Methodology for Ensuring Accuracy and Validity of Infusion Pump Alarm Data

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Clinical alarm reduction is a priority goal among national organizations, professional societies, healthcare facilities, and industry.[1] The Joint Commission's National Patient Safety Goal on clinical alarm safety requires healthcare facilities to identify the most important medical device alarms to manage, then make improvements to ensure that these alarms are heard and addressed.[2,3] The collection of data is among the first steps in assessing and identifying which alarms to manage. Data are essential to healthcare facilities' ability to identify which medical devices to target and which alarms are most problematic. Because these data will serve as the basis for measuring and reporting clinical alarm outcomes, they should be meaningful and accurate and the methodology for extracting them should be reliable and valid.

To date, most research on medical device alarms has focused on physiological monitoring, with little to no published benchmarks on infusion pump alarms. Using infusion pump data from U.S. hospitals, we sought to establish a baseline regarding alarm incidence and duration. These hospitals were using a validated proprietary data management software application that collected infusion data in real time and collated the data into various clinical reports. Although the software application collected infusion alarm data, the version in use at the time of this study did not compile collected alarm data into a preassembled, standardized report. Therefore, we were tasked with collating the validated software alarm data from various hospitals and assembling it in a meaningful way for clinical analysis.

Collating data across multiple hospitals and running queries on that data entails intricate management of complex data; therefore, we were compelled to apply sound research methodology to ensure accuracy and validity. Finding no comparable process or validation protocol for collating and/or assembling infusion pump data in the literature, we created and tested a validation methodology using one pump platform. Establishing a validated process for ensuring the reliability of assembled data is an important first step that needs to precede the development of infusion alarm data metrics and reported benchmarks.

The goals of this article are to share insights on the complexities of collating and assembling infusion pump alarm data across multiple hospital datasets and to describe a research-based process to maximize the accuracy and validity of the data. For health-care facilities that are not using a validated software program that collects and assembles alarm data, these same principles and/or methods can be applied to best ensure the quality of the data.

Infusion Pump Alarm Data

For the purpose of this research, we defined an infusion pump alarm as an audible and visual message that continues or repeats until the user addresses it or silences it via a key press or other action. An alarm is different than an alert; the latter refers to a single message (audile and/or visual) during pump programming. Examples of alerts include dosing alerts that warn the user that she/he is outside the drug library limits and advisory alerts that advise the user of special infusion instructions. Typical infusion pump alarms include infusion complete, battery low, hold expired, downstream and upstream occlusion, air in line, keep vein open (KVO), door open, set misloaded, and system error. Infusion pump alarms may cause a running infusion to stop or to slow down (e.g., KVO) or may occur during a hold state. These alarms can affect patient care by delaying therapy and disrupting patient sleep.

Collecting data and establishing baselines on infusion alarms will help to quantify the

extent of this issue, identify key variables to help mitigate these alarms, and help hospitals prioritize the most important medical device alarms to address.

Most modern infusion pumps offer the option of an infusion management software application that collects wirelessly transmitted infusion data and generates reports that indicate how the pumps are being used, programmed, and managed. Ideally, these reports should include data on pump alarms, which by nature of the device and its use, require a complex set of variables to collect and analyze, including alarm type, frequency, duration, care unit, drug name, date, and time of day.

In absence of a validated program that collects and assembles alarm data, data analysts, informaticists, and/or biostatisticians are encouraged to apply sound research principles to help optimize the accuracy of assembled data. "Data cleaning" and "data validation" are two applicable research principles that help ensure the accuracy of reported results when working with large sets of complex data.[4,5]

Data Cleaning

The enormous amounts of complex data that pumps capture and report may contain clinically nonsignificant data that require clinical and operational insight to assess and resolve. In the case of pump alarms, for example, excluding alarms that are longer than 60 minutes in duration may be necessary, as those alarms can occur while a patient is ambulating and off the unit or during biomedical testing and service. Although few in number, these alarms can inappropriately skew the alarm data, resulting in a deceptively higher average alarm duration. Alarms that are only a few seconds, which can occur during pump programming, are another example. These alarms may not be clinically significant and can deceptively lower the average alarm duration. In addition, inconsistencies in wireless communication can cause gaps or omissions in alarm data; this incomplete data can create inconsistencies or inaccuracies in pump alarm reporting and analysis.

