

Quantifying the Impact of Infusion Alerts and Alarms on Nursing Workflows: A Retrospective Analysis

Denny Yu^{1,2} Marian Obuseh^{1,2} Poching DeLaurentis²

¹School of Industrial Engineering, Purdue University, West Lafayette, Indiana, United States

²Regenstrief Center for Healthcare Engineering, Purdue University, West Lafayette, Indiana, United States

Address for correspondence Poching DeLaurentis, PhD, Regenstrief Center for Healthcare Engineering, Purdue University, Gerald D. and Edna E. Mann Hall, Suite 225, 203 S. Martin Jischke Drive, West Lafayette, IN 47907, United States (e-mail: poching@purdue.edu).

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Abstract

Background Smart infusion pumps affect workflows as they add alerts and alarms in an information-rich clinical environment where alarm fatigue is already a major concern. An analytic approach is needed to quantify the impact of these alerts and alarms on nursing workflows and patient safety.

Objectives To analyze a detailed infusion dataset from a smart infusion pump system and identify contributing factors for infusion programming alerts, operational alarms, and alarm resolution times.

Methods We analyzed detailed infusion pump data across four hospitals in a health system for up to 1 year. The prevalence of alerts and alarms was grouped by infusion type and a selected list of 32 high-alert medications (HAMs). Logistic regression was used to explore the relationship between a set of risk factors and the occurrence of alerts and alarms. We used nonparametric tests to explore the relationship between alarm resolution times and a subset of predictor variables.

Results The study dataset included 745,641 unique infusions with a total of 3,231,300 infusion events. Overall, 28.7% of all unique infusions had at least one operational alarm, and 2.1% of all unique infusions had at least one programming alert. Alarms averaged two per infusion, whereas at least one alert happened in every 48 unique infusions. Eight percent of alarms took over 4 minutes to resolve. Intravenous fluid infusions had the highest rate of error-state occurrence. HAMs had 1.64 more odds for alerts than the rest of the infusions. On average, HAMs had a higher alert rate than maintenance fluids.

Conclusion Infusion pump alerts and alarms impact clinical care, as alerts and alarms by design interrupt clinical workflow. Our study showcases how hospital system leadership teams can leverage infusion pump informatics to prioritize quality improvement and patient safety initiatives pertaining to infusion practices.

Keywords

- smart infusion pumps
- analytics
- clinical workflows
- alerts
- alarms

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Georg Thieme Verlag KG,
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Background and Significance

Infusion pumps are medical devices that deliver medication, fluids, and nutrients in a precise, timely, and controlled manner that is critical to patient care. They are widely used across both inpatient and outpatient care settings to provide critical and life-saving care for illnesses that span the range of dehydration to cancer. Smart infusion pumps are those equipped with dose error reduction systems (DERS) that can alert users of programming mistakes (e.g., drug dose error by applying preset drug limits) and operation errors (e.g., occlusion in intravenous lines). These safety features have facilitated the adoption of the smart infusion pump in U.S. hospitals with a rate of nearly 90% in 2017.¹

To understand the varying impact of smart infusion pumps on patient care, many studies have explored the care provider and work system perspective, for example, technology design, usability, and sociotechnical system integration.^{2–15} Although some investigators have shown that automated smart infusion pumps improve perceived safety, workflows, and workloads compared with manual pumps, many studies highlighted concerns of the technology's impact on use errors, suitability across the wide range of use environments, and workflow efficiencies.¹⁶ Moreover, even though smart infusion pumps have the technological capabilities to reduce the incidence of adverse drug event and medication administration errors,¹⁷ they could also be a potential source of patient harm.^{4,6,7,11,18–22} These show that smart pumps might have limited effects on improving patient safety.^{7,22}

The extent of smartness of DERS depends on the dosing limit set in the drug library. Errors in these limits can lead to programming alerts that are disruptive to nursing workflows. Drug limits with wide ranges can potentially decrease the frequency of alert occurrence, whereas more stringent limits can ensure adequate patient safety. The balance between such efficacy and efficiency of a smart pump is largely reliant on the hospital system's risk management strategy. The Institute for Safe Medication Practices (ISMP) recommends that hospital systems routinely review and revise their dose limit settings in the drug library to reflect changes in available infusion supplies, clinical practices, or patient populations.²³

Smart infusion pumps have a significant impact on care environments and care providers' workflow. By design, they issue alerts and alarms to users. However, these audio- or visual-based alerts and alarms can worsen the information overload situation already experienced by clinicians. Moreover, clinicians have to address each of these infusion alerts and alarms, thus distracting and disrupting their workflow. One study found 64% of perioperative monitor alarms in patients undergoing anesthesia to be clinically irrelevant.^{24,25} These clinically irrelevant alarms disrupt clinical workflows, compete for the health care provider's attention, and can be troubling to patients. In addition to disrupting workflows, a bad alarm system implementation can lead to alarm fatigue and, in some cases, contribute to patient deaths.^{26,27}

