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A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients*

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Objective: Intravenous medications are vital during inpatient management. Errors associated with the administration of medications through intravenous infusion pumps to critically ill patients can result in adverse drug events. We sought to assess the impact of smart pumps with integrated decision support software on the incidence and nature of medication errors and adverse drug events.

Design: We performed a prospective, randomized time-series trial and compared the serious medication error rate between intervention (decision support on) and control (decision support off) periods. Serious medication errors included both near-misses and preventable adverse drug events. Pump software produced log reports to help identify potential events. Events were presented to physicians for rating of event type, preventability, and severity.

Setting: Cardiac surgical intensive care and step-down units between February and December 2002.

Patients: Pump data were available for 744 cardiac surgery admissions.

Interventions: Decision support during medication administration provided feedback including alerts, reminders, and unit-specific drug rate limits.

Measurements and Main Results: We found a total of 180 serious medication errors, including 14 and 11 preventable adverse drug events and 73 and 82 nonintercepted potential adverse drug events in the control and intervention periods, respectively. The serious medication error rates in the control and intervention periods were 2.03 and 2.41 per 100 patient-pump-days, respectively ($p = .124$). We also found numerous opportunities for safety improvement. Violations of infusion practice during the intervention periods included 571 (25%) bypasses of the drug library. Medications were also frequently administered without documentation of physician orders in both periods (n = 823; 7.7%).

Conclusion: Intravenous medication errors and adverse drug events were frequent and could be detected using smart pumps. We found no measurable impact on the serious medication error rate, likely in part due to poor compliance. Although smart pumps have great promise, technological and nursing behavioral factors must be addressed if these pumps are to achieve their potential for improving medication safety (Crit Care Med 2005; 33:533–540).

Key Words: medication safety; adverse drug events; intravenous infusion pump; bedside decision support; human factors; critical care nursing; intensive care units

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In the groundbreaking report from the Institute of Medicine, *To Err is Human*, patient safety was defined as freedom from accidental injury (1). Accidental injuries, also known as adverse events, result from interactions between potentially unsafe conditions at the systems level, also know as the blunt end, and individual performance at the sharp end (2). The medication administration process is a complex series including many steps (3).

Medication errors are frequent and can lead to adverse drug events (ADEs) (4). The Harvard Medical Practice Study found that the most common type of adverse event were injuries cause by drugs (5). The ADE Prevention Study found a rate of 6.5 ADEs for every 100 admissions, of which 28% were preventable, that is, due to a medication error (6). In the ADE Prevention Study, medication administration by nursing was the second most common stage (38%) associated with ADEs. The most common proximal causes of ADEs during the nursing medication administration stage were inadequate drug knowledge and problems related to intravenous infusion pumps and parenteral delivery problems.

Intravenous medications are vital in the therapeutic management of hospitalized patients and are often delivered with infusion pump systems. Critically ill patients are particularly susceptible to ADEs (7) and frequently receive potent intravenous drugs with narrow safety margins that require careful titration of dosage. Although these medications can be life saving, errors in administering them present a high risk for severe adverse events, including fatalities (8–11).

Several technologies have been demonstrated to reduce serious medication error rates including computerized physician order entry (12), decision support (13), and pharmacy ADE surveillance systems (14). However, these technologies have had little if any impact on errors associated with the administration of intravenous drugs. A misprogrammed decimal point can have dangerous consequences, including death. Newly developed "smart intravenous infusion pumps" have been designed to reduce the rates of these types of errors (15). Smart pumps have drug libraries and provide point-of-care decision support feedback for overly high or low intravenous infusion rates and doses.

Few studies have evaluated the frequency or potential consequences of medication errors in infusion pump use (11). Therefore, we sought to study the impact of introducing a smart infusion pump system on serious medication error rates. This study also provided an opportunity to study integration of a new technology into critical care nursing practice. Caring for critically ill patients involves complex interactions between clinicians, patients, and the many devices used for patient support. Human factors principles represent vital considerations in the design of new devices, which necessarily affect workflow and practice patterns. This is especially important in critical care nursing because of the frequent need to quickly provide urgent treatments.

