Risk of Medication Errors With Infusion Pumps

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

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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*

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1,004

Events

132

Hospitals Reporting an Event

19%

of Events Had a Rate Error

85%

of Events Reached the Patient

22%

Events Involving a High-Alert Drug

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.[1] 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.[2-7] 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 39 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 field 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 that 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 across the stages of the 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 field for all 187 event reports with a Rate error to better understand the nature of the events.

We independently classified each of the 187 events to determine how the rate of medication differed from what was

* PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety–related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential, and no information about individual facilities or providers is made public.

† According to the FDA, "medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected."[8]

‡ "Incident" is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.[9]

"Serious Event" is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.[9]

** High-alert medications are defined as drugs that bear a heightened risk of causing significant patient harm when they are used in error.[10]

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

Types of Med Error	Total Events[1]	Stages of Medication Process					
		Prescribing	Transcription	Preparation	Administration	Monitoring	Other
Dose omission	126	0	0	2	114	6	7
Extra dose	16	2	0	0	12	1	3
Wrong*	595	34	23	39	468	50	58
Prescription/refill delayed	13	6	0	3	4	0	1
Medication list incorrect	2	1	1	1	0	0	1
Monitoring error	32	1	1	2	19	9	3
Unauthorized drug	7	1	0	1	4	1	1
Inadequate pain management	2	0	0	0	2	0	0
Other	211	18	9	20	129	27	37
Total Events	**1,004**	**63**	**34**	**68**	**752**	**94**	**111**

[1]Events may have involved more than one stage of medication process.
*"Wrong" is a term used in the PA-PSRS taxonomy to describe a type of medication error. Wrong is defined by 11 subtypes, which are listed in Figure 1.

intended (e.g., faster or slower). To assess inter-rater reliability of our classification, we used the kappa statistic,[11] which indicates that we had a substantial level of agreement (K = 0.812).[12] 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 free-text narrative field. We independently applied a categorization system that consisted of seven contributing factors, which are defined in **Table 2**. We evaluated our inter-rater reliability of event classification with the Kappa statistic,[11] which revealed that we had a substantial level of agreement (K = 0.730).[12] We agreed on Rate classification in 84% (n = 157 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,