Multiple factors that adversely affect nursing staff's experience with smart infusion pumps, including technical performance issues, alarm fatigue, and usability, have been

identified.^{6,25} Many efforts to study these issues have been qualitative,^{28–31} and interviews performed by researchers revealed numerous local nursing workarounds to address mismatches between infusion pump interface design and patient care requirements.^{32–34} Such workarounds are significant concerns and may jeopardize patient safety.³² In addition, some quantitative and mixed method approaches to studying these issues have also been reported.^{32,35–37} One study identified the volume of infusion alarms specific to critical short half-life infusions to evaluate user response times to these alarms.³⁸ In another study, formal central infusion monitoring and environmental changes in a neonatal intensive care unit (NICU) were found to reduce alarm fatigue, improve reaction time, and improve preempting of avoidable alarms.³⁹ These efforts are critical in improving nursing workflows, patient safety, and overall health care delivery.

Objectives

This study aims to leverage the wealth of infusion event data recorded by the smart infusion pump to understand the impact of infusion alerts and alarms on the care provider's workflow during live use in dynamic and complex clinical settings. Specifically, we examine the following with our dataset:

- Risk factors that influence the occurrence of infusion programming alerts.
- Risk factors that influence the occurrence of infusion operational alarms.
- Contributory factors to long alarm resolution times that disrupt clinical workflows.

Methods

Dataset

The dataset used for this study was from a member health system of the Regenstrief National Center for Medical Device Informatics (REMEDI) community of practice over a 1-year period, within the past 5 years. REMEDI consists of a collaborative community of 400+ hospitals that contribute infusion data to CatalyzeCare.org, a big data management hub maintained by the Regenstrief Center for Healthcare Engineering at Purdue University. The dataset contained infusion events from one specialty hospital and three community hospitals. The infusion pumps of this health system were not interoperable with the electronic health record (EHR) system at the time of data collection. The infusion data were fully de-identified and contained only infusion event data.

Continuous full-day time-stamped "all-infusion detail report" data were extracted from the Alaris System (Alaris System, BD/CareFusion, San Diego, CA⁴⁰). In this study, we defined an infusion to be a series of infusion events grouped by a unique infusion identifier (ID) assigned by the pump system. Exclusion criteria (including incomplete and unreasonable records, patient-controlled analgesia, and keep-vein-open infusions) were applied to 808,445 infusions, resulting in 745,641 unique infusions used for the analysis.

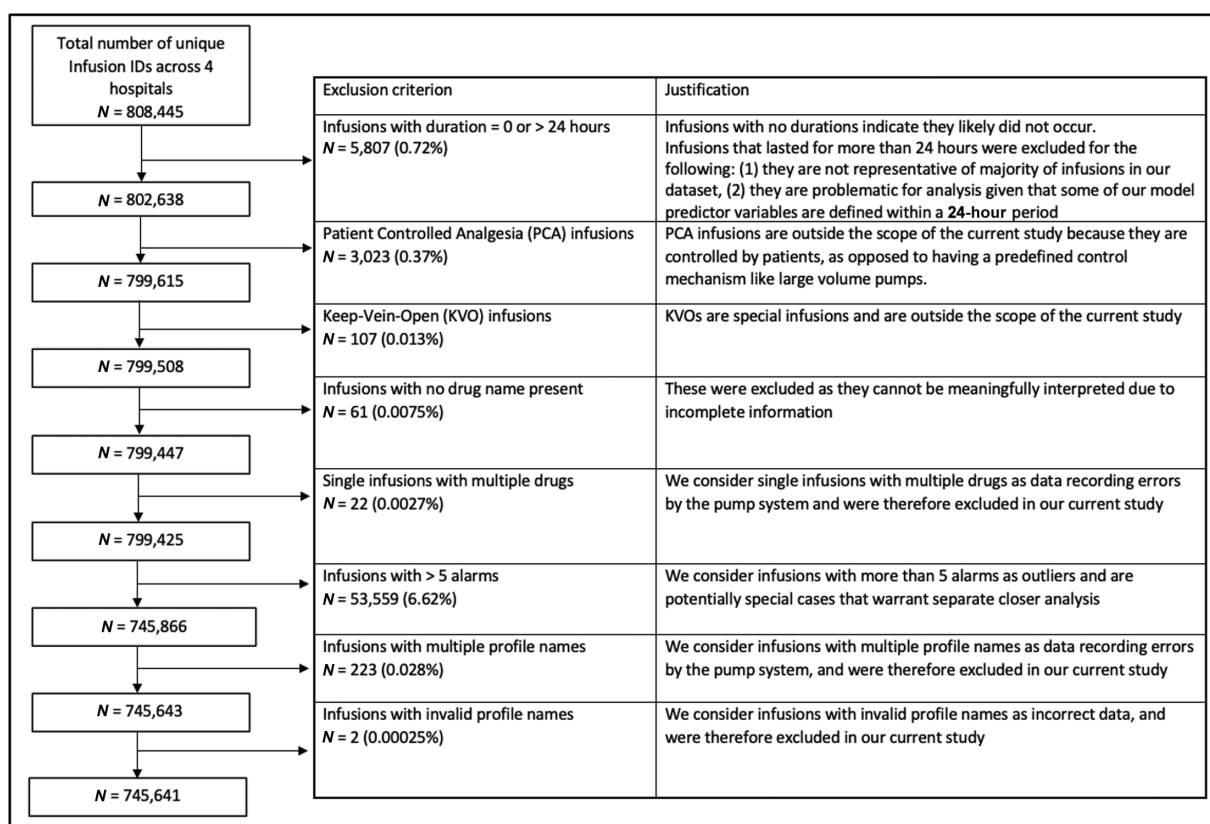


Fig. 1 Exclusion criteria and justifications for the all-infusion dataset.