MATERIALS AND METHODS

STUDY SITE AND PATIENT POPULATION

This study was conducted at Brigham and Women's Hospital, a 720-bed tertiary care, academic medical center. Cardiac surgery (CS) patients admitted between February 2002 and December 2002 to two CS intensive care units (ICUs) and two CS step-down monitored units were eligible for study enrollment. The units are staffed by a surgical intensivist and cardiac surgery fellows. Clinical pharmacists reviewed orders but did not participate during physician rounds. The study was performed with the approval of the institutional human subjects review board.

IMPLEMENTATION OF THE NEW INTRAVENOUS PUMP

New intravenous infusion pumps (Alaris Medley Medication Safety System or Medley pump, Alaris Medical Systems, San Diego, CA) replaced the preexisting intravenous pumps 2 wks before data collection. Nurse educators and Alaris staff trained nursing and anesthesia staff with standard in-services, including computer-based training and hands-on practice with the new pumps. Medley pumps have a modular design that can support up to four infusions. The CS nursing staff was instructed to use the drug library option when programming medications contained in the library and to program all other medications as generic infusions. Following discontinuation of intravenous therapy, research staff downloaded and cleared the pump's internal log reports before they were reused for other patients.

STUDY DESIGN AND INTERVENTION

The study design was a nonblinded, prospective time series spanning four 8-wk data collection periods each separated by a 2-wk transition phase used to reconfigure the pumps for the next study period. The first and third period were control/off periods and the second and fourth periods were intervention periods. Patients admitted during the transition phases were excluded.

Following each control period, pumps were reconfigured to provide point-of-care real-time decision support (DS) feedback for the intervention/on periods. The feedback feature was inactivated during the following transition phase and control period.

FEATURES OF THE INTELLIGENT INTRAVENOUS PUMP

The Medley pumps shared certain safety features with old pumps including dose calculation functions, free-flow protection, and occlusion alerts. However, smart pumps also included a drug library with standardized concentrations for commonly used drugs that permitted automatic weight

based volume and rate calculations and provided dose and rate limits and alerts based on predetermined limits. Alerts could be set up either as "soft," which allowed overrides, or "hard," which cannot be overridden. Hard limits were not implemented during our study. Nurses had the option to select a drug and concentration from the drug library list or could bypass the drug library by entering a drug as a nonspecific or generic infusion. Generic infusion selections were meant for less commonly used drugs not included in the library and thus had no predetermined dosing or rate limits and alerts. Programming for starting new intravenous medications with the pump version used during the study required selecting additional prompts to move from the default generic infusion mode to the drug library mode.

DEFINITIONS

We used the following definitions (6): *Medication errors* include errors during ordering, transcribing, dispensing, administering, or monitoring. Not all medication errors have the potential to harm a patient. *Adverse drug events (ADEs)* were injuries due to a medication and are classified as preventable (associated with a medication error) or nonpreventable. An example of a nonpreventable ADE would be to infuse penicillin into a patient with no prior allergy history who then develops urticaria. An example of a preventable ADE would be administering penicillin to a patient with a known penicillin allergy who then develops anaphylaxis. A *potential adverse drug event (PADE)* or near-miss was a medication error that had the potential to cause harm but did not because it was either intercepted before reaching the patient (*intercepted PADE)* or reached the patient and because of luck did not cause harm (*nonintercepted PADE). Serious medication errors* have the capacity to cause injury and reach the patient. They include both nonintercepted PADEs and preventable ADEs; the serious medication error rate was the primary outcome of interest. Intercepted PADEs are excluded from this category because successful safety interventions can be expected to result in an increase in interceptions of these near-miss events.

DATA COLLECTION

Patient-related data collection included demographics, admitting diagnoses, operative procedures, comorbidities, and total number of intravenous medications. Medications were categorized into therapeutic classifications. Preoperative cardiac surgery risk stratification scores included the Fortescue (16) and Tu scores (17).

