Programmable Infusion Pumps in ICUs: An Analysis of Corresponding Adverse Drug Events

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BACKGROUND: Patients in intensive care units (ICUs) frequently experience adverse drug events involving intravenous medications (IV-ADEs), which are often preventable.

OBJECTIVES: To determine how frequently preventable IV-ADEs in ICUs match the safety features of a programmable infusion pump with safety software ("smart pump") and to suggest potential improvements in smart-pump design.

DESIGN: Using retrospective medical-record review, we examined preventable IV-ADEs in ICUs before and after 2 hospitals replaced conventional pumps with smart pumps. The smart pumps alerted users when programmed to deliver duplicate infusions or continuous-infusion doses outside hospital-defined ranges.

PARTICIPANTS: 4,604 critically ill adults at 1 academic and 1 nonacademic hospital.

MEASUREMENTS: Preventable IV-ADEs matching smart-pump features and errors involved in preventable IV-ADEs.

RESULTS: Of 100 preventable IV-ADEs identified, 4 involved errors matching smart-pump features. Two occurred before and 2 after smart-pump implementation. Overall, 29% of preventable IV-ADEs involved overdoses; 37%, failures to monitor for potential problems; and 45%, failures to intervene when problems appeared. Error descriptions suggested that expanding smart pumps’ capabilities might enable them to prevent more IV-ADEs.

CONCLUSION: The smart pumps we evaluated are unlikely to reduce preventable IV-ADEs in ICUs because they address only 4% of them. Expanding smart-pump capabilities might prevent more IV-ADEs.

KEY WORDS: drug therapy; medication error; prevention and control; infusion pump; decision making, computer-assisted; critical care.

INTRODUCTION

Preventable adverse drug events involving intravenous medications (preventable IV-ADEs: injuries owing to intravenous medication errors) occur frequently in intensive care units (ICUs). Preventable IV-ADEs occur in 29% of drug-related harms and are typical of many medication errors. Preventable IV-ADEs are preventable if medication errors can be identified early. This identification requires the ability to track and verify the correct dosage and route of medication. Smart pumps have been designed to alert medical staff to potential errors by displaying alerts if continuous-infusion doses exceed hospital-defined ranges or if a pump is programmed to deliver duplicate infusions.

Three studies indicate that the reprogramming of smart pumps in response to alerts occurs frequently. However, because most medication errors happen not to cause harm, the ability of smart pumps to reduce IV-ADEs also warrants investigation. One study evaluated whether smart pumps prevent IV-ADEs and found no significant decrease. No studies have assessed how often preventable IV-ADEs actually match smart-pump safety features or whether expanding pump capabilities might prevent additional types of IV-ADEs.

In this study, we sought to determine how frequently preventable IV-ADEs match one smart pump’s features and to identify additional smart-pump capabilities. Our ultimate objective was to compare preventable IV-ADE incidence rates between smart pumps and conventional pumps.

METHODS

Overview

We used quantitative and qualitative methods to examine preventable IV-ADEs in adult ICUs before and after 2 hospitals replaced conventional pumps with smart pumps.

Setting and Subjects

With assistance from the study sponsor (Cardinal Health, San Diego, CA, USA), we selected 2 hospitals that had implemented their smart pumps in 2003 (Alaris version 5): an academic hospital in the northeast and a nonacademic hospital in the west. We examined 20,000 bed-days of care in surgical,
Smart-Pump Features
A programmable unit within the pump controlled up to 4 attached infusion devices and recorded ("logged") programming errors, alerts, reprogramming events, and overrides. Before implementation, study hospitals developed software libraries for drugs given by continuous infusion; bolus dosing was not addressed. The manufacturer suggested dosing limits then hospitals made modifications. ICU libraries included over 50 drugs.

Nurses could program the pumps as if they were conventional or use the library’s safety features. Once in the library, nurses selected a drug and standard concentration then entered the dose. For weight-based dosing, nurses entered patient weights and doses, then the software calculated flow rates. When doses exceeded library limits or duplicate infusions were programmed, the software provided alerts and prevented infusion until they were addressed; overrides were permitted.

