Risk of Medication Errors With Infusion Pumps

A Study of 1,004 Events From 132 Hospitals Across Pennsylvania

Matthew Taylor, PhD* & Rebecca Jones, MBA, RN**

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The risk of medication errors with infusion pumps is well established, yet a better understanding is needed of the scenarios and factors associated with the errors. Our study explored the frequency of medication errors with infusion pumps, based on events reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS) during calendar year 2018. Our study identified a total of 1,004 events involving a medication error and use of an infusion pump, which occurred at 132 different hospitals in Pennsylvania. Fortunately, a majority of medication errors did not cause patient harm or death; however, we did find that 22% of events involved a high-alert medication. Our study shows that the frequency of events varies widely across the stages of medication process and types of medication error. In a subset of our data, we manually reviewed a free-text narrative field in each event report to better understand the nature of errors. For example, we found that a majority of wrong rate errors led to medication being infused at a faster rate than intended, and user programming was the most common contributing factor. Overall, results from our study can help providers identify areas to target for risk mitigation related to medication errors and the use of infusion pumps.

Keywords: infusion pump, IV pump, smart pump, medication error, risk factors, adverse events, patient safety, Pennsylvania, high-alert medication, medical device

*Corresponding author

**Patient Safety Authority

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Infusion pumps are essential for administering fluid, nutrients, and medications intravenously (IV) to patients; however, the use of infusion pumps is also associated with a high frequency of adverse events. Previous research has noted the need for studies that capture the prevalence and context of errors associated with infusion pumps, as such knowledge is necessary to better understand scenarios and factors associated with greater risk. Unfortunately, few studies have assessed medication errors with infusion pumps across more than 10 hospitals, during an extended period of time, and across multiple factors (e.g., stage of medication process, type of medication error, and contributing factor).

Study Methods and Results

In this study, we explored the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events reported as a medication error that included the use of an infusion pump. Our database query included a total of 19 unique keywords that were paired with the term "pump." The 39 unique keywords consisted of "infusion," "IV," "smart," and 36 company names. We selected only names of companies who submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) during years 2000–2018. In addition to using a keyword filter during our query of PA-PSRS, we also narrowed our search to events that occurred at hospitals and were submitted to PA-PSRS between January 1 and December 31, 2018. Based on our query of PA-PSRS, we identified a total of 1,004 events, from which we selected a random sample of 30% (n = 300 of 1,004) for manual review. One author manually reviewed the sample of 300 events and confirmed that the free-text narrative framework in all event reports (100%; n = 300 of 300) described a medication error with use of an infusion pump. This finding indicates a high degree of confidence in the results of our database query. 95% CI (98.8%-100%) Clopper-Pearson exact method), so we proceeded to include the full data set of 1,004 events in our analysis.

Our study revealed that the 1,004 events were concentrated at 132 of the hospitals in Pennsylvania. Among the 132 hospitals with an event, we found the median was 3 events per hospital and a mean of 7.61 (SD: 14.79) per hospital. Based on information provided by event reporters, 99% (n = 996 of 1,004) of the events were identified as incidents; and 1% (n = 8 of 1,004) as Serious Events. Also, 85% (n = 856 of 1,004) of all medication errors reached the patient and high-alert medications were involved in 22% (n = 217 of 1,004) of the events. Table 1 shows a cross tabulation of the 1,004 events. The data show that the frequency of events varies widely depending on the type of medication process and types of medication error. In particular, the data reveal that 59% (n = 595 of 1,004) of events were categorized as PA-PSRS medication error taxonomy type "Wrong." This type of medication error is further categorized into 11 different subtypes (see Figure 1).

In Figure 1, we focused on the subtypes of wrong medication error and found that 19% (n = 187 of 1,004) of the events were categorized as having a Rate error. Based on this finding, we manually reviewed the free-text narrative framework for all 187 event reports with a Rate error to better understand the nature of these events.

