

Assessing Medication Safety Technology in the Intensive Care Unit

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Understanding the strengths and weaknesses of a technology in the context of the distributed system in which it is working is critical to assessing and improving the performance of that system. Taking a systems approach requires knowledge about how all agents in a system work together to achieve the goals of that system. With these aims, the alerting mechanism of infusion pumps containing Dose-Error Reduction Software (DERS) was studied to determine its effectiveness in the Intensive Care Units (ICU's) of three hospitals. In 1,146 of the 9,557 pump alerts (12.0%), the alert caused the clinician to change the input. Of these, 1,030 were changed to within the hospital's recommended dosing limits. The alert was overridden for 8,400 (88.0%) of the alerts. The data show that this technology successfully informed clinicians over 1000 times that unintended doses had been inputted and stopped those doses from reaching the patient, thereby averting potential Medication Events. The data also suggest that, because nearly 90% of the alerts were overridden, a well-intended and valuable alert may be perceived by the clinicians as a false alarm and may be overlooked. Another key finding from this analysis was that clinicians may have used potentially unsafe workarounds to administer intravenous drug boluses (i.e., more rapid infusion of a defined dose or volume) and to keep the patient's line active between infusions. In a separate parallel study, clinician self-report of potentially harmful medication events was studied. During 559 hours of direct observation, clinicians detected 27 (IV and non-IV) medication events. All of the reported events were outside of the scope of what DERS technology was designed to detect. In addition, during the same time period the technology detected five potentially harmful IV medication events that the clinicians did not report. The results of these two studies indicate two possible classes of solutions that could reduce the impact and likelihood of medication administration errors. One class of solutions involves the procedures and policies of the hospital, ensuring that process and technology implementations are optimally tuned, taking human performance and the current practice of the clinicians into account. The other class of solutions involves using new strategies and technologies to ensure that each system agent has access to other agents' perspectives, and the broader system's perspective. Studies such as these can provide insight into the use of safety technology during critical care processes and provide direction for future research, including more effective design of alerting mechanisms of ICU devices.

INTRODUCTION

In a modern hospital's intensive care unit (ICU), clinicians must face many competing demands. In addition to patient diagnosis, patient treatment, and requests from other clinicians, the technology in the ICU continues to demand more attention. This technology has been put in place not only to perform certain patient care procedures, including the medication administration, but also to alert the clinician to the possibility of a situation that could be dangerous to a patient and to assist the clinician in responding to and ameliorating such situations.

However, there is a real cost associated with the increasing use of technology in the ICU. To effectively use modern medical technology, clinicians must employ their clinical experience and knowledge to operate the technology. The multitudes of devices in a typical ICU are built by diverse manufacturers for various purposes, with little or no recognition of each others' existence. These devices often use very different alerting and interaction paradigms. Yet, to assure high-quality patient care, ICU clinicians must expertly assimilate all of the devices into complicated care processes. The successful integration of these technologies requires extra attention, increasing mental workload while reducing time and attention resources dedicated to other critical clinical tasks.

The problem is exacerbated by the high level of uncertainty in the care of critically ill patients and imperfect physiological sensors on which the devices rely. While alarms and other alerting mechanisms have been widely implemented in medical devices, the problem of false alarms (Weinger, 2000; Weinger and Smith, 1993) has been well described.

Dose-Error Reduction Software

Because of the recognized importance of medication errors in patient safety (Institute of Medicine, 2001), a new type of alerting mechanism has recently been introduced in intravenous (IV) infusion pumps, known as Dose-Error Reduction Software (DERS) (Keller, et. al., 2006). This software was designed to mitigate the risk of slips and mistakes committed by the clinician while programming the pump. With DERS, a hospital specifies upper and lower limits for drug administration (i.e., rate or dose) which are then implemented in every pump in that hospital. When a clinician attempts to program the pump to deliver a drug dose outside of these prescribed limits, the pump gives a visual and audible alert, thereby critiquing the clinician. When presented with a soft alert, the clinician is expected to use clinical judgment to determine if the programmed dose was an inadvertent programming error, or if the patient's clinical condition warrants the overrides of the alert. Alerts that effectively

notify the clinician of an unintended dose substantially improve patient safety, since intravenous drug administration errors has been associated with a high risk of patient harm (Wilson and Sullivan, 2004; Williams and Maddox, 2005).