Pump-related transaction data were obtained from pump log downloads. Log reports included the pump identification number, key press dates and times, drug concentrations and rates, drug names (when selected from the drug library), and alert opportunities. Research staff identified drug infusions that either were not in the drug library or bypassed the library by matching the date, time, and rate of the infusion in the log report to the ICU flow sheets.

CASE FINDING AND EVENT CLASSIFICATION

In addition to alerts generated by pump log reports, cases were found by several previously described methods (6) including chart review, solicited staff reports, hospital incident reports, and a computerized ADE surveillance monitor (14). Trained research nurses abstracted charts and created incidence case summaries for presentations to physicians. Two independent physician reviewers with expertise in judging adverse events rated cases (6). Physician raters judged severity using a 4-point Likert scale and preventability using a 5-point Likert scale. Disagreements were resolved by discussion.

Medical errors were categorized as harmful or not and mapped to the National Coordinating Council for Medication Error Reporting and Prevention Levels E–1 and B–D, respectively (18). Serious medication errors were analyzed for injury severity or potential severity as well as systems-related factors. Medication error stages were categorized as ordering, filling, administration, or monitoring. Error types such as wrong doses were also selected.

In addition, we detected several potentially risky practices: bypassing the drug library knowledge base when the drug was in the library, overrides of warning alerts when judged clinically inappropriate, and undocumented verbal orders for administered medications. Bypassing the library prevented the smart pumps from checking drug limits or providing feedback alerts. Overrides were defined as either continuation of a medication at a higher rate than the preset alert limit or bolusing of medications for brief periods at rates far in excess of the alert limit. Medication boluses (e.g., rates of 999 mL/hr) were considered violations if the practice was not consistent with hospital nursing guidelines and/or the bolus lasted > 15 secs. If boluses were used under extremely urgent conditions such as life-threatening hypotension (e.g., norepinephrine bolus), they were considered clinically appropriate. Only boluses and overrides associated with preventable and nonintercepted potential ADE were included as medication errors.

In addition to the intention-to-treat findings, we assessed the potential impact of correctly using the pump's safety features on preventing medication errors due to violations. We rerated the preventable ADEs and nonintercepted potential ADEs that escaped interception during the intervention period due to bolus and override violations. Excluding these violations provides an assessment of the pumps' capabilities for preventing serious errors.

STATISTICAL ANALYSIS

The unit of analysis was the patient-pump-day. Log reports did not permit capture of the total number of pump medications

per patient per day. Several patients had prolonged hospitalizations and crossed over from one study period past the transition phase into the next study period (n = 10, 1.3%). Therefore, pump use days were divided into segments of care during either the control or intervention periods. Comparisons of categorical variables were made using the chi-square test or the Fisher's exact test. Comparisons of continuous variables were made using the Wilcoxon rank-sum test or Student's *t*-test. Comparisons of event rates were made using a Poisson regression with intervention and period of the trial as the predictor variables and the number of patient-pump days as a covariate with total number of medications as the offset. All statistical programming was performed using SAS analytical software (release 6.12, SAS Institute, Cary, NC). Prediscussion interrater reliability was compared for level of agreement using the k statistic.

RESULTS

PATIENT DEMOGRAPHICS AND MEDICATION USE

There were a total of 800 CS admissions including 393 during the control periods and 407 during the intervention periods. After we excluded 29 control admissions (7.4%) and 27 intervention admissions (6.6%) with missing pump data logs, 744 admissions (735 patients) were analyzed. Pump log data were sometimes lost when untagged pumps were used for only a few hours or only on weekends when logs were not downloaded. Patients admitted in both sets of periods were similar with regard to diagnoses, Charlson comorbidity index, preoperative risk stratification scores, and surgical procedures (Table 1). None of the nine (1.2%) crossover patients had events in both the control and intervention periods.