We independently classified each of the 187 events to determine how the rate of medication differed from what was intended (e.g., faster or slower). To assess inter-rater reliability of our classification, we used the kappa statistic,[12] which indicates that we had a substantial level of agreement (K = 0.812). During our initial review we agreed on Rate classification in 88% (n = 165 of 187) of events. Thereafter, we reviewed all 22 disagreements and came to consensus on the appropriate Rate classification per event, which ultimately yielded 100% agreement and increased the accuracy of our results. Results from our classification revealed that 85% (n = 158 of 187) of event reports provided sufficient information to determine how the medication rate differed from what was intended. Based on events with sufficient information, we found that 64% (n = 101 of 158) of events involved medication infusion at a faster rate than intended, 32% (n = 50 of 158) infused at a slower rate, and 4% (n = 7 of 158) had both a faster and slower rate (e.g., single event included two medications and were swapped on pump channels). While reviewing the 187 events with a Rate error, we attempted to identify the key contributing factor for each event, based on information provided in the pre-text narrative framework. We independently applied a categorization system that consisted of seven contributing factors, which are defined in Table 2. We evaluated our inter-rater agreement of event classification with the Kappa statistic,[10] which revealed that we had a substantial level of agreement (K = 0.730). We agreed on Rate classification in 97% (n = 152 of 187) of events during our initial review. To increase the accuracy of our results, we reviewed all 30 disagreements and came to consensus on the appropriate contributing factor classification for each event, which then resulted in 100% classification agreement.

Results from our classification of Rate errors showed that 91% (n = 171 of 187) of events had sufficient information to identify a key contributing factor. Based on events with sufficient information, we recommend that patients be warned of the significance of medication error by highlighting the results of our study. The most common negative outcomes were medication errors during medication administration and patient safety incidents during medication administration. Medication errors during medication administration were associated with high alert medications.

### Table 1. Frequency of Events During 2018 With a Medication Error and Use of an Infusion Pump

| Types of Medication Error | Total Events |
|---------------------------|-------------|
| Dose infusion             | 126         |
| Extra dose                | 34          |
| Wrong                     | 595         |
| Prescribed drug delayed   | 13          |
| Medication list incorrect | 2           |
| Monitoring error          | 32          |
| Unintended drug           | 7           |
| Inadequate pump managed   | 2           |
| Other                     | 211         |
| Total Events              | 1,004       |

| Categories of Medication Error | Prescribing | Transcription | Preparation | Administration | Monitoring | Other |
|-------------------------------|-------------|--------------|-------------|----------------|------------|-------|
| Events                        | 0           | 2            | 118         | 6              | 2          | 7     |

**Note:** Events may have involved more than one stage of medication process.

Figure 1. Subtypes of “Wrong” Medication Errors

| Error Type | Rate (n=187) | Concentration (n=158) | Drug (n=155) | Duration (n=152) | Time (n=152) |
|------------|--------------|------------------------|--------------|------------------|--------------|
| Infusion   | 56%          | 28%                    | 19%          | 8%               | 7%           |
| Underdose  | 3%           | 1%                     | 11%          | 16%              | 1%           |
| Overdose   | 2%           | 12%                    | 7%           | 9%               | 2%           |
| Technique | 1%           | 21%                    | 4%           | 19%              | 21%          |

Figure 2. Factors Contributing to Rate Error

| Error Type | Device Maintenance | Malfunction | Patient Behavior | Insufficient Information | Pre-Administration Process Problem | Tubing/ Connections | Programming |
|------------|--------------------|-------------|------------------|--------------------------|-----------------------------------|---------------------|-------------|
| Rate       | 4%                 | 16%         | 12%              | 38%                      | 19%                               | 14%                 | 19%         |
## Table 2. Factors Contributing to a Medication Rate Error With an Infusion Pump