However, there has not yet been a rigorous study in the DERS literature of the relative proportion of “useful” alerts vs. those of little use (i.e., because the alert was of limited relevance to the specific clinical situation). Moreover, alerting technology, especially when it provides incorrect or already known information, can be frustrating to clinicians and add to their workload. In addition, when faced with dysfunctional processes or technology (e.g., perceived added work without added value), humans will often develop workarounds (Woods and Hollnagel, 2006) that can actually make work processes less safe.

Finally, data are still limited as to the extent to which DERS actually prevents serious medication errors. Current methods of detecting and analyzing medication errors are fraught with limitations including under-reporting, misreporting, and hindsight bias. Clinicians significantly underreport medical errors (Barach and Small, 2000) and alternative detection methods are either costly (direct observation, chart review) or limited in scope (computer-generated clinical triggers) (Weinger, et al., 2003). In theory, DERS should eliminate a large proportion of intravenous medication errors associated with manual data entry. Such errors could be due to incorrect clinical decisions (wrong dose selected), mental computation errors, keystroke errors, or user interface related use errors (e.g., mistaking weight field for dose field). Moreover, DERS can help hospitals standardize IV medication practices by informing (i.e., soft limits) or constraining (hard limits) individual clinicians to institution-wide medication dosing practices. Another advantage of DERS is that the software captures each alert and the clinician’s response to that alert, thereby allowing a hospital to understand the effectiveness of the DERS limits that it has programmed into the pumps.

Questions regarding the role of safety technology (including DERS) in the ICU need to be more broadly framed. Fundamentally, we are interested in human-technology collaboration to enhance useful work. Such a framing raises more general questions: What are the optimal methods for designing and implementing technology into complex processes? What are the consequences of suboptimal design and implementation of this technology? More specifically, how can alerting systems be designed to provide users with useful information in a timely and non-disruptive manner? These types of inquiries fall within the domain of cognitive systems engineering and are amenable to its methods.

Background on infusion pumps

Infusion pumps are used to deliver fluids, medication or nutrients into a patient’s circulatory system. Infusions are generally administered intravenously, although subcutaneous, arterial, and epidural infusions are administered for specific indications.

Infusion pumps have a central processing unit (CPU) that controls one or more infusions. Each infusion must be set-up

individually by a clinician, typically a nurse. Set-up includes configuring the disposable plastic tubing, inserting it into the pump module, and programming the pump with infusion-specific information (e.g., drug, volume, concentration), using the CPU. Then, the nurse inputs the desired dosage with a 10-digit keypad. This dose is shown on the display of the pump module.

Overview of current studies

The DERS and medication event data analyzed here represent a sub-analysis of data obtained as part of a much larger study of hospital medication errors. The *a priori* study hypotheses were that: 1) DERS alerts would be effective, and that 2) DERS would detect more potential IV medication events than would nurse self-report.

Two studies were performed. The first study sought to understand the effectiveness of the alerts generated by DERS in three hospital ICU’s. Effectiveness was defined as the proportion of alerts that caused the clinician to change the course of treatment (i.e., reprogram the pump to dose that fell within DERS defined limits).

The second study sought to look at the alerting and communication capabilities of the broader distributed system, which includes clinicians, processes and technology. To understand that context, nurses were directly observed by a trained researcher. After the observation period, a brief structured interview was performed to elicit information about specific Medication Events that occurred during the observation period. A Medication Event (ME) was defined as a “significant deviation in optimal medication processes” (Weinger and Slagle, 2006; Weinger, et al., 2003). A subset of the pump alert data gathered as part of the first study, directly corresponding with the observation periods, were analyzed and compared with events reported by the nurses. In this way, the detection abilities of the pump were framed against the backdrop of the knowledge and abilities of the clinicians.

METHOD

After receiving IRB approval and clinician informed consent, the two studies were performed in four San Diego hospitals. Included were the capture of DERS data, ecological momentary assessment of physicians and nurses (reported elsewhere), direct structured observation of ICU nurses (reported elsewhere), and observer-facilitated surveys of ICU nurse reports of ME’s.