Data Collection
This included abstracting medical records and rating suspected ADEs. We did not observe pump use or abstract smart-pump logs.

Critical care nurses (4–5 per hospital; uninvolved in study participants’ care) received 4-day trainings in medical-record abstraction and ADE identification (reading manuals, discussing examples, and reviewing sample records). During data collection, nurses recorded clinical and demographic data then used manual trigger-tool review (which uses key words as sentinels to identify ADEs) plus implicit review (professional judgment) to identify suspected ADEs and any events that infusion pumps might have caused. For each suspected ADE, they summarized relevant details of medication therapy, errors, and injuries. Reliability assessment involved reabstracting 100 records.

Four board-certified Internal Medicine physicians (unaffiliated with study hospitals) rated suspected ADEs. Two reviewed each electronic summary individually then met to reach consensus, rating whether an ADE occurred, drugs involved, routes/modes of administration, preventability, errors involved, and whether errors matched smart-pump functions at each hospital (i.e., whether continuous-infusion doses were outside library limits or present in multiple infusions). Reliability assessment involved randomly selecting 50 suspected ADEs.

Quantitative Analysis
We used SAS version 9.1.3. First, we examined administration routes/modes, drugs, stages in delivery, and errors involved in preventable IV-ADEs overall. Second, we calculated incidence rates (preventable IV-ADEs per 1,000 patient-days in ICU) for preventable IV-ADEs matching smart-pump functions in each study period. Third, we compared total preventable IV-ADEs incidence rates between conventional-pump and smart-pump periods using Poisson regression models that included multiparameter demographic and clinical variables. We had 80% power (alpha=0.05) to detect a 46% change. Finally, we determined intraclass correlations for nurse and physician ratings.

Qualitative Analysis
For events matching smart-pump features, we summarized errors involved. For other events, we summarized examples of common errors and explored additional smart-pump capabilities.

RESULTS
Among 4,604 patients with 20,559 bed-days in ICU, we identified 100 preventable IV-ADEs (4.86 per 1,000 patient-days). Half of preventable IV-ADEs involved continuous infusions and 40% boluses. Morphine, insulin, leuprolide, and propofol represented 44% of all drugs involved. Half of errors occurred during ordering, 14% during administration, and 35% during monitoring. Failure to intervene, failure to monitor (37% combining subtypes, not shown), and overdose were common errors (Table 1). Two preventable IV-ADEs in each study period (4%, 0.19 per 1,000 patient-days) matched smart-pump functions at each hospital (Table 2). No pumps caused any injuries.

As noted in the Introduction, our ultimate objective was to compare total preventable IV-ADEs incidence rates between conventional-pump and smart-pump periods. However, given that few preventable IV-ADEs matched smart-pump features, statistical power was severely inadequate. The conventional-pump rate was 4.78 per 1,000 patient-days and the smart-pump rate was 4.95 (adjusted mean difference 0.04 per 1,000 patient-days, p=0.96).

Event descriptions suggested that expanding smart-pump library applications, integrating pumps with vital-sign and laboratory data, integrating pumps with computerized physician order entry (CPOE), and automating medication titration

Table 1. Types of IV Medication Errors Causing Preventable IV-ADEs in Both Study Periods Combined