(→Fig. 1). This dataset had 40 variables describing the state of the infusion pump, the type or nature of the infusion, and the state of each infusion event.

On the infusion pump, an alert sounds and visually appears on the screen when the programmed infusion parameters exceed the drug's preset limits, whereas an alarm occurs when an ongoing infusion is physically or operationally interrupted (such as due to air-in-line or occlusion). For the purpose of this study, we deemed alerts and alarms as undesirable "error states" during an infusion process because they are deviations from normality, require troubleshooting steps and clinicians' extra cognitive attention, and interrupt clinical workflows.

Data Analysis

All the analyses in this study were done with R⁴¹ in the RStudio integrated development environment.⁴² We used descriptive statistics, generalized linear models (specifically logistic regression), and nonparametric tests for the all-infusion dataset in the study. Nonparametric post hoc tests were performed for multiple pairwise comparisons. We identified three dependent variables for the models used in this study: (1) presence of alerts, (2) presence of alarms, and (3) alarm resolution times.

Some key variables like drug name, infusion type, event start time, event reason, alarm type, etc., were extracted from the data used in this study. From these key variables, new features including shift and day of infusion as derived

Table 1 Custom variables derived from the all-infusion dataset

| Derived variables | Definitions | Frequency observed |
|-----------------------------|-------------|--------------------|
| Institution | Hospital 1 | 207,960 |
| | Hospital 2 | 68,757 |
| | Hospital 3 | 288,745 |
| | Hospital 4 | 180,179 |
| Shift | Dayshift | 213,522 |
| | Nightshift | 114,880 |
| | Overlap | 417,239 |
| Day of the week | Weekday | 576,777 |
| | Weekend | 168,864 |
| High-risk medication | Yes | 173,297 |
| | No | 572,344 |
| Total infusion duration (h) | Hospital 1 | 398,084 |
| | Hospital 2 | 171,691 |
| | Hospital 3 | 575,951 |
| | Hospital 4 | 392,665 |
| Date range (months) | Hospital 1 | 12 |
| | Hospital 2 | 12 |
| | Hospital 3 | 8 |
| | Hospital 4 | 11 |

from infusion timestamps, total infusion duration, etc., were derived (→ **Table 1**). We categorized all infusions that started from 6 a.m. and ended before 6 p.m. as occurring during the dayshift, whereas those that started from 6 p.m. and ended before 6 a.m. as occurring during the nightshift. An infusion that spanned across both day and night shifts (starting in the dayshift and ending in the nightshift and vice versa) was categorized as shift “overlap.” Infusions spanning through Monday to Friday were categorized as occurring during the weekday, whereas those spanning from Saturday to Sunday were categorized as occurring during the weekend. We curated a list of 32 high-alert medications (HAMs) commonly used in hospital settings based on the American Society of Health-Systems Pharmacists (ASHP) Standardize 4 Safety (S4S) initiative list of high-risk adult continuous infusion drugs (→ **Supplementary Table S1** [available in the online version]).⁴³

All predictor variables used in the models were selected by experts (clinical and health researchers). → **Table 2** lists and describes each of these variables and their justification

for inclusion in the models. Multicollinearity across the predictor variables for the generalized linear model (GLM) was checked using the generalized variance inflation factor (GVIF) where each GVIF value was raised to the power of (1/2 df) for comparability across dimensions⁴⁴ (df = predictor variable degree of freedom). Because this value is analogous to the square root of the usual VIF,⁴⁵ we square it and apply the usual VIF rule of thumb.

The three study objectives were addressed as follows:

- **Risk factors for alerts:** A logistic regression model was used to explore the relationship between the predictor variables and the occurrence of alerts at the infusion programming stage. The predictor variables in the model for alerts include hospital, care unit, shift, HAM, and day. The binary response variable for this model was coded as 0 (absence of an alert during programming) and 1 (presence of at least one alert during programming).
- **Risk factors for alarms:** A logistic regression model was used to explore the relationship between the predictor