TABLE 1

Patient Demographics			
	Control Periods	**Intervention Periods**	***p* Value**
Admissions, n	364	380	
Mean age, yrs	66.2	67.0	.43
Male, n (%)	226 (63)	261 (68)	.08
Mean LOS	13.9	12.1	.06
Mean intensive care unit LOS, days	5.6	3.7	.001
Mean step-down unit LOS, days	6.9	6.7	.66
Race, n (%)			.97
Caucasian	326 (91)	343 (91)	
Black	12 (3)	19 (5)	
Hispanic	7 (2)	3 (1)	
Other/unknown	13 (4)	12 (3)	
Admitting diagnosis, n			.15
CAD only (including ACS and AMI)	145	182	
Mitral valve disease only	42	51	
Aortic valve disease only	61	50	
CAD and mitral valve disease	19	16	
CAD and aortic valve disease	25	17	
CAD and other nonvalve disease	36	26	
All other diagnoses	36	38	
Procedures, n			.53
CABG (only)	151	176	
Mitral valve repair (only)	51	43	
Aortic valve repair (only)	38	44	
Combined CABG and mitral valve repair	21	14	
Combined CABC and other procedure	53	47	

TABLE 1 ***(Cont.)***

Patient Demographics			
	Control Periods	**Intervention Periods**	***p* Value**
Heart transplantation	4	3	
All other procedures	46	53	
Tu score (mean) (17)	4.45	4.4	.73
Fortescue Score (mean) (16)	14.0	13.9	.94

LOS, length of stay; CAD, coronary artery disease; ACS, acute coronary syndrome; AMI, acute myocardial infarction; CABG, coronary artery bypass graft; Tu score, a preoperative risk stratification score for patients undergoing CABG and/or valve procedures; Fortescue score, a preoperative risk stratification score for patients undergoing coronary artery bypass graft.

There were 4,276 and 3,869 patient-pump days in the control and intervention periods, respectively. A total of 5,364 and 5,295 intravenous medications were ordered in the control and intervention periods, respectively. Cardiac surgery patients on average used ten different classes of medications during their hospitalization. Overall, the most common drugs infused through intravenous pumps were electrolyte solutions, antibiotics, and colloids. The most commonly used drugs in the library were vasopressors, diuretics, and propofol (Table 2).

TABLE 2

Intravenous Drug Categories and Bypassing of Pump Library and Alerts During Intervention Periods			
Drug Category	**Drug Orders During Control Periods No. (%)**	**Drug Orders During Intervention Periods No. (%)**	**Drug Orders Bypassing the Drug Library During Intervention Periods No. (%)**
Drugs in the Pump Library			
Vasopressors	378 (7)	380 (7.2)	107 (28.2)
Diuretics	338 (6.3)	348 (6.6)	35 (10.1)
Intravenous anesthetics (e.g., propofol)	332 (6.2)	344 (6.5)	235 (68.3)
Narcotic Analgesics	298 (5.6)	303 (5.7)	3 (1)
Nitrates	215 (4)	240 (4.5)	40 (16.7)
α-, β-, or calcium-blockers	167 (3.1)	191 (3.6)	5 (2.6)
Insulin	148 (2.8)	182 (3.4)	112 (61.5)
Heparin	140 (2.6)	119 (2.2)	14 (11.8)
Sedative/hypnotics	105 (2)	100 (1.9)	6 (6)
Antiarrhythmics	56 (1)	54 (1)	6 (11.1)
Inotropic agents	31 (0.6)	31 (0.6)	5 (16.1)
Others	26 (0.5)	20 (0.4)	3 (15)
Total	2234 (41.6)	2312 (43.7)	571 (24.7)
Drugs not in the pump library			
Electrolyte concentrations	923 (17.2)	890 (16.8)	
Antibiotics	572 (10.7)	550 (10.4)	
Colloids	445 (8.3)	461 (8.7)	

(Continues)