| Errors | Non-Smart-Pump | Smart-Pump | Total Preventable |
|--------|----------------|------------|------------------|
| Improper dose: overdose, no. (%) | 29 (29.0%) | 59 (59.0%) | 88 (88.0%) |
| Improper dose: undose, no. (%) | 3 (3.0%) | 2 (2.0%) | 5 (5.0%) |
| Improper dose: extra dose, no. (%) | 0 (0.0%) | 1 (1.0%) | 1 (1.0%) |
| Wrong strength/concentration: too high, no. (%) | 1 (1.0%) | 0 (0.0%) | 1 (1.0%) |
| Wrong rate, no. (%) | 1 (1.0%) | 1 (1.0%) | 2 (2.0%) |
| Wrong duration, no. (%) | 4 (4.0%) | 4 (4.0%) | 8 (8.0%) |
| Improper dose: underdose, no. (%) | 3 (3.0%) | 4 (4.0%) | 7 (7.0%) |
| Improper dose: overdose, no. (%) | 29 (29.0%) | 59 (59.0%) | 88 (88.0%) |
| Improper dose: underdose, no. (%) | 3 (3.0%) | 2 (2.0%) | 5 (5.0%) |
| Improper dose: overdose, no. (%) | 29 (29.0%) | 59 (59.0%) | 88 (88.0%) |
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*Each preventable IV-ADE may be associated with more than 1 type of error.

IV-ADE = adverse drug events involving intravenous medications
Table 2. Qualitative Analysis of Errors Causing Preventable IV-ADEs

| IV-ADE Description                                                                 | Description of Smart-pump Features                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Preventable IV-ADEs matching existing smart-pump functions at the same hospital and  | Practice standardization: After smart pumps implementation, 1 mg/mL was the only concentration of labetalol used in ICUs at this hospital.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| existing smart-pump functions                                                      | Overdose detection: Smart pumps at this hospital alerted nurses when labetalol infused at a dose above 120 mg/h.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Preventable IV-ADEs matching existing smart-pump functions at the same hospital and  | Overdose detection: Smart pumps at this hospital alerted nurses when labetalol infused at a dose above 120 mg/h.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| existing smart-pump functions                                                      | Duplicate medication detection: Smart pumps at this hospital alerted nurses when labetalol was administered concurrently in 2 different lines.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Examples of common preventable IV-ADEs and expanding pump library capabilities      | Overdose detection: Smart pumps at this hospital alerted nurses when labetalol infused at a dose above 120 mg/h.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| to prevent additional IV-ADEs                                                      | Overdose detection: Smart pumps at this hospital alerted nurses when labetalol infused at a dose above 120 mg/h.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Failure to intervene: A middle-aged female on morphine PCA pump for postoperative  | Modifications to intercept errors: For patients on IV opiates, a smart pump could detect when IV antiemetics are given and alert nurses that switching opiates should be considered.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| pain experienced 3 episodes of vomiting. She received 3 doses of ondansetron and 1  | Modifications to intercept errors: For patients on IV opiates, a smart pump could detect when IV antiemetics are given and alert nurses that switching opiates should be considered.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| of promethazime. After 24 h, the opiate was changed to hydromorphone and the       | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| vomiting stopped.                                                                  | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Overdose: An elderly female with a stroke and a systolic blood pressure in         | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 190s received 2 doses of IV hydralazine 20 mg 5 min apart. She developed           | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| hypotension and a severe brain stem infarct.                                      | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Examples of common preventable IV-ADEs and incorporating real-time vital-sign or    | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| laboratory test data to prevent additional IV-ADEs                                | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Overdose, failure to monitor, failure to intervene: An elderly male was given       | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 100 mcg IV fentanyl bolus and propofol infusion at 35 mcg/kg/min for a bedside     | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| procedure. Blood pressure dropped to 60 s systolic. He received 250 mL of normal    | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| saline, but propofol was not changed. Blood pressure was rechecked 90 min later     | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| and was still in 60 s systolic.                                                    | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Failure to monitor, failure to intervene: An elderly female was started on an IV   | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| heparin infusion for acute myocardial infarction. Daily PTT results were repeatedly  | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| above therapeutic range. Dose was lowered but PTT was not repeated until the next    | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| day when it was still high. Patient developed a retroperitoneal hematoma and died.  | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Failure to monitor: An elderly female with end-stage renal failure was a given     | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| standard insulin infusion protocol to manage her blood glucose but no glucose was   | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| provided via the enteral route or IV. Her blood glucose dropped to 33 then rebounced  | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| to over 200 after glucose was given.                                              | Modifications to intercept errors: For patients on IV hydralazine, a smart pump could track cumulative doses, have limits per designated period of time, and alert nurses if doses exceeded these limits.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

IV-ADE = adverse drug events involving intravenous medications, PTT = partial thromboplastin time
might prevent additional IV-ADEs (Table 2). The intracluster correlation for nurses identifying suspected events was 0.39. Physician intracluster correlations were: for ADEs, 0.71; preventability, 0.90; and smart-pump preventability, 1.0.