| Contributing Factor          | Definition and Sample Event                                                                                                                                                                                                 |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Programming**              | **Definition**: Entered incorrect setting or value into infusion pump interface. Provider may have entered incorrect information for a range of reasons, such as miscalculation due to incorrect patient weight or chose incorrect units of measure when calculating rate (e.g., ml/hr vs. kg/hr), failure to adjust rate post-bolus, entered too few or too many digits (e.g., entered 0.2 instead of 0.02 or 488 instead of 48), entered a value into the rate field that was intended for dose or Volume To Be Infused field (i.e., entered 50 units but failed to choose correct medication in drug library or instead entered as custom concentration, entered drug information into incorrect pump channel (i.e., pump channel swap), or failed to start pump after entering information. **Sample Event**: A 61 year-old male was taken to the Emergency Dept after being found unresponsive at home. On arrival, his blood sugar was 1,594. An insulin bolus and drip were ordered. After verification by two nurses, the 10-unit bolus was administered and the drip (100 mL bag with 100 units of insulin) was started. Just a few minutes later, the IV pump alarmed and the nurse discovered that the entire 100 mL bag had infused due to erroneous pump programming. Treatment was administered, but the patient soon became short of breath with an irregular heart rhythm and a Code Blue was called. The patient was resuscitated and admitted to the ICU. |
| **Pre-Administration Process Problem** | **Definition**: Incorrect order, transcription, or preparation of medication. For example, medication order may have had incorrect or conflicting rate or dose information, transcription of medication order was misinterpreted, erroneous laboratory test result led to wrong rate, medication prepared as a volume greater or lesser than ordered. **Sample Event**: Nurse noticed that patient’s dosing weight for Heparin was listed as 176 kg, but the order was written using a weight of 64 kg and the pump was set for 64 kg. Nurse contacted physician and Heparin rate was decreased to match the appropriate dosing weight of 58 kg. 2) **Sample Event**: Handwritten orders in patient’s chart contained conflicting information regarding the rate of infusion for chemotherapy drugs (1 hour vs. 2 hours). Pharmacy profiled the medication to be infused over 1 hour and it was administered accordingly. After the infusion was complete, it was determined the rate was too fast for the patient and the medication should have been infused over 2 hours. |
| **Tubing/Connections**       | **Definition**: Failure to correctly connect or clamp IV tubing. For example, if the provider may have erroneously administered medication via gravity flow instead of via the pump, connected IV tubing to the incorrect access port, connected tubing meant for the IV fluids and the entire 80 mg dose had infused over less than 10 minutes. **Sample Event**: While assessing the patient, the nurse noticed the IV fluids were set for 80 year old male patient was ordered to receive Protonix 80 mg/100 mL at a rate of 10 mL/hr continuously, along with IV fluids at a rate of 80 mL/hr continuously. Within minutes of starting the Protonix infusion, the nurse heard the pump alarming and realized the Protonix bag was spiked using the tubing meant for the IV fluids and the entire 80 mg dose had infused over less than 10 minutes. |
| **Malfunction**              | **Definition**: Despite correct programming and set-up, the pump or tubing valve did not function properly. **Sample Event**: As a result of a pump malfunction, the patient’s diuretic medication was delivered at a faster rate than programmed. Patient was ordered to receive 3 mL/hr—and pump was accurately programmed at 5 mL/hr—but drip rate was observed for one minute and noted to be much greater than 5 mL/hr. The pump was taken out of service and sent to the biomedical department for evaluation and repair. |
| **Device Maintenance**       | **Definition**: Device was not maintained properly, which prevented it from functioning as intended. For example, the drug library was not set-up properly or multiple pumps had the same barcode. **Sample Event**: When attempting to program IV pump, the incorrect rate was shown for the IV fluids she was intending to administer. After investigating the problem, it was discovered that two different pumps had the same barcode assigned to Line A. Both pumps were removed from service. |
| **Patient Behavior**         | **Definition**: Patient intentionally or unintentionally adjusted programming of the pump. **Sample Event**: While assessing the patient, the nurse noticed the IV fluids were set at a rate of 700 mL/hr instead of 100 mL/hr as ordered. The patient told the nurse he pushed some buttons on the pump and must have changed the rate. The nurse corrected the rate to 100 mL and locked the pump. |
| **Insufficient Information** | **Definition**: Inadequate information that prevented us from confidently identifying the contributing factor. The event report provided little information beyond stating that the medication was infused too quickly or too slowly. |
Enhanced safety associated with smart pumps is dependent on the setup and maintenance of the device.

For example, studies have reported that use of a comprehensive drug library that is regularly maintained/updated is associated with a reduction in use errors.1415 With an incomplete and outdated drug library, users are more likely to enter custom concentrations and identify workarounds that nullify the potential benefits of the “smart” technology.1316 Furthermore, studies have shown that use of “soft limit” settings, rather than “hard limit” settings, has little impact on the reduction of use errors.1415 With the use of soft limits, staff are able to bypass the warning and administer a potentially unsafe drug dose or rate.14 In contrast, if the infusion pump is set up with “hard limits,” and a human factor scientist identifies a reduction in use errors with an infusion pump that included a barcode reader.1318 Additionally, a study reported observing fewer wrong patient errors with a smart pump that was designed to reduce risk.

The Institute for Safe Medication Practices (ISMP) recommends using a system that includes an infusion pump with a barcode reader to facilitate bidirectional interoperability with electronic health records. Successful implementation of this type of system would dramatically reduce the need for providers to manually enter information and instead use autoprogramming. Greater use of autoprogramming will likely reduce errors across the various stages of the medication administration process. Although the use of autoprogramming should be the goal, facilities should note that successful implementation and maintenance of a bidirectional interoperable system is dependent on many variables and a rather complex process. As a result, ISMP recommends using a multidisciplinary team that includes stakeholders from 12 different departments to develop a pump design. Despite the many potential benefits of “smart” infusion pumps, staff should keep in mind that the technology will not prevent all use errors and the degree of reduction in use errors is heavily dependent on the staff’s adoption of the safety-related features that are designed to reduce risk.18 Overall, hospitals should continue to adopt smart infusion pumps and put forth significant effort to ensure that pumps are set up and maintained properly, and that the safety-related features are adopted by staff.1112

