Standard Drug Concentrations and Smart-Pump Technology Reduce Continuous-Medication-Infusion Errors in Pediatric Patients

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ABSTRACT. *Objective.* **To determine if combining standard drug concentrations with "smart-pump" technology reduces reported medication-infusion errors.**

Design. **Preintervention and postintervention comparison of reported medication errors related to infusion therapies during the calendar years 2002 and 2003.**

Setting. **A 242-bed university-affiliated tertiary pediatric hospital.**

Intervention. **Change in continuous-medication-infusion process, comprising the adoption of (1) standard drug concentrations, (2) "smart" syringe pumps, and (3) human-engineered medication labels.**

Main Outcome Measures. **Comparison of reported continuous-medication-infusion errors before and after the intervention.**

Results. **The number of reported errors dropped by 73% for an absolute risk reduction of 3.1 to 0.8 per 1000 doses. Preparation errors that occurred in the pharmacy decreased from 0.66 to 0.16 per 1000 doses; the number of 10-fold errors in dosage decreased from 0.41 to 0.08 per 1000 doses.**

Conclusions. **The use of standard drug concentrations, smart syringe pumps, and user-friendly labels reduces reported errors associated with continuous medication infusions. Standard drug concentrations can be chosen to allow most neonates to receive needed medications without concerns related to excess fluid administration.** *Pediatrics* **2005;116:e21–e25. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2004-2452;** ***rule of six, intensive care unit, children, patient safety, medication errors.***

Medication errors are a major source of potential and actual harm in pediatric patients.[1–3] Pediatric patients are at greater risk for medication error than adult patients because of the need for weight-based dosing and individualized dose calculation for most medications. Effective communication about symptoms and elicitation of pertinent clinical findings is often difficult in children.[2,4] Medical complexity and the need for multiple medications places hospitalized children at an even greater risk; nowhere is this more evident than in intensive care units.[2–5]

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Continuous medication infusions are a category of medications delivered to hospitalized patients that often include "high-alert" medications. As defined by the Institute of Safe Medication Practice, high-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error and may lead to devastating complications for patients.[6] The process of ordering, preparing, and administering continuous medication infusions offers several opportunities for error.[4,7–9] Providing the correct weight-adjusted dose (at an acceptable rate, concentration, and volume) usually requires a multivariable calculation; moreover, a new calculation must be performed whenever the dose is changed. The need for individualized concentrations makes drip preparation a high-frequency and time-consuming task for the pharmacy. The appropriate information must be entered correctly into the pump initially and when changes are made.

Several common practices influence the likelihood of continuous-medication-infusion errors. The "rule of 6" is a calculation aid that was developed originally to facilitate rapid dose calculation and drip preparation in emergency situations but is now in general use. The rule states that the dose (μg/kg per min) equals the rate (mL/hour) when the concentration is prepared according to the following formula: $6 \times$ patient weight (kg) = amount of drug (mg/100 mL).[10] The use of standard drug concentrations eliminates the need to prepare a large number of individualized concentrations.[11] However, facilities that use standard drug concentrations must then rely on dosing charts, which are tables of precalculated values, to reduce the need for calculations. Recently, "smart-pump" technology has become available. Smart pumps incorporate sophisticated computer technologies for storing drug information (ie, drug library), making calculations, and checking entered information against dosing parameters (ie, safety net).[12] Advantages and disadvantages of these approaches are summarized briefly in Table 1; however, there is no consensus among providers regarding the optimal practice to limit medication errors associated with continuous medication infusions while providing acceptable fluid volumes in pediatric patients.[13]

This study evaluated whether 3 concurrent changes in practice—standard drug concentrations, smart syringe pumps, and redesigned labels—would decrease reported errors associated with continuous medication infusions.

TABLE 1. Advantages and Disadvantages of 4 Approaches for Reducing Infusion Errors

Approach	Advantages	Disadvantages
Rule of 6	Makes calculation of initial dose/rate easy Facilitates volume adjustment for low-weight patients	Requires individualized concentrations, resulting in increased frequency and complexity of preparation Often difficult to use when making dose/rate changes Practitioners must remember slightly different formulas for different medications
Standard concentrations	Fewer concentrations prepared Reduces number of steps required to prepare drip Simplifies medication ordering Reduces costs Improves pharmacy quality control	Requires more complex initial dose calculation Often difficult to use when making dose/rate changes Limits choices of volume and rate that can be delivered
Dosing charts	Minimizes need to perform calculations, reducing risk of calculation errors	Substitutes risk of perceptual tracking errors for risk of calculation errors Limited range of values unless tables are large
Smart pumps	Eliminates need for calculations Alerts for out-of-range entries Drug libraries and default settings facilitate selection of correct medication and dose Better information display and feedback	High initial capital expenditure Likelihood of selection errors increases with number of different concentrations available in drug library