Figure 1. Subtypes of "Wrong" Medication Errors

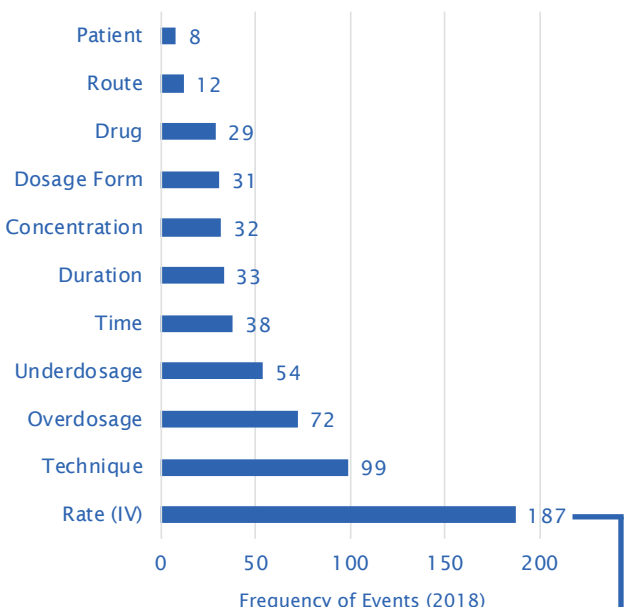

Figure 2. Factors Contributing to Rate Error

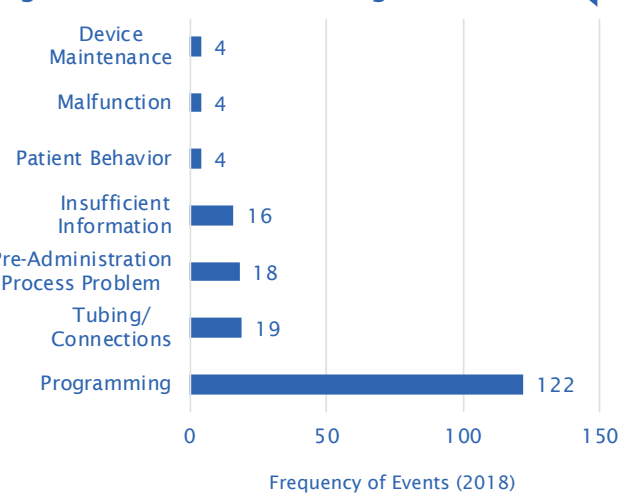

Table 2. Factors Contributing to a Medication Rate Error With an Infusion Pump

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. mg/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., field swap), 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. **1) 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 (100mL bag with 100 units of insulin) was started. Just a few minutes later, the IV pump alarmed and the nurse discovered that the entire 100mL 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. **2) Sample Event:** When the oncoming nurse checked the PCA pump to verify the patient's HYDROmorphone rates, he noticed that that the pump was programmed incorrectly. The basal rate ordered for 0.6mg/hr was running at 0.3mg/hr and the PCA dose ordered for 0.3mg was set at 0.6mg. The rates were corrected and the patient was closely monitored. **3) Sample Event:** While hanging IV fluids to run with an anesthetic drug, the nurse set the pump at 999mL/hr to clear the air in the tubing. The rate was not subsequently changed to the actual rate ordered for the fluids (10mL/hr) and the patient received a significant bolus of fluid as a result. The physician was notified and the patient's vital signed were checked more frequently overnight. **4) Sample Event:** Patient with a history of red man syndrome asked nurse to infuse his vancomycin slower than usual. Vancomycin was ordered to infuse over 1 hour and nurse intended to program the pump to infuse the medication over 2 hours. However, the nurse inadvertently programmed the pump to infuse over 15 minutes instead of over 2 hours. The patient subsequently developed hives and extreme itching. The physician was notified and Benadryl was administered. **5) Sample Event:** Oncoming nurse noticed that the infusion pump was programmed to infuse epinephrine to the patient based on a weight of 76kg. However, patient's weight listed in medical record as 176kg. Nurse verified correct weight was 176kg and adjusted the pump settings accordingly.
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. **1) Sample Event:** Nurse noticed that patient's dosing weight for Heparin was listed as 58 kg, but the order was written using a weight of 64kg and the pump was set for 64kg. Nurse contacted physician and Heparin rate was decreased to match appropriate dosing weight of 58kg. **2) Sample Event:** Handwritten orders in patient's chart contained conflicting information regarding the rate of infusion for chemotherapy drug (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.

Contributing Factor	Definition and Sample Event
Tubing/Connections	**Definition:** Failure to correctly connect or clamp IV tubing. For example, the provider may have erroneously administered medication as gravity flow instead of via the pump, connected IV tubing to the incorrect access port, connected tubing meant for another medication into wrong bag, or failed to close or open the tubing clamp. **1) Sample Event:** 25 year-old female patient ordered to receive an immunosuppressant drug to be infused over 4 hours. While hanging the medication, the nurse became distracted and inadvertently hung the medication by gravity instead of loading it into the pump. This resulted in the medication being infused over 5 minutes instead of over 4 hours as ordered. The patient immediately complained of chest pain. She was placed on increased monitoring and an EKG and other testing was ordered. All tests came back within normal limits. **2) Sample Event:** 80 year old male patient was ordered to receive Protonix 80mg/100mL at a rate of 10 ml/hr continuously, along with IV fluids at a rate of 80mL/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 80mg 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 5mL/hr—and pump was accurately programmed at 5mL/hr—but drip rate was observed for one minute and noted to be much greater than 5mL/hr. The pump was taken out of service and sent to the biomedical department for evaluation
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 showing 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 700mL/hr instead of 100mL/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 100mL 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.

