Two weeks of preintervention data collection was followed by 3 months of site-specific error reduction interventions. A 2-wk postintervention data collection then was completed. An order inconsistent with good medical practice in any one or more of these steps was reconciled with the prescriber and recorded on the medication error report form. Orders that were incomplete with respect to date and/or time were stratified separately. A member of the medication use oversight team collected medication error survey forms daily from the pharmacy and the PICU. Data were extracted from survey forms and tallied in a summary matrix by a site coordinator (Appendix C). Only summary data were submitted for inclusion into the collaborative database by each CHAI hospital to deal with these sensitive data. For cases of an actual ADE, the patient was observed for resolution or up to 2 wks postevent to assess ADE severity and outcome disposition.

Prescribing errors were categorized according to perceived potential to result in adverse events. Incomplete orders were considered to have the lowest potential for adverse events since an order with missing information required resolution before the order could be acted upon. Intercepted prescribing errors that held significant potential to result

in harm to the patient (critical information was incorrect in the order) yet were intercepted before an opportunity for harm occurred were considered to have a higher potential for adverse events. Nonintercepted prescribing errors that held significant potential to result in harm to the patient yet did not result in an ADE were considered to hold even greater potential for adverse events. Preventable ADEs were considered to be of the highest potential for harm, since some adversity occurred, and thus were rated for severity level.

*Devising Interventions to Reduce Error.* Based on the findings of the baseline surveillance summary data, the collaborative met and discussed potential interventions at a 2-day conference. This was facilitated by involvement of the Institute for Healthcare Improvement (16). The collaborative fostered shared learning; no efforts were undertaken to standardize or assign interventions across member sites. Rather, sites used their typical internal performance improvement approaches to deploy interventions expected to offer optimal results. All but one site used a variety of approaches simultaneously (Table 1).

Interventions implemented to reduce errors were categorized into three categories, including dosing assists, communication/educational, and floor stocks. Of all interventions reported, 47.2% were categorized as communication/educational, 38.9% as dosing assists, and 13.9% as floor stocks. Of the individual strategies reported, the most common involved the systematic education of physicians (e.g., residents; 66.7% of organizations), availability of dosing references, guidelines or "cheat" sheets (55.6% of organizations), and the implementation of forced-function order sheets (44.4% of organizations). After implementation of selected interventions, another 2-wk surveillance period ensued.

### Statistical Analysis

The duration of the data collection period was based on the necessary sample size required at each hospital to achieve statistical validity. After we conducted a power analysis using assumptions of 80% power, an alpha coefficient of .05, a desire to detect a 5% reduction in errors, a minimum sample required for detection of 863, and the baseline number of orders and errors, three high-volume sites targeted fewer orders than at baseline.

The prescribing error rate (percent) was calculated as the percent of errors relative to total orders. The percent change in error rate was determined as follows:

$$\frac{\% \text{ errors postintervention} - \% \text{ errors and baseline}}{\% \text{ errors at baseline}} \times 100 \quad [1]$$

An order may have contained more than one medication error. The cumulative impact of

Table 1. Interventions implemented by participating Child Health Accountability Initiative (CHAI) hospitals

Hospital	Dosing Assists							Communication / Education					Floor Stock		
	Available dosing references, guidelines, cheat sheets	Forced-function order sheets	Administrative support for automated order entry	Automated IV administration record	Real-time feedback w/house staff as orders were written	Complete medication order model at every bedside	Systematic education of physicians (incl. residents)	Systematic education of nurses	Written communique, newsletter	Reduction in verbal orders	Timely, regular reports re: medication errors	Creation of a Medical Safety Committee	Intervening with individual physicians	Enhancement of pharmacist staffing in PICU	Second RN check system
A	X									X	X				
B							X		X	X					
C	X						X							X	
D		X		X			X		X						
E		X			X		X	X	X	X					
F	X	X				X	X							X	
G	X	X	X				X		X				X		
H	X		X						X			X			
I													X		
Percent of 9 Organizations Using Each Intervention	55.6%	44.4%	22.2%	11.1%	11.1%	11.1%	66.7%	22.2%	33.3%	22.2%	33.3%	11.1%	11.1%	22.2%	22.2%
Percent of 9 Organizations Using Intervention Type	7 of 9= 77.8%						8 of 9= 88.9%					5 of 9= 55.6%			
Percent of All Interventions	14 of 36= 38.9%						17 of 36= 47.2%					5 of 36= 13.9%			100%

improvement initiatives was calculated for all participating sites and reported as the mean percent change. Prescribing error types and outcome categories were grouped. Pre- and postintervention comparisons were made of changes in medication error incidence across sites cumulatively.