TABLE 2 *(Cont.)*

Intravenous Drug Categories and Bypassing of Pump Library and Alerts During Intervention Periods			
Drug Category	**Drug Orders During Control Periods No. (%)**	**Drug Orders During Intervention Periods No. (%)**	**Drug Orders Bypassing the Drug Library During Intervention Periods No. (%)**
Blood products	365 (6.8)	305 (5.8)	
Crystalloids	244 (4.5)	172 (3.2)	
Non-narcotic analgesics	179 (3.3)	180 (3.4)	
Gastrointestinal agents	228 (4.3)	239 (4.5)	
Others	174 (3.2)	186 (3.5)	
Total	3130 (58.4)	2983 (56.3)	
All drugs	5364	5295	

ADVERSE DRUG EVENTS AND MEDICATION ERRORS

In the intervention period we found 22 ADEs, of which 11 were preventable (0.28 of 100 patient-pump days) and 82 nonintercepted ADEs (2.12 of 100 patient-pump days). In the control period, the comparable numbers were 28 ADEs, 14 preventable ADEs (0.33 of 100 patient-pump days), and 73 nonintercepted PADEs (1.7 of 100 patient-pump days). There were no statistically significant differences in any of these rates between the intervention and control periods and including the control phase of the study (Table 3).

Drugs being given with no documented order were frequent and were not included as potential ADEs in our analysis. Among all 10, 659 administered intravenous medications, there were 823 undocumented physician verbal orders (7.7%), including 427 in the control and 396 in the intervention groups.

Overall, we found a total of 219 intravenous medication errors. In this study, our detection strategy focused mainly on the administration stage, so it is not surprising that the administration stage was the most common error stage for errors. The most common types of error were incorrect dosing of titratable drugs incorrect intravenous drug rates (Table 4). The most common medications resulting in ADEs were vasopressors (20%; 1.3% of vasopressor orders), electrolyte concentrations (18%; 1.3% of electrolyte orders), and diuretics (14%; 0.4% of diuretic orders). The most common

TABLE 3

Medication Errors and Adverse Drug Events				
	Control Period	**Intervention Period**	**All Periods**	***p* Value**
Adverse drug events				
Preventable	14 (0.33)	11 (.28)	25 (0.31)	.874
Nonpreventable	14 (0.33)	11 (.28)	25 (0.31)	.801
Total	28 (.65)	22 (.57)	50 (0.61)	.772
Potential adverse drug events				
Intercepted	19 (0.44)	20 (0.52)	39 (0.48)	.588
Nonintercepted	73 (1.70)	82 (2.12)	155 (1.90)	.086
Total	92 (2.15)	102 (2.64)	194 (2.38)	.076
Serious medication errors				
Total	87 (2.03)	93 (2.41)	180 (2.21)	.124

Values are given as no. (rate per 100 patient-pump-days). Serious medication errors are preventable adverse drug events and nonintercepted potential (or near-miss) adverse drug events. *p* values compare event rates per 100 patient days between the control and intervention periods.

TABLE 4

Systems Analysis of Medication Errors (Excluding Undocumented Physician Orders)		
	Control Periods n = 106 (%)	**Intervention Periods n = 113 (%)**
Stages[a]		
Administration	99 (93)	104 (92)
Monitoring	6 (6)	8 (7)
Ordering	4 (4)	2 (2)
Filling	1 (1)	0 (0)
Type[a]		
Wrong dose-titratable	70 (66)	88 (78)
Wrong dose-nontitratable	11 (10)	7 (6)
Wrong rate	11 (10)	6 (5)
Wrong concentration error	6 (6)	3 (3)
Known allergy	3 (3)	1 (1)
Omitted medication	1 (1)	0
Wrong medication	0	1 (1)
Other	12 (11)	10 (9)

[a]Medication errors may be associated with multiple stages and/or types, so that the percent totals exceed 100%.

injuries resulting from ADEs were cardiovascular, especially hypotension defined as a systolic blood pressure < 90 mm Hg (40%), and metabolic derangements such as severe hypoglycemia or hyperkalemia (24%). Most preventable ADEs were serious or life-threatening (18 of 25, 72%). Additional, most potential ADEs were rated as having the potential for serious or life-threatening injury (183 of 194, 94%). There was no difference in event severity between the control and intervention groups. Examples of intercepted medication errors are provided in Table 5. The levels of interrater agreement for incident classification (k = .89), preventability (k = .91), and severity (k = 0.66) were good.