Data cleaning is the process of detecting, diagnosing, and editing clinically nonsignifi-

cant data,[6] which, although time consuming, is a paramount first step in the data analysis process. Data cleaning requires in-depth knowledge of a particular pump's operation, user interface, operating software, and infusion management software. It is estimated that approximately 80% of data analysis time will be spent on this cleaning step.[4] Cleaning, however, is fundamental to the capture of valid, accurate, and complete infusion pump alarm data.

Data Validation

During the process of collating and assembling data across different hospitals, infusion platforms, or software programs into a data assembly tool, one should consider validating the data assembly process. Validation is checking the accuracy and quality of data before using, importing, or otherwise processing the data.[7] Data validation can be operationally defined as "a process that ensures the correspondence of the final data with a number of quality characteristics."[8] To make data validation systematic, Di Zio et al.[9] describe a methodology that includes "rules for technical integrity of a data file" and "rules for logical validation and consistency." These rules include checks for duplicate records, complete data fields, range, and combining data fields by functions (e.g., sums, differences, ratios).

Typically, validating all data points/entries is not realistic. Therefore, sampling techniques combined with appropriate statistical determinations are key components of the data validation process. Pageler et al.[10] used statistical techniques to determine the validity of data during an electronic health record conversion. Based on a predetermined confidence level and error limits, they randomized samples within each data type and manually validated the sampled portion of records. They concluded that this technique promoted efficiency and consistent confidence levels. The data extraction, cleaning, collecting, and assembly processes should be validated. This will help instill confidence in the quality improvement recommendations that one makes based on the resulting infusion pump alarm analytic reports.

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Our Validation Process

Goal

At present, no published validation protocols or tools are available for collating and assembling infusion pump data. Our goal was to establish a valid and reliable process for cleaning and analyzing pump alarm data across multiple hospitals, resulting in accurate and complete data that could be confidently used to establish benchmarks related to the descriptive qualities of infusion pump alarms.

Step 1: Create Exclusion Criteria (Data Cleaning)

Factors that may cause pump alarm data elements to be missing or inaccurate (or inconsistent) include data communication errors, system errors, and maintenance/service.

To best control for missing data elements that could lead to inaccuracies in data analysis, we excluded all alarms with any potential missing data (e.g., any incomplete alarm records). Only alarm records with complete and consistent data elements were included in the analysis. A complete alarm record included all data elements from alarm start to alarm silence, and a consistent alarm record had matching data elements from alarm start to alarm silence. For example, certain data elements cannot be changed during a single alarm state (e.g., drug name, rate, dose or volume to be delivered). If any of these data elements were different at the start of the alarm compared with at the end, this alarm record

was deemed inconsistent and discarded. Making sure the alarm records were complete and consistent helped to facilitate data accuracy.

The occurrence of duplicate pump serial numbers in the data also was an exclusion criteria. For example, pumps undergoing main board replacement could have had their serial number wiped out, and if not re-entered, the hospital could have pumps with a "0" serial number. Therefore, the data from these 0 serial number pumps would appear to originate from a single device; however, in actuality, this could result from a combination of data elements from multiple devices. Therefore, any alarm data associated with a duplicate serial number were excluded from the dataset.

During the randomly chosen 24-hour testing period, there were 1,389 alarms from 338 infusion pumps. A total of 100 alarms were excluded (7%); 75 were excluded due to incomplete records, six due to duplicate serial numbers, and 19 for both reasons (Figure 1).

Step 2: Establish Metrics

A review of published infusion pump alarm studies revealed no previously established metrics and operational definitions for infusion pump alarms. Defined terms and standardized descriptions regarding how these terms are operationalized are missing foundational components needed to establish national benchmarks for alarm research. Without the establishment of metrics and their operational definitions, knowing what
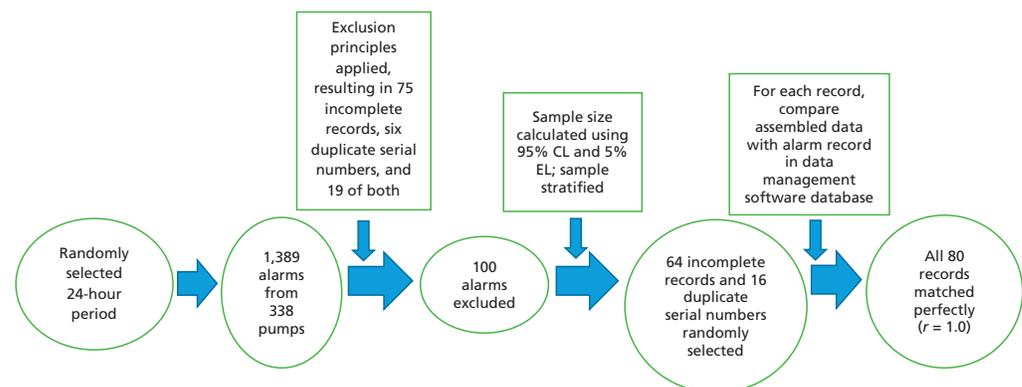
Figure 1. Validation of exclusion principles using excluded alarm sample. Abbreviations used: CL, confidence level; EL, error level.

is actually being measured is difficult and accurately comparing results from various studies is impossible.