Figure 2 shows that 71% (n = 122 of 171) of Rate errors were related to programming of the infusion pump, 11% (n = 19 of 171) were related to tubing/connections, and 11% (n = 18 of 171) were related to preadministration process problems. As indicated by the definition of "programming" in **Table 2**, the factor is broad and includes a range of elements. We would have preferred to present the data according to more specific categories of contributing factors, such as miscalculations and human factors; however, most of the event narratives did not include adequate information to make such a determination.

Limitations

Although our study is based on reports from 132 hospitals, our findings only reflect reports that matched our query. It is possible that some reports of medication errors involving infusion pumps from other hospitals were not included in the results based on the event type selection and language used to report them in PA-PSRS. In addition, although hospitals are mandated to report all Incidents and Serious Events, it is possible that some underreporting may have occurred. Therefore, we caution against using our findings as an estimate of the absolute number of events across Pennsylvania. Instead, we encourage focusing on the information gleaned from the reports discussed in this study.

Safety Strategies

Our findings shown in the figures and tables are a testament to event reporters at 132 of the hospitals in Pennsylvania. By studying the event reports we are able to collectively learn from the events, better understand the nature of the events, and subsequently devise strategies to mitigate risk. Our findings suggest that the conditions associated with programming create the greatest risk for patient harm. As indicated in **Table 2**, a breadth of conditions contribute to the events with erroneous programming. Due to the myriad of variables that contribute to erroneous pump programming, hospital staff should consider an array of strategies for minimizing risk of errors. Based on our findings and various references, we outlined several strategies that may help providers and hospitals decrease the risk of infusion pump programming errors.

1. Ensure appropriate setup, maintenance, and integration of smart pumps. Modern infusion pumps, often referred to as smart pumps, incorporate numerous design features that are intended to prevent various types of use errors.[1] For example, many models of infusion pumps now include the capability for uploading a drug library with preset limits specific to each drug. This technology can help prevent wrong dose, wrong rate, and various other setting errors.[13,14] Despite the potential benefits of this technology, when compared to traditional infusion pump models, many of the advantages are dependent on the setup and maintenance of the pump.[13,15]

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.[16,17] 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.[13,18] Furthermore, studies have shown that use of "soft limit" settings, rather than "hard limit" settings, has little impact on the reduction of use errors.[15,19] 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", then studies have shown a significantly lower rate of errors when compared to traditional infusion pumps.[13,15,19] Additionally, a study reported observing fewer wrong patient errors with a smart pump that included a barcode reader.[19]

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.[20] Successful implementation of this type of system would dramatically reduce the need for providers to manually enter information and instead increase the use of autoprogramming. Greater use of autoprogramming likely will reduce errors across the various stages of the medication process. Although greater 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 groups to develop and maintain the system.

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.[14] 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.[16,21,22]

2. Apply a multidisciplinary approach when evaluating and procuring infusion pump. Given the implications for patient safety and cost associated with a large procurement of infusion pumps, it is very important that all relevant parties are involved in the decision-making process.[23-25] 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 that is being considered for procurement.[25,26] This experience allows a representative of frontline staff, who will be the regular user of the pump, to consider how the 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.[25,26] In addition to frontline staff, it is important that representatives from pharmacy and biomedical engineering teams also are given an opportunity to evaluate the pump and drug library software for set up and maintenance.[23]

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.[27] The heuristic assessment is a popular approach because it is considered an efficient and low-cost method for identifying usability problems, which are often associated with the occurrence of medical errors.[28,29]

As demonstrated by Zhang et al.,[28] a heuristic assessment can be applied to evaluate the usability of infusion pumps. In their study, they used 14 heuristics (i.e., empirically guided principles) to evaluate the design of two models of infusion pumps and found that one pump had 89 usability problems and the other pump had 52 usability problems.