We evaluated 12,026 medication orders during the baseline period and 9,187 orders during the postintervention period. Prescribing errors identified were categorized according to the list of standardized definitions and generalizable reporting format. These errors were summarized using the summary matrix form allowing for a common basis for discussion and rapid identification of predominant error types.

## RESULTS

Among the nine participating hospitals, a baseline rate of orders with errors

(excluding those missing only date and/or time) was 11.1% compared with a rate of 7.6% following implementation of hospital-specific error reduction interventions ( $Z = 10.5, p < .001$ ; Table 2). Thus, a 31.6% reduction in orders with prescribing medication errors was noted, representing the cumulative impact of improvement initiatives. The total prescribing errors per order decreased from 0.22 at baseline to 0.17 during the follow-up period, a 24.7% reduction ( $Z = 3.22, p < .05$ ).

The rate of incomplete orders identified during the baseline was 18.7% before implementation of interventions and 13.8% postintervention, a reduction of 26.5% ( $Z = 13.92, p < .001$ ; Table 3). The greatest reduction occurred for those "missing information" error types in which a medication could not be dispensed or administered un-

til the information was obtained, such as missing drug, dose, route, dosage form, or dosage interval. The rate of intercepted prescribing errors at baseline was 1.6% compared with 2.0% during postintervention period, a 30.8% increase with the greatest impact occurring for wrong dose errors ( $Z = 4.37, p < .01$ ). A nonintercepted error rate of 2.0% was evident during the baseline period and 0.8% during the postintervention period, a 61.7% decrease with the greatest reductions observed in the wrong dose, omissions, and wrong drug error types ( $Z = 9.71, p < .001$ ).

Preventable ADEs were uncommon, with a rate of 0.13% of all orders during the baseline period and 0.03% during the postintervention period ( $Z = 3.04, p < .05$ ). The error type most associated with preventable ADEs was the wrong dose. The severity level of ADEs was generally

low. Preventable ADEs during both observation periods produced temporary harm at most.

Considerable variability existed in baseline medication error rates as well as in the relative reduction in error rates following implementation of the various site-specific interventions. Seven of the nine sites showed a relative reduction in error rates, whereas two of the nine sites had an increase in error rates (Table 4).

Several attempts were made to identify factors that could account for the variability in medication error rates between sites during the baseline period. Using responses from critical care unit description questionnaires returned from seven sites, the only factor that accounted for differences was the patient to prescriber ratio. Sites that reported a patient to physician ratio of  $\leq 4$  had a mean medication error rate of 12.3% compared with a mean rate of 37.5% for sites having a ratio  $> 4$  ( $Z = 11.30, p < .01$ ).

## DISCUSSION

ADEs (injuries, large or small, caused by the use, misuse, or underuse of a drug) have been the focus of considerable study (3–8, 17–22). ADEs are important because they pose an immediate risk to patients and can be costly for the health care system, and some are considered to be avoidable mistakes (3, 4, 9, 19–21, 23, 24). The total injury rate is estimated to be  $> 1$  million patients annually, and medication use accounts for 19.4% of all injuries suffered by hospitalized patients (18). Deaths from medication errors that take place both in and outside of hospitals exceed 7,000 annually (surpassing deaths from workplace injuries) (10).

The Premier Health Alliance with 25 tertiary center members undertook an analysis of  $> 9,000$  errors in 1 yr (25). Children's hospitals within Premier Health Alliance had an error rate of 4.37 per 1,000, "eclipsing" the 1.97 per 1,000 of all hospitals. Children  $\leq 5$  yrs were at highest risk for errors that reached patients, and risk for infants  $< 1$  yr was more than double the next risk-prone group, aged 65–70. Mistakes in prescribing represented 42% of all errors. In another study, error rates within critical care units of a 160-bed Canadian children's hospital were 7.1% in the intensive care nursery and 11.7% in the PICU excluding wrong-time errors (26). These two reports differ dramatically from rates reported in a study

Table 2. Summary impact of intervention strategies for Child Health Accountability collaborative