METHODS

The setting for this preintervention and postintervention study was Primary Children's Medical Center (Salt Lake City, UT), a 242-bed university-affiliated tertiary pediatric hospital. Before the intervention, the continuous-medication-infusion process consisted of the following steps: (1) orders were handwritten by clinicians either as free text or directly onto preprinted infusion sheets and sent to the pharmacy; (2) pharmacists entered data into a computer that calculated, based on the rule of 6, individualized "recipes" for mixing concentrations; (3) the infusion was mixed and delivered to the units with dosing charts specific to that concentration; and (4) the nurses either used the dosing charts to determine the appropriate infusion rate or made the rate calculation by hand and then programmed the infusion rate into the pumps.

The intervention consisted of 3 changes to this process. First, standard concentrations were developed for 32 common medications delivered by intravenous continuous infusion (Table 2). These medications collectively make up ~95% of the medications in the hospital infused continuously via syringe pumps. For each medication, the choice of concentration was based on available commercial concentrations, standard drug concentrations surveyed from 10 other pediatric facilities, and an analysis of past usage at our facility. To verify that these standard concentrations were appropriate in the NICU, we looked at the range of concentrations prepared by the rule of 6 over a 2-week period and then matched the standard concentrations to that range. Depending on the infusion drug, we determined that between 1 and 4 standard concentrations met the fluid requirements of most of our patients.

Second, a multidisciplinary task force consisting of nursing, pharmacy, clinical engineering, physicians (neonatologist, pediatric intensivist, cardiothoracic surgeon, and anesthesiologist), and

TABLE 2. Medications Selected for Standard Drug Concentrations

Medication	Concentration 1	Concentration 2	Concentration 3, 4
Amiodarone	2 mg/mL	6 mg/mL	—
Aprotinin	1.4 mg/mL	—	—
Dobutamine	1 mg/mL	4 mg/mL	—
Dopamine	0.8 mg/mL	3.2 mg/mL	—
Epinephrine	8 μg/mL	64 μg/mL	—
Esmolol	10 mg/mL	—	—
Fentanyl	10 μg/mL	50 μg/mL	—
Furosemide	1 mg/mL	10 mg/mL	—
Heparin	50 U/mL	100 U/mL	—
Hydromorphone	1 mg/mL	—	—
Insulin	0.1 U/mL	1 U/mL	—
Isoproterenol	8 μg/mL	64 μg/mL	—
Ketamine	10 mg/mL	100 mg/mL	—
Lidocaine	4 mg/mL	8 mg/mL	—
Midazolam	1.0 mg/mL	5 mg/mL	—
Milrinone	200 μg/mL	400 μg/mL	—
Morphine	1 mg/mL	—	—
Nitroprusside	400 μg/mL	1 mg/mL	—
Norepinephrine	8 μg/mL	64 μg/mL	—
Pancuronium	1 mg/mL	—	—
Phenylephrine	50 μg/mL	100 μg/mL	—
Potassium	0.2 mEq/mL	1 mEq/mL	—
Procainamide	4 mg/mL	8 mg/mL	—
Propofol	10 mg/mL	—	—
Prostaglandin	5 μg/mL	—	—
Remifentanil	25 μg/mL	50 μg/mL	—
Sodium bicarbonate	1 mEq/mL	—	—
Sufentanil	0.5 μg/mL	1 μg/mL	5 μg/mL, 10 μg/mL
Terbutaline	1 mg/mL	—	—
Tranexamic acid	5 mg/mL	10 mg/mL	25 mg/mL, 50 mg/mL
Vasopressin	0.025 U/mL	1 U/mL	—
Vecuronium	2 mg/mL	—	—

the hospital safety manager developed criteria to select a smart syringe pump (Table 3). Once a syringe pump that met all criteria was identified (Medex, Carlsbad, CA), 340 pumps were purchased. The smart pump included a modifiable drug library from which the practitioner could choose the drug to be administered. The smart pump calculated the rate of administration, provided an alert if the dose entered exceeded the limits of the safety net, and provided a clear visual display of the drug, dose, and rate being infused. The task force determined the appropriate drugs and dosing ranges for the drug library. The dosing ranges were individually selected for each drug with the intent to avoid 10-fold overdoses.