DISCUSSION

Examining preventable IV-ADEs among 4,600 adult ICU patients, we found that only 4% could be intercepted by a smart pump that detects duplicate and excessive doses of continuous infusions. There were several reasons for the low rate of corresponding events: these pumps did not address boluses, the dosing ranges appeared too wide for certain patients, and monitoring problems were more common than administration ones. Nevertheless, we observed that expanding pump functions and integrating them with real-time clinical data might enable smart-pump technology to reduce other common, harmful errors.

Four evaluations of similar smart pumps came to more positive conclusions. Comparing 426 infused medications with physician orders during a 9-hour period, researchers judged 1 error to be smart-pump-preventable because it was a rate-deviation error involving a pump-programming mistake.13 Three studies examining smart-pump logs found that reprogramming events, assumed to be intercepted errors, were common.5,7

Because errors have unpredictable relationships to injuries, however, preventable IV-ADEs must also be examined; for example, 0.9% of medication errors caused ADEs in medical floor units versus 11% in cardiac ICUs.2,8 A controlled trial evaluating a similar pump did consider preventable ADEs and found no significant reduction, because of limited power and because nurses used its safety features inconsistently.8

In contrast, our analysis revealed that substantially reduc-

preventable IV-ADEs in ICUs would require smarter pumps. Many preventable IV-ADEs involved failures to monitor for or adequately respond to undesirable medication effects. Smart-pump technology could alert nurses to such failures by integrating infusions with CPOE, and real-time vital-sign and laboratory data. Perhaps more controversially, smart pumps could automate some titration tasks. Intensive insulin infusions seem particularly amenable to automation because complex protocols create many opportunities for error; clinical assessment is rarely required; and an automated technique for tightly controlling blood glucose, the euglycemic glucose clamp, already exists.14 Others have described closed-loop systems for titrating sedatives.15

The manufacturer of the pumps we evaluated has already expanded applications to include boluses, syringe pumps, and patient-controlled analgesia. An integrated bar-code reader has been designed to address wrong-patient and wrong-drug errors. A patient-controlled analgesia pump monitors oxygen saturation and end-tidal carbon dioxide, issuing an alert or shutting off if values deviate from hospital-defined ranges (Butterfield, personal communication, 2006).

As with any technology, new smart-pump capabilities have potential barriers to overcome. Integration with bar coding and CPOE assumes that hospitals are adopting these technologies, which may not be the case.16 Incorporating real-time vital-sign data may require nursing practice changes. Integration with laboratory data would require software development. Automating monitoring and titration tasks would reduce nurses’ opportunities to practice these skills.17 Finally, new safety technologies can introduce new errors.18 Consequently, expanding smart-pump applications will require careful development and testing.

Regarding limitations, we may have underestimated events matching smart-pump functions because we could not evaluate smart-pump logs or observe users. Nursing agreement was only fair, possibly owing to insufficient training or reabstracting too few records; other studies have not reported nurse agreement. However, we used standard methods and documented physician agreement comparable to prior studies.19 We studied 2 hospitals, 1 clinical setting, and 1 time period. Smart-pump technology is evolving rapidly and future research should include non-ICU settings, where IV-ADEs may not be detected quickly.

CONCLUSIONS

The smart pumps we evaluated are unlikely to reduce preventable IV-ADEs in ICUs because they address only 4% of them. Expanding smart-pump capabilities might prevent more IV-ADEs.

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Conflict of Interest: Funding for this project was provided to RAND by Cardinal Health (formerly Alaris Medical Systems). Jeffrey M. Rothschild consulted for Aptima, Inc: 2004–2005. The other authors reported no conflicts of interest.

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