In addition to a heuristic assessment, a facility may also consider hiring a human factors scientist to conduct full-scale usability testing in a simulated clinical environment with frontline staff.[26,30] The information gathered from this type of testing may help to elucidate and confirm hypotheses generated from a heuristic assessment.[23,31] Overall, input from a knowledgeable human factors scientist likely will generate highly valuable information that will help to inform the procurement of a well-designed infusion pump and mitigate risk of an adverse event.[25]

In the procurement process, personnel should also factor in which models of pumps are already used at the facility. Greater standardization or uniformity among the inventory of pumps could decrease maintenance errors and use errors.[16,32] For example, if the entire inventory of pumps within a unit is uniform, then personnel are less likely to have a problem operating the pumps.

Furthermore, if pumps are uniform across units, then personnel likely will have fewer challenges when transferring patients from one unit to another. Additionally, personnel who work in various units (e.g., float nurses) would be less likely to have a problem operating the pumps if all units use the same model of infusion pump. In contrast, when personnel use multiple models of a medical device, then the variability in design across models may increase the likelihood for misinterpretation of a device interface and induce a use error.[33-35] As a result, facilities should consider using a uniform inventory of infusion pumps, which may reduce the likelihood of erroneous pump programming.

3. Develop a process to regularly collect safety-related data, review the data, and create solutions to address pump-related concerns. Given the complexity of this recommendation, we urge facilities to develop a multidisciplinary team and apply a continuous quality-improvement process.[20] This type of process has been shown to produce a range of improvements in healthcare facilities, including those related to the use of infusion pumps.[18,32] One of the primary components of this process is collecting information, 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.[36-39] 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 miss" events. Near misses are particularly important because they are a warning signal of the potential for a Serious Event. As a result, we recommend that healthcare facilities develop a robust system for collecting reports of actual and near miss patient safety events.

Leverage event log data from pumps to gain additional insight.

We also encourage facilities to leverage data from infusion pump event logs (i.e., onboard memory), which are often overlooked. Event logs from infusion pumps, much like black boxes in aviation, can be used to provide insight about how staff are using the device.[5,20] For example, the event logs can be used to assess staff's compliance with alerts by level and type, and compliance with the dose error reduction system (DERS) by care area and medication.[20] The insights gathered from event logs are low effort and efficient, when compared to direct observation of

users engaging with the device. Furthermore, the event log data are often considered to be objective and reliable, which may enhance confidence in the process of developing solutions to address concerns with infusion pumps.

With quality data, a team could apply a continuous quality improvement process to analyze the data, investigate the concerns, and develop robust solutions to improve patient safety. Given the complexity of a healthcare environment and the many groups involved in ensuring patient safety during use of infusion pumps, there are many possible solutions to mitigate risk.[20] For example, depending on the nature of the concerns, the multidisciplinary team may recommend replacing the problem pump with a better 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 hard limits rather than soft limits).[21,30,40] As another possible solution, the team may recommend developing a staffwide training program with concrete strategies to reduce the likelihood of a specific use error.[30,38,41-43] Although training can be effective, engineering controls or design-oriented strategies are often more reliable in preventing a use error.[13] Nevertheless, we recognize that facilities often have no 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 using 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), correspondence between the trained behavior and the desired behavior in a clinical context, similarity and distinction among stimulus properties in the training environment and the target clinical environment, and rigor of the skill assessment.[44-46] Regardless of the solution selected to mitigate risk, the effectiveness of a safety program is heavily dependent on a culture of reporting near misses.

Conclusion

Despite recent advances in infusion pump technology, hospitals continue to experience medication errors while using infusion pumps. The current study provides insight into the frequency of events by stages 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 preadministration process problems are the primary factors contributing 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 event reporting, including near miss events. With that information, a safety program can proactively identify problems and subsequently develop solutions. As we have highlighted, there are many potential solutions to mitigating risk of medication errors with infusion pumps. Personnel should carefully consider all possible solutions, which will range from acquiring better-designed pumps, adjusting settings on the pumps, or developing a robust error reporting and training program to address use errors.

Notes

This analysis was exempted from review by the Advarra Institutional Review Board.

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