	Preintervention	Postintervention	Percent Change
Total medication orders, n	12,026	9,187	
Orders with errors, %	27.1	23.7	-12.6 <sup>a</sup>
Time and date only, %	16.0	16.1	0.6
All other errors, %	11.1	7.6	-31.6 <sup>a</sup>
Orders without errors, %	72.91	76.3	4.7 <sup>a</sup>
	100.0	100.0	
Error rates			
Per order, n	0.22	0.17	-24.7 <sup>a</sup>
Per order with errors, n	2.0	2.2	10.0

<sup>a</sup>Statistically significant difference between pre- and postintervention ( $p < .01$ ).

Table 3. Percent of orders with prescribing errors categorized by potential to result in an adverse drug event (ADE)

Prescribing Error Category	Preintervention	Postintervention	Percent Change
Number of orders	12,026	9,187	
Low ADE potential (missing information), %	18.7	13.8	-26.5 <sup>a</sup>
Intercepted with potential for ADEs, %	1.6	2.0	30.8 <sup>a</sup>
Nonintercepted with potential for ADEs, %	2.0	0.8	-61.7 <sup>a</sup>
Adverse drug events, %	0.13	0.03	-76.9 <sup>a</sup>

<sup>a</sup>Statistically significant difference between pre- and postintervention ( $p < .01$ ).

Table 4. Baseline and postintervention with relative reductions in medication error rates by site

Hospital Site	Baseline Error Rate	Postintervention Error Rate	Relative Reduction
A	2	2	35
B	5	4	-24
C	19	7	-61
D	23	19	-16
E	33	17	-50
F	37	11	-71
G	42	58	38
H	21	19	-8
I	17	15	-11

All values are percentages.

of two California hospitals, where the error rates were 4.9 and 4.5 per 1,000 medication orders (12).

Neither a measurement standard nor a consistent benchmark for errors yet exists. This situation is substantiated by recommendations advanced through various sources for reducing medication errors in pediatric settings, including increased involvement of pharmacists and pharmacy satellites, especially in the critical care areas (12, 24, 26–28). Clearly, error rates need to be addressed and consistent methods of tabulation and benchmarking adopted.

This study a) demonstrated the usefulness of a generalizable method used to identify, document, and analyze prescribing errors across a broad range of pediatric

hospital PICUs; b) identified an overall rate of prescribing errors among participating pediatric hospital PICUs categorized according to potential for causing harm (benchmark); and c) described the effectiveness of a variety of hospital-specific, self-selected interventions in reducing medication errors and ADEs. The three-tiered methodology for the identification and documentation of prescribing errors, the matrix format for categorizing errors as to cause and type (promoting the rapid identification of predominant errors), and the use of severity scoring of preventable ADEs were refined. Although standardized among facilities, the approach was flexible enough to be used among collaborative sites despite intersite differences in medication use systems, fostering a common

**A** benchmark for medication prescribing errors in the pediatric intensive care unit was identified among nine children's hospitals.

approach and set of definitions for addressing the problem of medication errors. These errors could be summarized using the summary matrix form, allowing for a common basis for discussion and rapid identification of predominant error types. Use of this methodology in the context of the collaborative precipitated improvement initiatives, the results of which were measurable by the same generalizable methodology. Accomplishment of this aspect of the project was a major goal of the collaborative given the variability among sites.

In our study, a baseline for medication prescribing errors in a PICU setting was established from these nine children's hospitals nationally. When date/time errors were excluded from review, aggregate rates of prescribing errors per order for these PICUs (11.1% preintervention) were more similar to reports by Tisdale (26) than the extremely low rates of occurrence reported among California children's hospitals (12). Although both these prior reports are dated, they represent the only published pediatric data. Recognizing the existence of site-specific differences, we observed an overall 24.7% decrease in prescribing error rate in our study. Considerable variation in reducing error rates among participating hospitals was found. Some hospitals reported dramatic reduction in error rates, whereas others did not anticipate such changes because a low medication error rate was evident during the baseline period. Error rates in two hospitals increased (A and G, Table 4), a finding that cannot be explained, other than the possibility that particular interventions used at those facilities did not address the underlying issues responsible for the medication error causes and types most frequently encountered at these sites. However, overall reductions in the rate of orders with prescribing errors and the prescribing error rate were noted in the majority of participating sites and for the hospitals collec-