1. Apply a multidisciplinary approach when evaluating and procuring infusion pump. Given the implications of a large procurement of infusion pumps, it is very important that all relevant parties are involved in the decision-making process.1920 In particular, it is important that frontline staff (e.g., nurses) are able to view a demonstration of the device and ideally have an opportunity for a hands-on experience with each device. With appropriate concerns for procurement,2122 This experience allows a representative of frontline staff, who will be the regular user of the pump, to comment on pump design and safety-related features will impact usability.

Previous studies have recommended that frontline staff formally review and evaluate the pumps in a systematic manner, in an effort to increase uniformity and reduce bias in the decision-making process.2324 In addition to frontline staff, it is important that purchases from pharmacy and biomedical engineering teams also give an opportunity to evaluate the pump and drug library software for set up and maintenance.

Last, we recommend that a human factors scientist be involved, if possible, to conduct a formal evaluation to identify any potential design problems with each infusion pump. A human factors scientist’s evaluation may range in complexity and depth from a heuristic assessment to full-scale usability testing.25 This process is popular because it is considered an efficient and low-cost method for identifying usability problems, which are often associated with the occurrence of medical errors.26

As demonstrated by Zhang et al.,27 a heuristic assessment of infusion pump has been shown to produce a range of improvements in healthcare facilities, including those related to the use of infusion pumps.2829 One of the primary components of this process is a heuristic assessment, which will inform the choice of solution(s).

Fortunately, healthcare facilities encourage and often mandate that employees report patient safety-related events to their in-house reporting system. In the interest of preventing Serious Events, we strongly encourage staff and leadership to place a high degree of value in the information gathered from “near misses” and events that are considered “serious.” As a result, facilities should leverage data from infusion pump event logs (i.e., onboard memory), as well as other components of this process.

Leverage event log data from pump to gain additional insight.

2. Apply a multidisciplinary approach when evaluating and procuring infusion pump. Given the implications of a large procurement of infusion pumps, it is very important that all relevant parties are involved in the decision-making process.1920 In particular, it is important that frontline staff (e.g., nurses) are able to view a demonstration of the device and ideally have an opportunity for a hands-on experience with each device. With appropriate concerns for procurement,2122 This experience allows a representative of frontline staff, who will be the regular user of the pump, to comment on pump design and safety-related features will impact usability.

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Leverage event log data from pump to gain additional insight.
event reporting, including near miss events. With that information, a safety program can proactively identify potential problems and develop solutions. As we have highlighted, there are many potential solutions to mitigating risk of medication errors with infusion pumps. However, it is crucial to have the support of the leadership and the many groups involved in ensuring patient safety during use of infusion pumps, there are many possible solutions to mitigate risk. For example, depending on the nature of the concurrence, the multidisciplinary team may recommend replacing the problem pump with a different designed pump. Alternatively, the team may reveal that a simple adjustment of a setting on the device could significantly reduce the likelihood of a use error (e.g., use of high limits rather than soft limits). As another possible solution, the team may recommend developing a staff-wide training program with concrete strategies to reduce the likelihood of a specific use error.10,11,41 Although training can be effective, controls engineering or design-oriented strategies are often more reliable in preventing a use error.42 Nevertheless, we recognize that these interventions may not be options other than training the staff to avoid specific use errors.

When developing a training program with the goal of helping staff prevent notable patient harm, we strongly recommend recruiting a well-qualified team to develop the training content. As demonstrated by previous research, the effectiveness of a training program can vary widely and depend on many variables, such as quality of feedback, complexity of the target behavior (e.g., recognition vs. kinesthetic repertoire), correctness of the trained behavior, and the desired behavior in a clinical context, similarity and distinction among stimuli present in the training environment, and the general training rigor of the skill assessment.43,44 Regardless of the solution selected to mitigate risk, the effectiveness of a safety program is highly dependent on a culture of reporting near misses.

Conclusion

Despite recent advances in infusion pump technology, hospitals continue to experience medication errors while using pumps. Current study provides insight into the frequency of events by stage of the medication process, types of medication errors, and contributing factors. Based on a subset of our data, the findings show that pump programming, tubing/connections, and predadministration process problems were the most common contributing factors to medication errors with infusion pumps. In an effort to mitigate risk of safety-related events, we urge personnel at healthcare facilities to foster a strong culture of

Notes

This analysis was excerpted from review by the Ad

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