Beyond the alarm data elements communicated from the infusion pumps, we also established specific metrics to provide the most clinically relevant and actionable baseline measures for analyzing alarm data. The metrics and their operational definitions are as follows:

- Active delivery state: total time (in minutes and seconds) and percentage of time pumps in hold, run, alarm, and KVO states; total time from "run" to "off" that a pump can alarm
- KVO state: total time (in minutes and seconds) and percentage of time pumps in KVO state
- Alarm state: total time (in minutes and seconds) and percentage of time pumps in alarm and KVO states
- Alarm frequency by type: number of alarms that fall within each alarm type in the defined date range
- Total deliveries: number of unique medication deliveries running in the defined date range
- Average alarms per delivery: total number of alarms divided by total deliveries
- Average alarm duration: cumulative duration (in minutes and seconds) of all alarm states divided by total number of alarms
- Total pumps available for analyses: number of unique pump serial numbers recorded in the defined date range

Step 3: Conduct Validity Testing (Data Validation)

After the exclusion criteria and metrics had been established, our next step was to manually validate them. Because our validation was completed manually, we could not realistically validate all records. Thus, using a rigorous random sampling technique that would allow the results to be applied to the entire dataset was important. We used a similar approach to Pageler et al.[10] A complete description of our methods and results is provided in the sidebar (on p. 196), and summary diagrams are shown in Figures 1 and 2. Using one randomly selected 24-hour period from a 600-bed acute care hospital's dataset, we compared results generated from the data assembly tool with the data management software database for randomly selected exclusion occurrences.

To validate the metrics, a different 24-hour period was randomly chosen from the same hospital dataset. For this 24-hour period, results from the data assembly tool were matched with the data management software database. A randomly selected number of alarms was examined, and specific data points used in the metrics were compared between the assembled data and the data management software database. A 95% confidence level and 5% error level were used to determine the exact number of random occurrences that needed to be sampled to validate both the exclusion criteria and metrics.
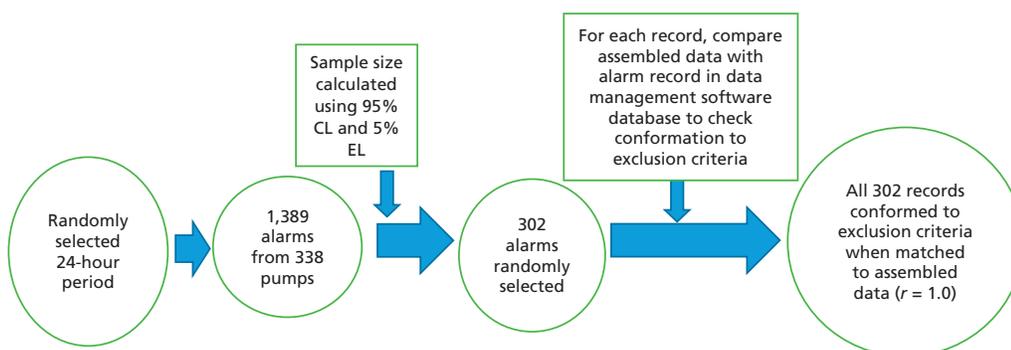
Figure 2. Validation of exclusion principles using total pre-exclusion alarm sample. Abbreviations used: CL, confidence level; EL, error level.

Infusion Pump Alarm Data Research: Methodology and Results

Method
Using the infusion pump data generated from the data assembly tool, each of the alarm data exclusions and metrics were compared with alarm records in the data management software for the same infusions, in order to measure how closely they matched.

Sample
One 24-hour period, randomly selected from a 600-bed acute care hospital dataset. The hospital had purchased 652 large volume infusion pumps.