tively. A positive impact in prescribing error rates occurred in the categories of incomplete orders, nonintercepted prescribing errors with ADE potential, and preventable ADEs, suggesting some success for the improvement initiatives implemented at the various sites for reducing medication errors in general. An increase in error rate occurred in the category of intercepted prescribing errors with ADE potential, suggesting a positive impact of improvement initiatives and project methodology on intercepting ADEs using an oversight team. Results from this study indicate that the methodology followed represents a readily adaptable and generalizable approach to collecting comprehensive data regarding medication-related errors in the PICU setting. As a result of this process, the majority of facilities participating experienced statistically significant reductions in errors. Although the generalizability of the methodology was not evaluated in this research, organizations seeking to better understand and remediate medication-related errors in settings other than PICUs could readily leverage the methodology and tools derived. Another important conclusion is that this kind of approach can yield improvements in medication errors without the implementation of expensive computerization. Even though it is generally believed that computerization (e.g., computer-based physician order entry) represents the desired long-term objective for controlling error rates, this approach is beyond the short-term capabilities of many health care organizations.

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Children's Hospital and Health Center, San Diego, CA  
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#### REFERENCES

1. Kohn L, Corrigan J, Donaldson M (Eds). *To Err Is Human: Building a Safer Health System*. Washington, DC, National Academy Press, 2000
2. Prevention of medication errors in the pediatric inpatient setting. American Academy of Pediatrics. Committee on Drugs and Committee on Hospital Care. *Pediatrics* 1998; 102:428-430
3. Bates DW, Boyle DL, VanderVliet MB, et al: Relationship between medication errors and adverse drug events. *J Gen Intern Med* 1995; 10:199-205
4. Bates DW, Cullen DJ, Laird N, et al: Incidence of adverse drug events and potential adverse drug events. Implications for prevention. *JAMA* 1995; 274:29-34
5. 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; 25:1289-1297
6. Lesar TS, Briceland L, Stein DS: Factors related to errors in medication prescribing. *JAMA* 1997; 277:312-317
7. Lesar TS, Lomaestro BM, Pohl H: Medication-prescribing errors in a teaching hospital. A 9-year experience. *Arch Intern Med* 1997; 157:1569-1576
8. Hunt ML Jr, Rapp RP: Intravenous medication errors. *J Intraven Nurs* 1996; 19:S9-S15
9. Leape LL, Bates DW, Cullen DJ, et al: Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995; 274:35-43
10. Koren G, Haslam RH: Pediatric medication errors: Predicting and preventing tenfold disasters. *J Clin Pharmacol* 1994; 34:1043-1045
11. Anderson BJ, Ellis JF: Common errors or drug administration in infants: Costs and avoidance. *Pediatr Drugs* 1999; 1:93-107
12. Folli HL, Poole RL, Benitz WE, et al: Medication error prevention by clinical pharmacists in two children's hospitals. *Pediatrics* 1987; 79:718-722
13. Draft guidelines for preventing medication errors in pediatrics. *J Pediatr Pharm Pract* 1998; 3:189-202
14. Meyer GE, Novielli KA, Smith JE: Use of refractive index measurement for quality assurance of pediatric parenteral nutrient solutions. *Am J Hosp Pharm* 1987; 44:1617-1620
15. Kaushal R, Bates DW, Landrigan C, et al: Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001; 285:2114-2120
16. Leape L, Kabacnel A, Berwick D, et al: Breakthrough Series Guide: Reducing Adverse Drug Events. Boston, MA, Institute for Healthcare Improvement, 1998
17. Leape LL: A systems analysis approach to medical error. *J Eval Clin Pract* 1997; 3:213-222
18. Leape LL, Brennan TA, Laird N, et al: The nature of adverse events in hospitalized pa-