Table 2 Predictor variables and justifications

| | Predictor variable | Justification |
|---|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Institution | Modeling this predictor variable accounts for institutional effects that can potentially affect our response (e.g., presence of alerts and alarms) and human factors and systems engineering focused predictor variables, e.g., shift and days of the week |
| 2 | Profile | Identifying critical care profiles at the highest risk of infusion-related errors can help determine areas to focus medication safety efforts. ²⁰ This can lead to minimized alerts and alarms and seamless nursing workflows. We model this variable to further corroborate the literature on the effect of care settings on nursing workflows |
| 3 | Shift | Researchers have studied the effects of day and night shifts on clinicians' cognitive functions, fatigue level, attention, and performance. ^{57–59} One study also found that with each successive hour that passed in a nurse's shift, response time to monitor alarms in a pediatric hospital was slower. ⁶⁰ We also understand that night shifts tend to be more understaffed than day shifts in hospitals. This is mostly anecdotal but very widely accepted. Therefore, we model this variable to address any variability of these shift situations and routines and to avoid trend bias |
| 4 | Day of the week | A recent study reported higher average number of alarms on Saturdays and Sundays and thought it warranted further investigation. ³⁶ We also understand that the weekend shifts tend to be less staffed than weekday shifts in hospital settings. We model this variable to further investigate its effect on the presence of alerts and alarms as well as alarm resolution times |
| 5 | High-alert medication (HAM) | Identifying HAM drugs as recognized by the ASHP ⁴³ as a potential predictor variable that can affect the occurrence of alerts corroborates the literature while shedding more light on how they can disrupt workflows |
| 6 | Number of alerts | We model whether or not the presence of an alert before an infusion has any effect on the presence of alarms during the infusion |
| 7 | Infusion duration | For medications with short half-life, there is a tradeoff between flow rate and time to occlusion alarm. Flow rate is a function of volume-to-be-infused (VTBI) and infusion duration. One study reported long times to occlusion alarm in peristaltic infusion devices at low flow rates. ⁶¹ We model this variable to further investigate any relationships between infusion duration and the presence of alarms |
| 8 | Infusion type | Different types of infusions (e.g., intermittent or continuous) might potentially affect the presence of alarms during an infusion. We consider this variable to get more insights into the effects of the various infusion types in the dataset on alarm occurrences |
| 9 | Alarm type | Depending on the nature of alarm encountered during an infusion, alarm resolution times might differ. ⁵⁴ We model this variable to determine which operational alarm types might affect alarm resolution times |

Table 3 Infusion alarmed dataset exclusion criteria

| | Criterion | Justification |
|---|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Excluded 77,016 (17.9%) unresolved/cancelled infusions | These were excluded because alarm resolution times could not be calculated from these infusions. This could be due to incomplete data capture by the pump system |
| 2 | Excluded 17,605 (4.1%) infusions alarmed with zero resolution time | These were excluded because zero resolution times are not physically feasible. This may be due to data capture issues and require closer examination |
| 3 | Excluded 33,563 (7.8%) infusions with alarm resolve time greater than the 90th percentile, i.e., outliers | These were excluded because of very long resolution times that could skew our results |
| 4 | Excluded 16,151 (3.8%) infusions due to missing pump values (incomplete data point) | These were excluded because of incomplete data possibly caused by pump data capture error |

variables and the occurrence of alarms during infusion. The following were the independent variables for this model: hospital, care unit, shift, infusion type, HAM, day, number of alerts, and infusion duration. The binary response variable for this model was coded as 0 (absence of an alarm during an infusion) and 1 (presence of at least one alarm during an infusion).

- **Alarm resolution times:** As a result of non-normal alarm resolution times across all alarmed infusions, a nonparametric alternative to the analysis of variance (ANOVA) was used. Specifically, Kruskal-Wallis tests were conducted to evaluate the differences among factor levels of some predictor variables on alarm resolution times. We applied some exclusion criteria to the alarmed infusion dataset before conducting these tests (→Table 3). The tests were corrected for tied ranks and Dunn's nonparametric post hoc tests were also performed for multiple pairwise comparisons across factor levels. The evaluated independent variables include alarm type, shift, and day.

Results

A total of 3,231,300 infusion events corresponding to 745,641 unique infusion IDs were observed for 1,538,391 total hours of infusion (an average of 2.06 hours per infusion) across the four facilities. Overall, 28.7% of all unique infusions had at least one operational alarm and 2.1% of all unique infusions had at least one programming alert.

Alert and Alarm Prevalence by Infusion Type

About 30% of all unique infusions encountered at least one error state. Grouped by infusion type, fluid infusions had the highest percentage of error-state occurrence (31%; →Table 4). Intermittent infusions were the most common infusion type in the dataset (33% of all infusions) with ~30% of them encountering an error state. Thirty-one percent of basic infusions, which are administered without using DERS, had alarms. By definition, basic infusions do not trigger programming alerts. Continuous/bolus infusions were the least common (18% of all infusions) and had the lowest percentage of error-state occurrence (27%).

Approximately 70% of infusions encountered no error states. However, ~29% of the infusions had at least one alarm event that required the caregiver's attention. Prevalence of alerts was lower than that of alarms at 1.5% of all unique infusions (→Table 4). Finally, a very small percentage of infusions had both an alarm and an alert (0.6%).