Study 1: Effectiveness of DERS alerts

Infusion pump data were downloaded from all pumps used in 3 ICU’s (3 hospitals) as part of the larger study. DERS logs included entries when a clinician programmed a dose outside the predetermined hospital limits (the automatic data collection system used to access these data unfortunately only logged this type of event, so that that is all that could be studied on a large scale). These data included the event that triggered the alert and subsequent clinician interaction with

the pump to either confirm or change the original dose that triggered the alert.

For each event, the pump's serial number, the type of event, the programmed dosage, the DERS dosage limits, the date and time of the event, and other attributes were collected.

The clinician's initial response to each alert was categorized into one of four mutually exclusive categories:

1. Changed the input to within the pump's recommended limits (defined as an effective alert);
2. Changed the input, but to a value still outside of the pump's recommended limits (also defined as an effective alert);
3. Confirmed the original input (causing drug infusion to begin), but changed the input to within the pump's recommended limits within two minutes.;
4. Confirmed the original input (causing drug infusion to begin), and did not change the input to within the pump's limits within two minutes.

The third and fourth categories were divided post hoc after preliminary data analysis of the data discerned a pattern. Input from subject matter experts (which was and validated by direct observations of ICU nurses) suggest that in category 3 events, the pump may have been used to perform a manual bolus, a behavior that may have been an unsafe workaround. A bolus is a large dose of medication given over a short time period. Even in DERS-enabled pumps that have a feature that automates the administration of a bolus, clinicians have been observed to temporarily administer the IV drug at a very high infusion rate, initially override the alert displayed by the pump, then shortly thereafter reduce the dosage to within the recommended limits when the intended bolus dose has been administered. The safety risk is that if the clinician is distracted or interrupted during this uncontrolled bolus process, the patient could receive an unintended (and potentially lethal) over-dosage.

Study 2: Medication Events captured during observation periods

For the second study, observational data were collected from the same ICU's in the same three hospitals. During 153 approximately 4-hour observation periods, a trained observer followed an ICU nurse, recording and categorizing all of the nurse's tasks using custom software (Fraind, et. al., 2002). These data are analyzed and reported elsewhere (Weinger and Slagle, 2006). Concurrently, the identity of each pump attached to each patient being cared for over time by the observed nurses was documented to associate the task data with the pump alert data.

At the end of each observation period, the observer administered a structured survey to the ICU nurse (Weinger and Slagle, 2002). The observer asked a series of questions to determine if a "Medication Event" had occurred during the observation period. If an ME occurred, its perceived etiology and consequences were noted.

Each ME was categorized using the National Coordinating Council of Medication Error Reporting and

Prevention scale for categorizing errors (A to I), which is used to measure the resulting harm to the affected patient (NCC MERP, 2006).

ME's were additionally categorized into one of the following two categories:

1. The ME could have been detected earlier or prevented by making information that was present somewhere in the system more readily available to the clinician.;
2. Information that would have allowed the ME to be detected or prevented earlier was not present anywhere in the system.

The DERS alert log was culled to capture only those alerts that occurred during the observation periods. When comparing the DERS alerts to the ME data, any alert that resulted in an input change (thereby implying that the pump alert averted a potentially harmful situation for the patient) was categorized in the MERP scale as a Category B error. Any alert that initially was confirmed but was adjusted within two minutes (the "manual bolus" described above) was categorized as a Category A error, meaning that the patient's care was not judged to be suboptimal, but this method of using the pump increased the risk of suboptimal care, also increasing the future risk of patient harm.

RESULTS

Study 1: DERS alerts

In 1,030 (12.0%) of the 9,557 DERS alerts recorded, the alert caused the clinician to change the input. The remaining 8,411 alerts resulted in the clinician confirming their original input (88.0%).