- tients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324:377–384
19. Johnson JA, Bootman LJ: Drug-related morbidity and mortality. *Arch Intern Med* 1995; 155:1949–1956
  20. Bates DW, Spell N, Cullen DJ, et al: The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. *JAMA* 1997; 277:307–311
  21. Classen DC, Pestotnik SL, Evans RS, et al: Adverse drug events in hospitalized patients. *JAMA* 1997; 277:301–305
  22. Tinkle R, Wu JK: Errors involving pediatric patients receiving chemotherapy: A literature review. *Med Pediatr Pharmacol* 1996; 26:344–351
  23. PMES Committee: Medication Error Study. Rockville, MD, Physician Insurers Association of America, 1993
  24. Prevention of medication errors in the pediatric setting. *Pediatrics* 1998; 102:428–430
  25. Study shows big picture on adverse drug events. *Modern Healthcare* July 24, 1995; 76
  26. Tisdale JE: Justifying a pediatric critical-care satellite pharmacy by medication-error reporting. *Am J Hosp Pharm* 1986; 43:368–371
  27. Leape LL, Cullen DJ, Clapp MD, et al: Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999; 282:267–270
  28. Levine SR: Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther* 2001; 6:426–442

## APPENDIX A: DEFINITIONS

### Medication Errors and Adverse Drug Events (ADEs)

**Medication Error.** This includes any error, large or small, at any point in the medication system from the time the drug is ordered until the patient receives it. This differs from some prior definitions that considered only deviations from the physician's order as errors. Since nearly half of all errors occur in the prescribing stage, these must be included in the definition. A medication error may or may not result in an ADE.

**Adverse Drug Event.** An ADE is an injury, large or small, caused by the use (including nonuse) of a drug. It can be as harmless as a drug rash or as serious as death from an overdose. There are two types of ADEs: those caused by errors and those that occur despite proper usage. If an ADE is caused by an error it is, by definition, preventable. Nonpreventable ADEs (injury, but no error) are called adverse drug reactions (ADRs).

**Preventable Adverse Drug Event.** A preventable ADR is an injury due to an error in use of a drug (including failure to

use). These would include an actual medication error (actual prescribing error) if associated with an adverse outcome.

**Adverse Drug Reaction.** This is defined by the World Health Organization to characterize injuries caused when drugs are used in the usual accepted fashion. By definition then, an ADR does not result from an error. Unfortunately, many have used this term as synonymous with ADE, which blurs an important distinction.

**Potential Adverse Drug Event (PADE).** A PADE is a serious medication error—one that has the potential to cause an ADE but did not. The PADEs are classified as nonintercepted, those ADEs with potential to harm but did not (e.g., the patient was not allergic to the drug despite a note in the record stating so), or intercepted (e.g., the nurse recognized an order for a medication to which the patient was allergic and called the physician to get it changed). Examining PADEs helps to identify both where the system is failing (the error) and where it is working (the interception).

**Nonintercepted PADE.** This is a PADE with no clinical consequence. A nonintercepted PADE would include a potential medication error (potential prescribing error) if not associated with an adverse outcome.

**Intercepted PADE.** This is a medication error that never reached the patient since it was prevented by existing mechanism. This includes errors that are reconciled, that is, intercepted potential medication errors (intercepted prescribing errors).

### Medication Error Cause

**Prescribing Error.** A prescribing error is an incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by a physician (or other legitimate prescriber); illegible prescriptions or medications orders that lead to errors that reach the patient; or use of nonstandard nomenclature or abbreviations.

**Other.** Other causes of errors such as those produced by drug administration, transcription, or dispensing errors were not included because they are beyond the scope of prescribing.

### Medication Error Type

Although many error types may not be applicable to medication errors due to prescribing causes, they are presented for completeness.

**Omissions.** The patient did not receive a given dose by the time the next dose is due.

**Wrong Patient.** The medication was given to a patient for whom the physician did not write an order.

**Wrong Drug.** A drug was given to the right patient outside a stated set of clinical guidelines or protocols (may refer to site-specific treatment protocols, guidelines, or care maps). Duplication of therapy will be considered inappropriate if inconsistent with the local standard of care.

Numeric Scale	Letter Scale	Description
0		No error occurred
0.5	A	Capacity to cause error, but no error occurred
0.5	B	Potential error
1	C	Error occurred without harm to the patient
2	D	Error occurred requiring increased patient monitoring, but no harm to patient or change in vital signs
3		Error occurred requiring increased patient monitoring and laboratory tests; there was a change in vital signs, but ultimately no harm
3.5	E	Error occurred resulting in the need for treatment or intervention and caused temporary harm
4	F	Error occurred and resulted in need for treatment with another drug, increased LOS, patient transfer to a higher level of care (eg, ICU) or required intervention to prevent permanent impairment or damage
5	G	Error occurred and resulted in permanent patient harm
5.5	H	Error occurred and resulted in a near death event (eg, anaphylaxis, cardiac arrest)
Numeric Scale	Letter Scale	Description
6	I	Error occurred and resulted in patient death

*Wrong Dose.* Dose administered differs from dose ordered or dose ordered is incorrect based on a stated set of clinical guidelines or protocols. These would include the wrong rate of administration (medication is administered at a rate above or below that which is appropriate for the medication; this error category applies especially to intravenous drips and infusions). Minor rounding of doses to fit standardized dosages for certain medications will be exempt.