High-Risk Medications

Alert and alarm prevalence varied for the 32 HAMs, as well as maintenance fluids (→Supplementary Table S1 [available in the online version]). These 32 high-risk drugs represented 17% of all infusions, and 24% of HAM infusions encountered at least an alert or an alarm. Propofol, heparin, insulin regular, fentanyl, and norepinephrine combined accounted for 58% of all HAM infusions. About 2.5% of all HAM infusions had programming alerts, whereas less than 0.1% of

Table 4 Prevalence of error-free and error-state infusions in all-infusion dataset by infusion type

| Infusion type | Error free | | Error state | | | | | Total infusion by type (% of total) |
|-------------------------------|-----------------------|---------------|---------------|---------------|--------------------|----------|------------|-------------------------------------|
| | No alert/ no alarm | % of total | Alarm only | Alert only | Alert and alarm | Subtotal | % of total | |
| Basic infusion | 147,753 | 68.6 | 67,723 | 0 | 0 | 67,723 | 31.4 | 215,476 (28.9) |
| Intermittent infusion | 174,619 | 69.8 | 66,528 | 6,698 | 2,466 | 75,692 | 30.2 | 250,311 (33.6) |
| Fluid infusion | 101,901 | 68.9 | 44,421 | 914 | 555 | 45,890 | 31.1 | 147,791 (19.8) |
| Continuous/ bolus infusion | 96,354 | 73.0 | 30,665 | 3,532 | 1,512 | 35,709 | 27.0 | 132,063 (17.7) |
| Subtotal | 520,627 | 69.8 | 209,337 | 11,144 | 4,533 | 225,014 | 30.2 | 745,641 |

maintenance fluids had such alerts. About 22% of all HAM infusions had operational alarms, whereas ~33% of maintenance fluids had such alarms.

Risk Factors Modeling and Analysis

Separate models were developed to address the objectives of this study. Results showed that all the variables used in the logistic regression models had VIF < 6, which suggested that multicollinearity was not a concern⁴⁶ [–Supplementary Material Tables S2 and S3, available in the online version].

Presence of Alerts

Care unit (profile), shift, day of the week, and HAM were significant predictors ($p < 0.01$) of alerts (–Table 5). The institution was not a statistically significant predictor variable in the model. Respectively, the odds of an alert were 1.79 and 2.13 higher for infusions in the pediatrics and labor/delivery profile than those in the adult medical/surgical profile. A medication infusion in the HAM list of this study was 1.64 times more likely to have a programming alert when com-

pared with all other infusions in the study dataset. For each of these odds ratio comparisons considered, all other predictor variables are kept constant (–Table 5).

Presence of Alarms

Institution, care unit (profile), shift, infusion type, HAM, infusion duration, and number of alerts were significant predictors ($p < 0.05$) of alarms (–Table 6). The day of the infusion was not a statistically significant alarm predictor. The odds of an alarm occurring are slightly reduced in the labor and delivery profile than in the adult medical/surgery profile (odds ratio = 0.92). The odds of an alarm occurring during infusions that span across shifts was 2.68 times more than those during the dayshift. Primary intermittent infusions were 1.68 times more likely to have an alarm than fluid infusions. For every 1-hour increase in the infusion duration, there was a 7% increase in the odds of an alarm occurring. For each of these odds ratio comparisons considered, all other predictor variables are kept constant (–Table 6).

Alarm Resolution Time

Mean number of alarms observed per unique infusion was 2.01 for a total of 430,585 alarm events. After applying all exclusion criteria, the data for this model had 286,250 alarm events. We defined alarm resolution as the process of an infusion moving from an alarm error state to an alarm error-free state. Therefore, this resolution time includes a wait time between when an alarm sounds and when the nurse gets to the patient's bedside to address it. This captures the disruptions caused by infusion alarms on clinical workflows as both wait times and actual time spent resolving alarms translate to an interruption in the nurse tasks at hand. In the study dataset, a total of 12,822.5 hours elapsed between when alarms sounded and when they got resolved. This translates to a total of 10 to 13 hours of nursing time for alarm resolution in a day for the community hospitals. For the specialty hospital in the study, it means a total of 2 hours of nursing time in a day was spent on alarm resolutions. These are concurrent and may include the wait times for nurses to get to the bedside to address these alarms. Mean resolution time for 74.5% of the alarms in the study dataset was ≤ 1 minute. However, ~8% of alarms took more than 4 minutes to get resolved.