Third, pharmacy-generated medication labels were changed to facilitate the correct transfer of information from the label to the pump (Fig 1), which involved using human-factor principles to separate the information that needed to be entered into the pump from other information, highlighting this information, and formatting the label to match the pump programming.

This entire process of development occurred over the course of 1 year. The 3 changes were implemented throughout the hospital over a 1-week period. Education of staff began during the week before and continued throughout the week of implementation. We used a "train-the-trainer" approach. Each class lasted 1 hour with up to 8 to 10 attendees per class. Each hospital unit had a trained clinician available on the day of implementation to answer questions and address issues. The pump manufacturer also made available clinical and technical support during the implementation week.

The main measurement outcome was reported errors associated with continuous medication infusions captured by the hospital's incident-reporting system. After the changes had been in place for 1 calendar year, errors reported for the 12-month period before the change (2002) were evaluated retrospectively and compared with errors reported during the 12-month period after the change (2003). All reported medication errors from this 2-year period were reviewed. A reported incident was considered a continuous-medication-infusion error if and only if it involved 1 of the 32 standardized medications and an infusion pump (patient-controlled analgesic pumps were excluded).

A 2-sample test of proportions was used to calculate the difference in error-reporting rates before and after the intervention. The change in error rate and corresponding 95% confidence interval were calculated. Data analysis was performed with Minitab 13.20 (State College, PA). The University of Utah Institutional Review Board granted approval for this study.

RESULTS

After the interventions, there was a 73% reduction in the number of reported errors associated with continuous medication infusions. Specifically, the error rate decreased from 3.1 to 0.8 per 1000 doses for an absolute risk reduction of 2.3 errors per 1000 doses (95% confidence interval: 1.1–3.4; $P < .001$). Preparation errors that occurred in the pharmacy decreased from 0.66 to 0.16 per 1000 doses. The number of 10-fold errors in dosage decreased from 0.41 to 0.08 per 1000 doses. These results are summarized in Table 4. The hospital-wide incident-reporting rate was identical for the preintervention and postintervention periods (0.03 incidents reported per inpatient day). We determined that 87% of the continuous medication infusions in the NICU and >99% in other areas of the hospital used standard drug concentrations (Table 2).

TABLE 3. Smart-Pump Selection Criteria

1. Accuracy: must pass clinical engineering bench testing
2. Intuitiveness of programming
3. "Safety Net": high- and low-dose programming parameters
4. Drug library: modifiable and hospital generated to meet institutional needs
5. Dose-rate calculator within the pump
6. Size: small enough to fit numerous pumps on intravenous line pole; request to be able to clamp pump to warmer in NICU
7. Syringe size: 1–60 mL from various manufacturers
8. Alarms: must be audible and visible
9. Rotating pole clamp: allow pump to be vertical or horizontal
10. Durability
11. Serviceability
12. Compatible with electronic charting
13. MRI compatible: can be taken into the scanner if necessary

Preintervention

JOHN DOE Bed: NB wt: 2kg
FENTANYL (PD* 0.01mg/ml, D5W)
Medication Concentration = 0.01mg/ml
Dose = 1 mcg/kg/hr @ Flow Rate 0.2ml/hour
Diluent (s) : D5W
Total Volume Dispensed = 15ml
Dispensed: 01/14/2003 Expires: 01/15/2003 @1300

Postintervention

JOHN DOE	Bed: PCMC
Med: **FENTANYL**	Dispensed: 01/14/2003
Conc.: **0.01** mg/ml	Expires: 01/15/2003 @1300
Weight: **2** kg	Total Volume Dispensed: 15ml
Dose: **1** mcg/kg/hr	Flow Rate: 0.2ml/hour
Diluent: D5W	

Fig 1. Pharmacy-generated labels for continuous medication infusions.

DISCUSSION

We found a significant decrease in reported errors involving continuous medication infusions in pediatric patients after implementation of standard drug concentrations, smart syringe pumps, and human-engineered medication labels to guide practitioner pump programming. The substantial reduction in reported errors may be attributed to several factors.

The use of standard drug concentrations reduces the number of individual concentrations prepared and the number of preparation steps. Both these reductions translate to fewer opportunities to make errors, and we found a reduction from 8 to 2 reported preparation errors.