*Wrong Dosage Interval.* Dosage interval administered differs from interval ordered or interval ordered is incorrect based on a stated set of clinical guidelines or protocols.

*Wrong Dosage Form.* Dosage form administered differs from dosage form ordered or dosage form ordered is incorrect based on a stated set of clinical guidelines or protocols.

Excluded would be accepted protocols (established by the Pharmacy and Therapeutics Committee or its equivalent) that authorize pharmacists to dispense alternate dosage forms for patients with special needs (e.g., liquid formulations for patients with nasogastric tubes or those who have difficulty swallowing), as allowed by state regulation.

*Wrong Duration of Therapy.* Duration of therapy ordered is incorrect based on a stated set of clinical guidelines or protocols.

*Wrong Route.* Drug administered by route not ordered or route ordered is incorrect based on a stated set of clinical guidelines or protocols.

*Wrong Time.* Medication is administered outside a predefined time interval from its scheduled administration time (e.g., 30 mins). This interval must be established by each individual health care facility.

*Unauthorized Dose.* The patient receives an additional dose or doses after the ordered medication has been discontinued.

*Monitoring.* There is a failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.

*Drug-Drug Interactions.* A drug-drug interaction exists for the medication prescribed. Only clinically relevant interactions will be considered here (any theoretical or nonmeasurable/clinically insignificant interaction will be exempt).

*Drug-Food Interactions.* A drug-food interaction exists for the medication prescribed.

*Compatibilities.* A drug incompatibility

exists in the manner in which the medication is prescribed or the manner in which the medication is prepared or administered.

*Laboratory and Drug Levels.* An error exists when pertinent laboratory including drug level information is either not ordered or not appropriately considered in the drug-ordering process.

*Allergy and Other Clinical Information.* An error exists when pertinent allergy and other clinical information is not appropriately considered in the drug-ordering process.

*Procedure Error.* There is a breach of standard procedure resulting in a medication error (e.g., patients transferred from recovery room to PICU with unlabelled intravenous medications resulting in an order for the wrong dose or infusion rate).

*Completeness of Prescription.* Missing information exists such as patient name, identification number, date and time of order, drug, dose, route, frequency, and prescriber signature.

*ADE Severity Level and Outcome.* A modified numeric scale will be used for this project (subcategorized using 0.5 increments reflective of letter scale differences). The letter scale is provided for reference.

## Medication Error Survey Form

Patient Name:  
MR#:

Date of Suspected Error:

**TYPE of ERROR [ Type and  Subtype]:**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Omission                | <input type="checkbox"/> Wrong Patient         | <input type="checkbox"/> Wrong Time                |
| <input type="checkbox"/> Extra Dose              | <input type="checkbox"/> Procedure error       | <input type="checkbox"/> Delay in Service          |
| <input type="checkbox"/> Prescription Incomplete |  |  |
| <input type="radio"/> Patient Name               | <input type="radio"/> ID number                | <input type="radio"/> Date of order                |
| <input type="radio"/> Time of order              | <input type="radio"/> Drug                     | <input type="radio"/> Dose                         |
| <input type="radio"/> Dosage form                | <input type="radio"/> Route                    | <input type="radio"/> Dose Interval                |
| <input type="radio"/> Prescriber signature       |  |  |
| <input type="checkbox"/> Wrong Drug              | <input type="checkbox"/> Wrong Dose            | <input type="checkbox"/> Wrong Route               |
| <input type="checkbox"/> Wrong Dosage form       | <input type="checkbox"/> Wrong dosage interval | <input type="checkbox"/> Wrong duration of therapy |
| <input type="checkbox"/> Monitoring              |  |  |
| <input type="radio"/> Drug-drug Interaction      | <input type="radio"/> Drug-food Interaction    | <input type="radio"/> Drug level                   |
| <input type="radio"/> IV Incompatibility         | <input type="radio"/> Laboratory               |  |
| <input type="radio"/> Allergy information        | <input type="radio"/> Clinical Information     |  |
| <input type="radio"/> Other _____                |  |  |