Kruskal–Wallis tests were conducted to evaluate differences among the types of operational alarms encountered during infusion, nursing shifts, and days on median change in alarm resolution times. The tests, corrected for tied ranks, were all significant for each independent variable at $p < 0.001$:

$\chi^2(11, N = 286,250) = 33,858$, $\chi^2(2, N = 286,250) = 6,071.6$, and $\chi^2(1, N = 286,250) = 358.74$

Follow-up Dunn's tests were performed to evaluate pairwise differences among the 12 types of alarms, 3 levels of shifts, and 2 groups of day variables. Type 1 errors across tests were controlled by Bonferroni's correction. Not all pairs of alarm types were statistically significant and median resolution times were longest for both cumulated air-in-line and

Table 5 Logit model coefficient estimates, odds ratios for alert occurrence (keeping other predictors constant), and corresponding p -values for predictor variables (with presence of alert as dependent variable)

| | Coefficients | Odds ratio | p -value |
|---------------------------------------------|-----------------|------------|------------|
| Intercept | –3.65 | 0.03 | 0.00 |
| Institution | | | |
| Institution 2 | Reference group | | |
| Institution 1 | –0.22 | 0.80 | 0.00 |
| Institution 3 | –0.22 | 0.80 | 0.00 |
| Institution 4 | –0.05 | 0.95 | 0.11 |
| Profile | | | |
| Adult medical/surgical profile | Reference group | | |
| Adult intensive care unit (ICU) | –0.32 | 0.73 | 0.00 |
| Labor and delivery | 0.76 | 2.13 | 0.00 |
| Nursery | 0.10 | 1.11 | 0.00 |
| Pediatrics | 0.58 | 1.79 | 0.00 |
| Shift | | | |
| Day shift | Reference group | | |
| Night shift | –0.41 | 0.66 | 0.00 |
| Overlap shift | –0.01 | 0.99 | 0.00 |
| Day of the week | | | |
| Weekday | Reference group | | |
| Weekend | –0.16 | 0.86 | 0.00 |
| High-alert medication (HAM) | | | |
| All drugs not on the HAM list in this study | Reference group | | |
| HAM | 0.50 | 1.64 | 0.00 |

Table 6 Logit model coefficient estimates, odds ratios for alarm occurrence (keeping other predictors constant), and corresponding *p*-values for predictor variables (with presence of alarm as dependent variable) logit model

| | Coefficients | Odds ratio | <i>p</i> -value |
|---------------------------------------------|-----------------|------------|-----------------|
| Intercept | −1.58 | 0.20 | 0.00 |
| Institution | | | |
| Institution 2 | Reference group | | |
| Institution 1 | 0.11 | 1.12 | 0.00 |
| Institution 3 | 0.08 | 1.08 | 0.00 |
| Institution 4 | −0.03 | 0.97 | 0.01 |
| Profile | | | |
| Adult medical/surgical profile | Reference group | | |
| Adult intensive care unit (ICU) | 0.00 | 1.00 | 0.90 |
| Labor and delivery | −0.09 | 0.92 | 0.00 |
| Nursery | −0.52 | 0.59 | 0.00 |
| Pediatrics | −0.67 | 0.51 | 0.00 |
| Shift | | | |
| Day shift | Reference group | | |
| Night shift | −0.05 | 0.95 | 0.00 |
| Overlap shift | 0.99 | 2.68 | 0.00 |
| Infusion type | | | |
| Fluid infusion | Reference group | | |
| Basic primary infusion | −0.08 | 0.92 | 0.00 |
| Basic secondary infusion | −0.59 | 0.56 | 0.00 |
| Continuous/bolus infusion | −0.01 | 0.99 | 0.13 |
| Drug Calculation Continuous/Bolus infusion | −0.60 | 0.55 | 0.00 |
| Primary intermittent infusion | 0.52 | 1.68 | 0.00 |
| Secondary intermittent infusion | −0.57 | 0.56 | 0.00 |
| Day of the week | | | |
| Weekday | Reference group | | |
| Weekend | 0.01 | 1.01 | 0.39 |
| High-alert medication (HAM) | | | |
| All drugs not on the HAM list in this study | Reference group | | |
| HAM | −0.53 | 0.59 | 0.00 |
| Infusion duration | 0.07 | 1.07 | 0.00 |
| Number of alerts | −0.06 | 0.94 | 0.00 |

patient-side occlusion alarms and shortest for door-close alarm ($p < 0.001$). All pairs of shift levels were statistically significant ($p < 0.001$) and median alarm resolution times were the longest for overlap shifts compared with both day and night shifts. Finally, median alarm resolution times were longer for weekends than weekdays.

Discussion

Infusion pump data analytics and human factor contributions continue to be an important area of research to reduce medication-related patient safety events. To minimize potential harm in clinical settings, the Association for the Advancement of Medical Instrumentation (AAMI), the U.S. Food and Drug Administration (FDA), and the ISMP have highlighted several patient safety priorities for use of infusion pumps, including establishing processes for analyzing infusion incidents, mitigating use errors, and understanding use environments.^{16,25} In this work, we leveraged big data available from smart infusion pumps and identified risk factors for programming alerts and operational alarms. Specifically, we analyzed infusion data from four hospitals and quantified infusion alert and alarm impact on nursing workflows, examined their potential effect on patient safety, and determined their associative factors related to patients and health care providers. This showcased how infusion pump informatics can facilitate our understanding of user-pump interactions in the highly dynamic and complex clinical setting.