For those alerts that did result in a pump programming change, 1,030 inputs (89.9%) were changed to doses that fell within the technology's recommended limits. Only 116 (10.1%) were changed to values that were still outside of the pump's recommended limits. The DERS alerts that caused the clinician to change the originally inputted dose imply that the technology assisted the clinician in detecting and correcting a data entry or dosing error. For example, in one event, the clinician inputted a dose of 6050 mcg/kg/min. After the DERS alert, the clinician immediately changed the dosage to 50. Because inputted dosages, before and after the alert, had oscillated between 50 and 60 mcg/kg/min, it is reasonable to assume that this alert occurred due to an inadvertent double entry (60 and 50).

For overridden alerts (i.e., the clinician confirmed their original input), 3,699 alerts (representing 39% of all alerts), although initially confirmed, were readjusted to within the pump's recommended limits in less than two minutes (implying that a manual bolus had been performed). Supporting this interpretation is that all of these alerts were for dose rates significantly above the recommended limits and that most (90%) of these initial inputs were more than ten times the subsequent adjusted input.

The remaining 4,712 (56%) of the overridden alerts were not readjusted to within the DERS's recommended limits in the study dataset. Of these alerts, 2,201 (46.7%) were "below

limit” with the remainder (53.3%) being “above limit” alerts. The overridden “below limit” alerts most likely result in delivering sub-therapeutic doses, which is generally discouraged. There are two likely behaviors that can explain this. The first is that the confirmation of the “below limit” dose was unintended, and can be categorized as a slip or mistake. It can also be explained by a clinician workaround. For a drug infusion to be “kept active” so that it can be used in the near future, a very low (essentially inactive) dose will be programmed rather than turning off the infusion and later having to reprogram a new (identical) infusion. Even though there is a restore function on some of the pumps that alleviates this problem, this workaround also appears to be common.

Study 2: Nurse-reported and DERS-detected alerts during observation periods

The 153 observation periods ranged from 2.7 to 4.6 hours. During the 559 hours of observation data, for the 194 infusion pumps used by the observed ICU nurses and roughly 3,000 interactions with the pumps (totaling an aggregate of 14.8 hours of interaction), only 5 DERS alerts were registered. Only one of these resulted in the clinician changing the input (20%). In the remaining alerts, the clinician confirmed the initial input but never changed it (80%). For two of these, the clinician initially confirmed the inputted dose, but adjusted it within the recommended limits within two minutes (i.e., a manual bolus dose).

The data gathered in the surveys following the observations yielded 27 ME's, all of which were outside the scope of what the technology was designed to detect. Twenty-five ME's had enough information to be categorized by severity (NCC MERP, 2006). Two (8%) did not reach the patient (Category B). Twenty (80%) reached the patient but did not cause harm (Categories C and D), although five of these required extra monitoring to ensure that no harm was done to the patient. Three (12%) caused patient harm (Categories E through H), one of which required an intervention necessary to sustain the patient's life.

The intravenous ME's included: 1) Low blood pressure after increasing an infusion of propofol (an intravenous sedative) during an out-of-ICU imaging procedure; 2) A two-fold excessive dose error for an infusion ordered as “do not titrate”; and 3) Low blood pressure when, during patient repositioning, the intravenous line containing the infusion of a drug to maintain blood pressure became occluded.

For these same 25 ME's, 19 (76%) could have been detected earlier or prevented if information present somewhere else in the system had been available to the clinician(s) directly responsible for patient care. In the remaining six (24%), no information was available in the system that would have allowed the situation to be detected earlier or prevented.

DISCUSSION

Informative pump alerts

When a DERS alert was generated, the clinician changed the pump's programming 12% of the time. This represents

over 1000 averted potential medication errors in these three ICU's, indicating the significant value of DERS in current infusion technology. These results provide new knowledge about the degree in which safety technology assists clinicians in this complex task domain.

Overridden pump alerts

Eight-thousand four-hundred eleven alerts were overridden, raising questions about the DERS technology analyzed in this study. If we assume that this high proportion of overrides could cause the clinician to perceive them as false alarms, this increases the chances that the clinician could overlook a valid and important alert, or unintentionally confirm the entered dose, overriding the pump alert (Woods and Hollnagel, 2006; Woods, 1995; Pritchett, 2001).