TABLE 5

Examples of Intercepted Medication Errors	
Error	**Case Summary**
Incorrect 10-fold-high rate (decimal error)	In a patient who was s/p cardiac transplant for end-stage cardiomyopathy, vasopressin was incorrectly programmed at a rate of 1 unit/min rather than the correct dose of 0.1 units/min
Incorrect 10-fold-high rate (decimal error)	In a patient who was s/p coronary artery bypass graft and mitral valve repair, dopamine was incorrectly programmed at a rate of 70 μg/kg/min rather than the correct rate of 7 μg/kg/min
Incorrect 16-fold-high rate (additional digit error)	In a patient who was s/p coronary artery bypass graft and aortic valve replacement for aortic stenosis, epinephrine was incorrectly programmed at a rate of 32 μg/kg/min rather than 2 μg/kg/min
Incorrect 1/5000th low concentration and low rate (rate entered instead of concentration)	In a patient who was s/p coronary artery bypass graft and mitral valve repair, heparin was incorrectly programmed at a concentration of 5 units/250 mL at a rate of 5 mL/hr, resulting in a dose of 0.1 units/hr. The correct concentration was 25,000 units/250 mL at 5 mL/hr to provide a dose of 500 units/hr

s/p, status post.
In each case, the error was intercepted within seconds, corrected immediately, and not associated with any adverse sequelae.

EXPECTED INCIDENT RATES WITH INFUSION PRACTICE IMPROVEMENTS

Two problematic intravenous administration practices, or violations, frequently occurred during the study: bypassing of the drug library and overriding alerts including the use of inappropriate boluses. During the intervention period, we found that among drugs preprogrammed in the drug library, a total of 573 infusions (24%) bypassed the library either accidentally or intentionally, especially propofol (68.3%) and insulin infusions (61.5%, Table 2). Among the bypasses, three were associated with preventable ADEs and 44 with nonintercepted potential ADEs. Overriden soft alerts resulted in one preventable ADE and 24 nonintercepted potential ADEs.

The findings in the intention-to-treat intervention period were then analyzed to reassess smart pump use if the safety features were correctly used during the intervention period. After we corrected for both library bypassing and alert overrides, the rates of preventable ADEs and nonintercepted potential ADEs during the intervention would have decreased from 0.28 to 0.18 ($p = .27$) and from 2.12 to 0.36 ($p < .0001$) per patient-pump days, respectively.

DISCUSSION

We found that medication errors and ADEs associated with intravenous infusion pumps in cardiac surgical patients were common and often potentially hazardous. Although smart intravenous pumps with decision support capabilities have the capacity to intercept many dangerous medication errors and allowed detection of many errors that would have been difficult to find through other mechanisms, smart pumps did not reduce the rate of serious medication errors in this study. This was probably the case, in part, because the pump setup made it easy for nurses to bypass the drug library and because overrides were frequent. Thus, we believe that no benefit was found because of the pump design and unforeseen clinical practices that included many violations.

These study findings are in contrast to recent studies in which we have demonstrated that decision support during computerized physician order entry significantly reduced serious ordering and transcription medication errors (12). In the computerized physician order entry intervention, the old paper order system was entirely replaced, but in this intervention, we did not achieve consistent use of smart pumps' new technological safety advances. On the other hand, we were able to uncover correctable unsafe practices such as administering many potent medications without documentation of physician verbal orders and the use of very high rates for certain drugs that we had not previously been aware of except on an anecdotal basis and which would have been difficult or impossible to quantitate through other mechanisms.

Safe medical practice depends on institutional (systems) factors such as standardization of medication concentrations and knowledgeable clinicians at the sharp end (9). Intravenous medication and fluid administration in critically ill patients are complex multiple-step processes that provide many opportunities for errors (19). Infusion pumps, similar to other complex medical devices and tools designed to improve patient care, may not always be used as intended and may result in unforeseen and unintended consequences (20).