Procedure
Exclusions. A stratified random sampling technique was used to select the necessary number of occurrences from each exclusion criteria. This technique included:

1. Determining the actual number of exclusion occurrences that fell into each of the categories.
2. Identifying the unique pump serial numbers for each type of exclusion and identifying data for each excluded alarm to help isolate those records in the data management software. Random samples from these groups of data were selected for the validation of specific alarm exclusions.
3. Computing the actual number of occurrences required to randomly select from each of the exclusion pools (subgroups). Sample size was determined using a 95% confidence level and 5% error level (confidence interval).[11]

In every selected case, the data generated from the data assembly tool was compared with the data management software database record for the same infusion, in order to measure how closely the logic matched. A perfect match was scored with a "1," and no match was scored with a "0."

Metrics. The 24 hours of data from the data assembly tool were extracted and matched with the data management software database records for the same time period. Specific data points used in the metrics were compared between the data generated from the data assembly tool and software database records.

Analysis
A sample size calculator[11] and 95% confidence level and 5% error level were used to determine number of random samples. SPSS Statistics version 22 (IBM, Armonk, NY) was used for all analyses. Sample Pearson correlation coefficients were used to describe how closely the exclusions and derived metrics matched the data management software records. Level of significance was set at $P \leq 0.05$.

Results
February 3, 2016, was the date randomly chosen from the dataset.

Exclusions. Applying our exclusion principles, 100 of the 1,389 alarms from 338 pumps (i.e., the number of pumps in use on February 3, 2016) were excluded. To achieve a 95% confidence level and 5% error level, 80 of the 100 alarms were randomly chosen and reviewed. The sample was stratified based on type of exclusion and proportionate to the number in the sample; 16 pumps with duplicate serial numbers and 64 records with incomplete and/or inconsistent alarm data elements were randomly selected from each of their respective exclusion groups. These records and all associated data elements matched perfectly ($r = 1.0$) (Figure 1).

To further verify that no additional exclusion principles should be implemented, we also sampled from the total 1,389 alarms. To achieve a 95% confidence level and 5% error level, 302 of the alarms were randomly selected and reviewed. All 302 ($r = 1.0$) alarms conformed to the exclusion criteria when matched with the data generated from the data assembly tool (Figure 2).

Metrics. All data points that were available to be compared on the data management software were validated and matched perfectly ($r = 1.0$) with the data generated from the data assembly tool.

Conclusion
Our data exclusion and metric logic is valid and can be used to accurately report pump alarm data.

Results
The results established that both the exclusion criteria and metrics attained perfect ($r = 1.0$) correlations between the assembly tool data and the data management software data, thus validating our exclusion criteria and metric logic.

Limitations
The current study had limitations. The testing was done using a single pump platform; therefore, the results cannot be generalized to other pump platforms. The current testing also included use of a single, proprietary infusion management software. Each software has different user report options and ways of managing database records to produce relevant pump metrics. It should not be assumed that the metrics reported and tested in the current study are identical to other infusion management software. It should also not be assumed that an infusion pump alarm data validation process is in place for any other infusion pump other than the one developed for this single pump platform.

Testing our exclusion criteria and metric logic by comparing assembly tool data with data management software records was one method of validating our criteria and logic; however, it is not the only method. Another way of validating would have been to simulate alarm conditions (e.g., kink the tubing to simulate an occlusion, install a discharged battery to simulate low battery, program a short infusion to simulate KVO) and measure if the assembly tool properly recorded them. This method was not used in the current study because the amount of time and labor required to test an adequate number of pumps and/or alarms was prohibitive.

Conclusion

Data cleaning and validation are vital steps in the data management and analysis process, helping to ensure the accuracy and completeness of results ascertained from the data. Without taking these steps, inaccurate results can potentially be used to make important policy and clinical practice decisions within guiding bodies and/or healthcare facilities. For example, inconsistencies in wireless network communication may result in incomplete infusion data. If alarms are not captured during interrupted connectivity, alarm incidence can be underreported. Also, when looking at alarm data for the purpose of identifying trends, baselines, and potential issues, clinically nonsignificant data may need to be excluded. An example of such data may be alarms that are longer than 60 minutes, as they typically occur when a pump is not being used on a patient (e.g., being repaired/tested, in a storage closet). These outlying, potentially clinically insignificant alarms have the potential to skew alarm duration data and inflate average alarm duration.

The data validation methodology described here can be applied to other pump platforms; however, the resulting analytics cannot be generalized. By sharing our insights, processes, and results, we hope to encourage industry, software developers, and informaticists to apply and/or disclose similar research methodology when assembling and managing data for the purposes of reporting infusion pump alarm outcomes.

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