One possible explanation for the frequent overriding of DERS alerts is that the hospital set its alert limits too narrowly, thus detecting virtually all unintended doses (i.e. high sensitivity), but creating a large number of uninformative alerts (i.e. low positive predictive value). This would most likely put the DERS limits at odds with the current practice of the clinicians. If the system could enable hospital management to (1) see and discern patterns in clinicians' override behavior and (2) expeditiously change often-overridden prescribed limits, it would most likely reduce clinician overrides.

It is also possible that uninformative alerts (including false alarms) occur because there is only one set of limits for a given drug in a given ICU. If the pump were more context-aware, such as having access to as the patient's history and current medications or the type of procedure that was being performed, it might be better tuned to decrease overridden alerts.

Finally, 44% of these alerts (3,699) may have been harbingers of an unsafe practice: the use of an uncontrolled rapid infusion rate to give boluses of a drug. Although some of the infusion pumps had an automated bolus feature, clinician self-reports suggest that it was not always used. Further work should examine why such features are unused and how technology can better support real clinical needs including bolus dosing, tubing priming, fewer air-in-line alerts, and piggyback (second) drug dosing.

Assessment of clinician-detected Medication Events

It is perhaps not surprising that only one effective pump alert (out of five total pump alerts) was registered over the same time period as 27 ME's reported by the clinicians. After all, the many of the ME's reported by the clinicians were unrelated to IV medication infusion. They spanned the entire medication process, including administration (for IV and oral medications) as well as dispensing and delivery of those medications to the ICU. DERS, however, is primarily designed to capture infusion pump programming errors as well as some IV drug dosing errors. It typically will not detect other pump errors such as programming the wrong pump or loading the wrong drug (e.g., if the pump is still using dosage limits of the drug the pump thinks is loaded). Moreover, DERS is not designed to detect adverse drug reactions (one of

the nurse-reported ME's), non-infused medications (i.e., IV push or oral drugs), logistical problems (drug not available when needed), and most prescribing or pharmacy dispensing errors. In fact, preliminary data suggest that, patient-specific information (e.g., allergies, other medications) is unavailable to it, current implementations of DERS technology may only be able to prevent about one-quarter of all intravenous drug errors, and perhaps less than five percent of all adverse drug events.

When analyzing the 25 clinician-detected ME's that could be categorized, our analysis indicates that 19 (76%) could have been detected earlier in the treatment process or prevented. In analyzing these preventable ME's, two themes emerged.

Theme 1 – Plan Conflict: Different clinicians formed conflicting treatment plans for a given patient, resulting in less than optimal treatment. This accounted for 74% of the events that could have been detected earlier or prevented. In the distributed work setting of the ICU, these plan conflicts were not initially evident, as each clinician had different goals, responsibilities, and perspectives for the treatment of the patient. Nine of these cases involved a conflict between the time that a patient needed to receive a medication (the nurse's plan) and the time that the medication was available (the pharmacist's plan). This discrepancy may be due to pharmacy workload, inefficient workflow, or the pharmacists' failure to adequately anticipate the ICU's needs. These events could be prevented with better coordination.

Theme 2 – Plan-Action Disparity: In 26% of preventable ME's, there was an unintended conflict between the overall treatment plan and the actions of one or more clinicians. In these, the clinicians' actions did not match their intent. Examples included mislabeled medications, incorrect medications being sent to the ICU, and one situation in which a patient's IV line was pulled out.

Unfortunately, the ME's that were associated with the greatest patient harm generally could not have been foreseen by the clinicians. For example, it is improbable that there was any information in the system that could have warned the clinicians about the adverse drug reaction events. In these circumstances, research and design efforts should be focused on the planning and communication activities that facilitate rapid detection and response to potentially harmful situations.

All of the ME's that were detected by the clinicians were found by comparing the current situation with the plan (and expected response) for that patient. This suggests the need to develop more effective ways to access information about goals and plans of the other "agents" in the system, including the supporting technologies. This point reinforces the notion that for technology to be an effective part of a system, it must be a partner that communicates in ways that meet the humans' needs and abilities.

The results of these studies need to be validated with further observational research and usability testing. A better understanding of clinicians' interactions with infusion pumps would be gained by study of how dosages are programmed and how "special features" are really used by clinicians during the complexity of actual care. Specifically, the usage of the bolus feature on the pump needs to be better understood.

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