Our analysis discovered a high prevalence of error-state occurrences of programming alerts and operational alarms during infusion pump use. An infusion alarm signals a physical issue that has stopped the ongoing infusion and requires the clinician's time and effort to resolve it. Unlike other types of alarms that occur in clinical settings, studies have shown that infusion pump alarms are unique because they require the caregiver's presence and interaction with the pump to resolve the alarm.^{35,47} In the study dataset, alarms averaged 2.01 times per infusion for a total of 745,641 infusions and 430,585 alarm events. Similar alarm analysis done with a different vendor infusion pump reported an average of 1.74 alarms per infusion for a total of 568,164 infusions and 987,240 alarm events.³⁶ This shows that even with differences in vendor infusion pumps and number of infusions delivered, infusion pump alarms are prevalent in clinical settings. Other studies have also reported this high prevalence of infusion pump alarms across various clinical settings.⁴⁸ Specifically, ~8% of the alarms took more than 4 minutes to resolve. These lengthy resolutions of infusion alarms can draw time away from other clinical tasks or interrupt the nurse's task at hand. Long infusion interruptions are even more undesirable as medications that have a short half-life for effectiveness require rapid alarm resolution, imposing an additional time pressure on clinicians.³⁸

The findings of this work provide additional insights into the impact of smart infusion pump alerts and alarms on nursing workflows. Infusion alerts and alarms are mechanisms designed to aid medication administration by drawing

caregivers' attention to issues that can potentially affect a patient's safety. However, there are tradeoffs between protecting patients and maximizing nursing workflow efficiency since alerts and alarms cause infusion interruptions. Because time and efficiency constraints are critical in busy, stressful, and very high-risk clinical settings, incessant infusion interruptions are undesirable. Smart infusion alarms add to an environment that is already saturated with other medical technologies that generate alarms. One study reported medical staff members in an intensive care unit (ICU) being repeatedly exposed to an average of 45.5 alarms per patient per hour, and infusion pumps contributed to almost 10% of the total alarm burden.³⁷ Consequently, large volumes of infusion pump false alarms can contribute to the alarm fatigue problem in these environments and lead to clinicians getting desensitized to these warnings. These alarms also sound at high decibels that can potentially lead to rest or sleep interruption and cause concern, annoyance, confusion, or burnout to patients.^{49,50} These issues can expand clinicians' roles and duties, erode their trust in medical technologies, and lead to stress and dissatisfaction.⁵¹ Therefore, hospital systems should create efficient risk management strategies that prioritize safe infusion processes for patients and clinicians alike.

Although the rate of infusion alert was lower than that of alarms in the dataset, alerts also had an impact on nursing workflows as they occurred at least once in every 48 unique infusions, for a total of 22,568 alert interruptions. These interruptions occurred during infusion programming steps, some of which resulted in reprogramming attempts. We recognized a portion of them may be "good catches" that averted potential patient harm. However, an increased alert rate can also contribute to the alert/alarm fatigue and desensitize clinicians' safety awareness. This may result in the clinician's override of an alert without proper confirmation. It may also contribute to ~30% of non-DERS (i.e., "basic infusions") use observed in the dataset as a way to avoid undesired alerts deemed by clinicians as disturbances. This fell short of the ISMP safe infusion guidelines of targeting 95% use of DERS,²³ and it indicates the need for more nursing education and trainings.

In this study, we found that more alerts occurred during the programming attempts of the selected HAMs—1.64 times more likely to occur than other drugs; other factors held constant. Since no standards have been established regarding an optimal alert rate, individual hospitals often conduct their own infusion practice reviews. If a drug's alert rate is deemed too high, the hospital needs to evaluate its limit settings. In some cases, these settings might not be in line with clinical use, or some nurses might not be well informed of the hospital's practice. We also observe higher frequencies of alarms and alerts for infusions that span across shifts in comparison to those during day shift. In particular, alarms were 2.68 times as likely to happen during infusions that span across shifts than during dayshift; other factors held constant. This may be attributed to issues around nursing handoffs (because of shift change) or increased patient movement during specific hours that lead to obstruction of

infusion flow. As seen in one study, implementing a mandatory alarm parameter checklist during nurse staffing handoffs might reduce the incidence of more alarms during infusions that span across shifts.³⁵

Researchers have investigated the incidence of infusion pump alarms and alerts in different care units.^{11,37,50} This study also performs similar analysis to investigate the effect of care unit on the occurrence of alerts and alarms. Our analysis showed that the odds for infusion alerts in labor/delivery profiles were 1.79 and 2.12 times higher than those in adult medical/surgical profiles; other factors held constant. Alarms were also as likely to occur in labor/delivery profiles as in adult medical/surgery profiles. These may be good indicators of higher complexity of medication use and patient conditions in the labor/delivery and similar units. One study reported a high volume of alerts clustered around specific patients and mediations in a NICU.⁵² This can potentially lead to a high alert burden and limit DERS safety benefit by desensitizing nurses to these alerts. Another study found that due to line occlusions, drug incompatibilities, and patient factors, alarms from infusion pumps were frequent in the NICU/pediatric ICU.⁵³ This also implies that more training or special coordination is required of nursing staff in those units with respect to infusion administration.