Human factors engineering such as pump interface design (21) has improved the safe use of intravenous infusion pumps. Current infusion pumps provide additional improvements over older models. Important safety advances include mechanisms to nearly eliminate the risk of free-flow, which has caused many fatalities (22). Other features such as enhanced programming options, convenience, and portability, although desirable, add complexity that may increase the risk of unsafe medication delivery (23). To attempt to "engineer out" errors, some of the newest smart pumps have features including drug/dose calculations, programmable volume and time calculations, improved alarms and indicators, and most, recently, inclusion of drug- or patient-specific decision support capabilities (24.)

In addition to improving safe drug delivery, human factors design is critical to speedy adoption and correct use of technologies such as infusion pumps (25). This involves making it easy to "do the right thing." A surprising unintended consequence found in this study was the infrequent use of the drug library. The default at the beginning of the study was not to use the drug library, and in fact during the intervention periods nurses only used the library 75% of the time and as infrequently as 31% for propofol, a high-risk medication. The extra programming for nurses to use the drug library proved to be an important barrier to library use compliance. As a result of these data, the drug library was subsequently made the default and the library was expanded. Some hospitals report that 98% of intravenous drugs are now administered this way (R. P. Maddox, personal communication, May 26, 2004).

To date there have been few prospective studies of medication safety associated with intravenous infusion pumps. Several studies and incident reports have described ADEs associated with the use of pumps, including medical device reports to the Food and Drug Administration (22, 26–29). Most of the reported infusion pump-related events were associated with human error rather than device failure. Similar hazardous programming errors have been reported with other infusion devices such as patient-controlled analgesia pumps (30). A recent ethnographic study of intravenous drug errors found that overly rapid administration of bolus doses was the most common error, but infusion pumps were infrequently used when boluses were given (31). The role of nurses in patient safety has recently received increased attention, especially with regard to nursing education levels and staffing conditions (33–35). New technology can present

challenges to existing nursing practices including potential workflow disruption (36). But such technology may also potentially save time, freeing nurses to engage in other tasks, which would be expected to result in safer care.

Successful adoption and correct use of the pump's safety features are critical to pumps' effectiveness in improving medication safety. Nurses need to be able to use these devices seamlessly and quickly to make sudden changes in infusion therapy for unstable patients. In an effort to meet these challenges, nurses may be taking shortcuts, or work-arounds (20), that violate safe intravenous infusion practice. Polet et al. (37) found that similar actions often result in errors in other industries. In medicine, and especially in ICUs, heavy workload pressures and acutely decompensating patient situations may result in risky behaviors such as alert override violations (37). Taxis and Barber (38) suggested that deliberate guideline violations such as excessively fast intravenous drug bolusing are due to a lack of perceived risk, poor role models, and available technology (e.g., no forcing function such as hard limits). Feedback analyses followed by adaptive constraints such as hard limits are potential solutions to these unsafe infusion practices (37).

The capture of bedside medication programming history in log recordings is an important benefit of smart pumps because this allows objective measurement of infusion practices, which can then be used to provide staff feedback. Logs can serve like "black-box" flight recorders to capture sentinel events. Logs can also be used to monitor several nursing practices including complaint use of the drug library and reducing overrides of drug dosing alerts.

Improving medication administration safety requires not only well-designed technological tools but demonstrable institutional support and behavioral improvements. Our analysis of the potential impact of smart pumps used under more "ideal" conditions is an additional important analysis. In response to the study findings and after learning of nursing practice violations, we have been able to address some of the contributing factors to violation behaviors (Table 6).