The smart pumps shift the calculation burden from practitioners and pharmacists to computers. The smart pump also allows practitioners to change the dose directly, without the need for any intervening calculation. The drug libraries within the smart pump automatically default to the appropriate concentration and measurement units (milligrams, micrograms, or units) when the medication is selected, which reduces the likelihood of confusing units, and eliminates the need to make unit conversions. The built-in safety net alerts the practitioner when the entered dose exceeds preprogrammed limits and requires a deliberate override to continue. The pump display provides a complete and accurate account of what is being delivered to the patient, which provides the practitioner with feedback about the correctness of their information entry and facilitates double-checks.

The primary source of information to be pro-

TABLE 4. Errors Reported for the 12-Month Period Before and After the Intervention

Time Period	Unit	No. of CMIs	No. of Errors	No. of Ordering Errors	No. of Preparation Errors	No. of Administration Errors	No. of ≥10-fold Overdose	Error Rate per 1000 Doses	% Standard Drug Concentrations of All CMIs Prepared
Preintervention period (2002)	PICU	7527	21					2.8	0
	NICU	3431	12					3.5	0
	Other	1151	4					3.5	
	Total	12 109	37	1	8	28	5	3.1	
Postintervention period (2003)	PICU	7520	5					0.7	>99
	NICU	3620	5					1.4	87
	Other	1259	0					0	
	Total	12 399	10	0	2	8	1	0.8	
Difference in total error rate								2.3*	

CMIs indicates continuous medication infusions.
* $P < .001$.

grammed into the pump is contained on the pharmacy-generated medication labels. The labels were designed to make it easy for the practitioner to identify the required information, to enter the information in the order to be entered, and to compare the information on the label with that entered into the pump.

A commonly stated objection to standard drug concentrations is that they do not work well with very small patients. For these patients, the flexibility afforded by individualized concentrations is seen as necessary for management of fluid volumes and maintaining a sufficient flow rate to keep lines patent. However, our experience is that with careful selection of standard concentrations, fluid volume and rate can be managed without difficulty for most of our patients. Through ongoing efforts in the year after the study period (2004), the percentage of continuous medication infusions that used standard drug concentrations increased from 87% to 94% in the NICU. Error rates associated with continuous medication infusions in the NICU decreased from the preintervention to postintervention periods yet remain higher than in other areas of the hospital. The reasons for the higher error rates in the NICU are unknown.

There are several limitations to this study. The primary data for this study were generated by the hospital-wide incident-reporting system. Incident reports have been demonstrated to underreport errors.[14] Nevertheless, consistent incident reports are a reasonable measurement of the relative number of errors. Because the absolute number of incident reports varied little throughout the study period, the decrease in errors can reasonably be attributed to the interventions. There were no apparent temporal trends in error rate. Error occurrence seemed to be random during both the preintervention and postintervention periods. The 3 interventions were introduced as a package, making it impossible to determine the extent to which each individual intervention contributed to the reduction in error. We cannot rule out the possibility that increased awareness and vigilance due to staff education may have contributed to the reduction in errors, but we are aware of no other organizational factors that might have contributed to the reduction. Three of the 37 preintervention events and 1 of the 10 postintervention events resulted in patient harm. The low frequency of harm makes it impossible to draw robust conclusions about the impact of the intervention on patient harm. However, the reduction in 10-fold dosing errors strongly suggests a trend toward increased safety.

Although the number of reported incidents involving continuous medication infusions is small, the true error rates might be much higher.[14] These errors often involve the delivery of high-alert medications to seriously ill patients, which makes it particularly important to minimize this type of error. We found a significant reduction in reported errors associated with continuous medication infusions; as a result, patient safety improved.

To maintain the gains in patient safety, we continued to provide education periodically on correct pump usage, added more drugs to the available standard drug concentration list, increased the usage of standard drug concentrations in the NICU, conducted an iterative process to improve the smart-pump software, and expanded the usage of the smart pumps for other noncontinuous medication infusions (eg, intralipids, electrolytes, and antibiotics).

CONCLUSIONS

A combination of standard drug concentrations, smart-pump technology, and human-engineered medication labels reduced reported errors associated with continuous medication infusions in hospitalized pediatric patients. The use of new technology allows health care providers working in medically complex environments to provide safer patient care. Ideal implementation would include development of standardized staff-education programs with scenario-based evaluation of smart-pump technology, a national consensus of standardized drug concentrations for pediatric patients, an interface with computerized order entry systems and electronic charting, and rigorous error-detection and -reporting systems.

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