Our analysis also showed that "door-close alarm" had the least effect on alarm resolution times. This is reasonable since "door-close alarm" simply signals that the pump door was properly closed after it opened during an infusion. We also notice that "cumulated air-in-line alarm" had one of the most significant effects on alarm resolution times. This aligns with our understanding of the physics of such alarms. They are caused by a large number of air bubbles in the infusion line which are detected by the pump sensor. It requires significant effort and time to clear the infusion line (including potentially priming) and resolve the alarm. An increased rate of occurrence of these alarms may require further investigation of the root cause. Depending on its exact nature, potential interventions include nursing education/training on spiking and priming processes, allowing cold intravenous solutions to warm before handling, and adding assisting devices such as an antisiphon valve (ASV). These have shown to be effective in reducing air-in-line for some drugs.⁵⁴

Although the independent variables used in our models are not exhaustive, our analysis identified some system variables that might be attributing to the presence of alerts and alarms and longer alarm resolve times. Since these are disruptive, they lead to clinical workflow interruptions. In 2005, Brixey et al showed that workflow interruptions in clinical settings are multidimensional across person-device and person-person interruptions, the physical layout of workspaces, and work practices within departments.²⁸ Factors like how fatigued clinicians are (gotten through psychophysiological measures), the pump maintenance culture in the facility, and the level of training given to the nurses can also affect the occurrence of alerts and alarms and their resolution times. More work is needed to explore how such factors directly influence the time needed to resolve alarms.

The results from this study have several implications for hospital management. For example, the proposed all-infusion analysis approach can be applied to prioritize medication administration processes or quality improvement initiatives. Specifically, medications with higher alert counts and rates may warrant a review of the drug limit settings. These reviews can help check for inconsistencies in the ordering set and the pump drug library. An unusually high frequency of some infusion alarms, such as an air-in-line alarm, may indicate a training issue with the nurses' priming practice. Furthermore, when the average infusion alarm resolution time is significantly longer at night and overlap shifts than day shifts in a specific unit, it may indicate nightshift understaffing in that unit. In summary, we envision these analyzed results can raise red flags and help the leadership prioritize how to utilize their limited resources (including technology, manpower, and time) on improving workflows and patient safety.

Limitations

Infusion data in this study were from one pump vendor. Thus, findings may not generalize to hospitals using a different vendor. However, the workflow analysis framework is applicable to all infusion pumps with similar available data. Infusion pump data in this study were not linked to clinical incidents or patient outcomes, and linked datasets are needed to understand direct infusion pump impacts on patients' safety. Studies have also shown that smart pump–EHR interoperability can decrease alert firing rate.^{23,55,56} Future intervention studies are needed to address the workflow disruptions caused by infusion events on user's trust of the pump, as well as their overall job satisfaction. Finally, the models in this study only explore the relationships between a nonexhaustive list of predictors and the presence of alerts and alarms during infusion. Machine learning algorithms for variable selection and predicting the occurrence of infusion alerts and alarms might provide more insight into future works.

Conclusion

This study presents an analysis of a detailed infusion pump dataset that captured over 700,000 unique infusions across four hospitals. Our results highlight several implications of pump alerts and alarms that may impact patient care and nursing workflows. This analytics-based approach can facilitate a greater understanding of infusion-related clinical tasks, workflow coordination, and patient safety considerations across various clinical settings through the use of infusion pump data in a manner not limited by observation-based methods.

Clinical Relevance Statement

The findings from this paper adds value to the body of knowledge about smart infusion pump use and practice, supporting how disruptive infusion pump alarms and alerts can be to nursing workflows and patient safety in clinical settings. Moreover, risk factors for these alarms and alerts have been identified, ensuring that clinicians are aware of

these contributory factors to workflow interruptions while using smart infusion pumps. Consequently, hospital management can apply this approach to deploy efficient risk strategies and quality improvement initiatives that prioritize safe medication infusion processes.

Multiple Choice Questions

- Which of the following has been discovered as an adverse effect of the adoption of smart infusion pumps in clinical settings?
 - Disruptions to nursing workflows.
 - Patient harm.
 - Alarm fatigue.
 - All of the above.

Correct Answer: The correct answer is option d. In as much as smart infusion pumps have tremendous advantages, their adoption comes with some adverse effects. These include disruptions to nursing workflows (as alarms and alerts require the caregiver's attention), patient harm, and alarm fatigue.

- High levels of smart infusion pump programming alert rate can lead to:
 - High levels of alarm rates.
 - Non-DERS infusions (i.e., without using drug limit settings in the pump software).
 - Longer alarm resolution times.
 - Elimination of all programming errors.

Correct Answer: The correct answer is option b. High levels of alerts can contribute to alert fatigue problem in the clinical environment and thus desensitize the caregiver's safety awareness and lead to unsafe overriding of programming alerts.

Protection of Human and Animal Subjects

There was no direct patient involvement in this study. The infusion pump data used in this study contained no patient identifier.

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Conflict of Interest

None declared.

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