- Floorstock Associated with Error?**       NO       YES
- If yes, Automated Dispensing machine in place?**       NO       YES
- Was order reconciled with prescriber?**       NO  
 YES  
 Not contacted

**COMMENTS:**

**Information below to be completed by the Medication Use Overview Team**

**ADVERSE DRUG EVENT [ADE] CLASSIFICATION [ Type and  Subtype]:**

- Preventable ADE [Describe Adverse Outcome: \_\_\_\_\_]
  - Failure to reconcile with prescriber
  - Missed by pharmacy [=dispensing error]
  - Missed by PICU [transcribing error]
  - Missed by PICU [drug administration error]
- Potential ADE
  - Nonintercepted potential ADE
  - Failure to reconcile with prescriber/
  - Missed by pharmacy [=dispensing error]
    - Missed by PICU [transcribing error]
    - Missed by PICU [drug administration error]
  - Intercepted ADE [Date & Time of Order Reconciliation]
    - Intercepted by Pharmacy
    - Intercepted by PICU Nursing
    - Intercepted by PICU Nursing (Date & Time missing only)
      - Intercepted by Medication Use Overview
  - Other: \_\_\_\_\_

**ADE ASSOCIATIONS:**

- Renal Dysfunction       Hepatic Dysfunction       Other: \_\_\_\_\_

**ADE SEVERITY:**

- 0 - No error occurred       0.5-A Capacity to cause error, but no error occurred       0.5-B Potential error
- Error occurred:
- 1-C Without harm to the patient
  - 2-D Requiring increased patient monitoring, but no harm to patient or change in vital signs
  - 3 Requiring increased patient monitoring and laboratory tests, with a change in vital signs but ultimately no harm
  - 3.5-E Resulting in the need for treatment or intervention and caused temporary harm
  - 4-F Resulted in need for treatment with another drug, increased LOS, patient transfer to a higher level of care [eg. ICU] or required intervention to prevent permanent impairment or damage
  - 5-G Resulted in permanent patient harm
  - 5.5-H Resulted in near-death event [eg. anaphylaxis, cardiac arrest]
  - 6-I Resulted in patient death

**MEDICATION ERROR IDENTIFIED BY [ all that apply]:**

- Pharmacy       PICU Nursing       Medication Overview       Incident/Occurrence Reporting Process

**COMMENTS:**



**Appendix C PICU Medication Error Maxtix Summary**

Hospital \_\_\_\_\_ (please Identify)

Error Type	Omission	Wrong Patient	Wrong Time	Extra Dose	Procedure Error	Incomplete Order*	Wrong Drug	Wrong Dose	Wrong Dosage Interval	Wrong Dosage Form	Wrong Route	Wrong Duration of Therapy	Drug-Drug Interaction	Drug-Food Interaction	Drug Compat.	Lab	Drug Level	Allergy	Clinical Inform.	Total	
<b>Prescribing Errors</b>																					
# Associated with Floor Stock																					
<b>Total # Preventable ADE</b>																					
Reconcile Failed																					
Dispensing Error																					
Transcription Error																					
Drug Admin. Error																					
<b>Total # Potential ADEs</b>																					
# nonintercepted ADEs																					
Reconcile Failed																					
Dispensing Error																					
Transcription Error																					
Drug Admin. Error																					
# Intercepted ADEs by:																					
Pharmacy																					
PICU Nursing																					
PICU Nursing DNT																					
Med Use Overview																					
Other																					
<b>ADE Severity</b>																					
Level 1																					
Level 2																					
Level 3																					
Level 3.5																					
Level 4																					
Level 5																					
Level 5.5																					
Level 6																					
<b>Error Identified by:</b>																					
Pharmacy																					
PICU Nursing																					
Med Use Overview																					
Incident Reporting																					

Total Orders (Number of Orders without Errors \_\_\_\_\_ + \*Number of Orders Incomplete for Date and/or Time Only \_\_\_\_\_ + Prescribing Errors \_\_\_\_\_) = \_

**Reducing Prescribing Errors  
Child Health Accountability Initiative**