TABLE 6

Medication Errors That Were Not Detected by the Smart Intravenous (IV) Infusion Pumps and Potential Prevention Strategies

Error Stage	Example	Error Type	Prevention Strategy
Ordering	A physician accidentally orders dopamine at 15 μg/kg/min when the intended order was 1.5 μg/kg/min. The alert limit was set at 20 μg/kg/min	Incorrect dose but not outside the dosing alert limits	CPOE with decision support guidelines and dosing recommendations
Transcription	Dopamine was ordered but dobutamine was accidentally administered instead	Incorrect dose was transcribed or administered	CPOE, BCMA, and wireless connectivity to IV pump
Administration	Nesiritide was not yet entered into the drug library database and was programmed as a generic drug at a rate of 30 μg/kg/min rather than 0.03 μg/kg/min or a 1000-fold overdose	Error associated with a drug that was not in the IV pump's drug library	Up-to-date maintenance of IV pump library and drub formulary
Administration	Insulin ordered at 0.5 units/hr but administered at 5.0 units/hr; alert limit was 20 units/hr	Error in drug administration but was not outside the alert limits	CPOE, BCMA, and wireless connectivity to IV pump
Administration	Patient weighs 140 pounds but the nurse enters 140 kg, resulting in a 2.2-fold dosing error, but still below the alert limit	Weight-based dosing error but the resulting dose was not outside the alert limits	CPOE, BCMA, and wireless connectivity to IV pump
Administration	Amrinone was in the drug library but the nurse bypassed the library and the drug was entered as a "generic" drug without being evaluated by the library's amrinone alert limits	Bypassing the drug library and not allowing the pump to evaluate the drug	Improved practices eliminates bypassing of drug library
Administration	Nurse administers propofol bolus at 500 μg/kg/min for 5 mins despite alerts for a maximum propofol rate of 50 μg/kg/min	Overriding the IV pump warning alerts	Improved practices eliminates overrides of dosing alerts
Monitoring	Heparin infusion rate increased from 1000 to 1200 units/hr, PTT was not checked for 12 hrs and then found to be > 150	Incorrect drug monitoring	Improved compliance with protocol for anticoagulation monitoring
Monitoring	Insulin drip at 2.5 units/hr and not held per protocol for glucose of 80. Next glucose is 65 and the patient was treated with 50 g IV dextrose	Protocol deviation	Improved compliance with protocol for glycemic monitoring

CPOE, computerized order entry; BCMA, bar-coded medication administration; PTT, partial thromboplastin time.

Interventions to improve our infusion practices included nursing and physician education to eliminate undocumented verbal orders; changing the workflow to make it easy to use the library, including a new pump interface automatically encountering the drug library rather than having to seek the library with additional keystrokes; expanding the library from 40 to 100 drugs for each clinical service; using an anesthesia mode for seamless transfer from the operating room to the ICU without reprogramming; providing education to increase user knowledge about the library and the safety features of the DS; adding an "indication for use" to the drug selection mode and adding clinical advisories during drug selection; changing the application to decrease the likelihood of programming errors that were more common with the new pumps; and expanding the pump's capability to better handle boluses.

This study had several limitations. The study was conducted on the cardiac surgical service in a single hospital and may not be generalizable to other critical care settings. A randomized control trial, although a more preferable study design, could not be safely implemented because the infusion pumps were initiated in the operating room, therefore making it clinically unsafe to change the pumps of unstable patients on arrival to the ICUs. The time-series design could have been associated with a temporal trend improvement that reduced the impact of the DS, although we did not see an improvement over the two control periods. Medication errors that were neither intercepted nor reported to the staff were determined from chart review and pump log reports. In the absence of direct observation or bar coded medication administration, we cannot be certain that the infused drug matched the medication that was documented by nurses into the medical administration record and ICS flow sheet. As described earlier, the extent of alert overrides and library bypasses may have reduced the effectiveness of the DS intervention. Our power for detecting a decrease in the rate of life-threatening errors, such as a ten-fold overdose of heparin, was limited because of their low frequency. Finally, any new technology such as smart pumps may also cause unanticipated safety risk (39), although no such risks were found in our study.

CONCLUSIONS

We found that there were many problems with infusion safety in critically ill patients that were under- or unrecognized before implementation of smart pumps. Although we found no impact on the serious error rate, we did identify important errors. To substantially improve infusion safety, it will be necessary to both refine the technologies involved and carefully consider human performance aspects of the intravenous infusion process.

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