FRESENIUS KABI

Infusion Pump Drug Libraries

Part 1: Challenges

Presented by

FRESENIUS KABI

IVENIX INFUSION SYSTEM

Executive Summary

Infusion pumps deliver medications, fluids and blood products to a patient intravenously. Today, most infusion pumps are equipped with computerized drug libraries, which contain information about an organization's drug formulary designed to help reduce infusion administration errors. Smart pumps are infusion pumps equipped with drug libraries with an associated Dose Error Reduction System (DERS).

However, despite these advances, infusion administration errors continue to rank as the most common medical technology error with more than 56,000 adverse events and 710 deaths reported between 2005 and 2009.[1]

Smart pump safety issues include users bypassing the drug library and its built-in dosing limits, failure to program limits, alert fatigue, a cumbersome library creation and non-standard update process, as well as underutilization of data resulting in missed quality improvement opportunities.

This paper is part one of a series and reviews these drug library challenges in detail. A companion paper examines solutions to these challenges.

Infusion Pump Drug Libraries

With the goal of enhancing patient safety, smart pump drug libraries typically provide a comprehensive list of an organization's available medications along with protocols for concentration, dosing unit and overall dosing limits, as well as clinical advisories for each drug. Limits help to prevent the end user, usually a nurse, from programming over- or under-delivery of a drug relative to a health care organization's best practice guidelines. Typically, these include soft limits that users can override and hard limits which require user re-programming to comply with protocols. The drug library also contains clinical advisories with important information about a specific drug. The advisories provide an avenue to specify drug specific instructions such as therapeutic indication or administration instructions.

The drug library is typically the core element of the infusion pump's DERS, which utilizes this information to help guide users in appropriate medication delivery and warn them about potential issues that may result in incorrect dosing.

In most organizations, the responsibility of maintaining and updating the drug library lies with pharmacy staff in collaboration with other departments (pharmacy and therapeutics committee). Collaboration from other departments ensures the library reflects the current formulary and clinical practice. Updating involves pooling resources from different departments such as pharmacy, nursing, informatics, and biomedical engineering.

Adverse Infusion Pump Incidents

The drug library is one of the safeguards that organizations rely on to help prevent infusion administration errors. Between January 1, 2005 and December 31, 2009, the U.S. Food and Drug Administration (FDA) received more than 56,000 adverse events and 710 deaths associated with infusion devices. During this time period, there also were 87 pump recalls.[1]

A Focus on Greater Safety

As a result, in 2010, infusion devices and drug libraries became the focus of a major summit to assess the scope of infusion device problems and to build a consensus on the most critical patient safety issues. FDA and the Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization, ran the meeting. One of the 13 priority issues identified during the summit involved the difficulties of uploading, managing and maintaining drug libraries.[1] Specifically, the summit highlighted a gap between pump management requirements and hospital capabilities, a steep learning curve to configure and manage drug libraries, as well as difficulty managing drugs used in multiple hospital units in multiple ways. Another issue was the ineffective alarm and alert management that can lead to high numbers of false alarms and difficulty in their prioritization.[1]

All of these issues can lead to unsafe patient conditions and care delivery. In fact, ECRI, an organization that reviews medical devices, recently listed infusion devices as the top health technology hazard for 2017 when safety steps are overlooked.[2]

Drug libraries within the smart pump unfortunately cannot prevent all administration and programming errors,[3] but they can create many opportunities to do so, which today are not fully exploited.

Drug Library Challenges

Bypassing Drug Libraries

Despite devoting significant financial resources to the purchase and maintenance of smart pumps and their libraries, many health care organizations fail to reap their full value. This is because in some instances, clinicians simply bypass the library and use manual dose calculations. This also overrides all library safeguards that can potentially prevent errors. In fact, in a prospective, multi-hospital study, Schnock et al. found that bypassing smart pump libraries was one of the most common factors associated with infusion errors (10%).[4] Some pumps make this easy by requiring the user to opt into the drug library rather than invoking it by default and requiring users to opt out, if desired.

Adverse events associated with overriding drug libraries are a testament to the magnitude of this problem. In an incident reported to the Pennsylvania Patient Safety Authority, a patient received a heparin infusion at a rate of 6000 units/hour. This event followed the transition of care from ambulance personnel to nursing staff, who erroneously stated that heparin was infusing at 60 mL/hour. They followed these dosing parameters. Once the error was discovered, the patient already had a markedly elevated PTT of 240 (Normal range = 25-35 seconds), INR of 43.4 (Normal range = 0.8-1.2) and low blood pressure. The patient had to be intubated and placed on a ventilator.[5]

In another case reported to the FDA, a nurse discovered that a patient was getting heparin 25,000 units/500 mL at a sub-therapeutic rate of 0.52 mL/hour (26 units/hour). This was 2% of the intended dose of 26 mL/hour. The patient had an amputation, although it was unclear if the error led to this outcome.[3]

In both cases, use of a drug library may have prevented the errors and possibly negative clinical outcomes. Both of the above cases demonstrate the effect of the drug library and the clinical impact it can have downstream.

In the above cases, inappropriate administration of heparin, a high alert medication, led to unintended outcomes.

Balancing Limits and Alert Fatigue

Drug library dosing limits are important, and lack of compliance typically triggers a user alert to keep infusions within hospital guidelines and standard practices. However, enabling limits is a delicate balance. Limits may also contribute to alert fatigue, which can lead to a reduced response to alerts and alarms.

The value of drug libraries in customizing default alarms to patient care areas, groups, or even conditions is unexploited.

> “Drug libraries when bypassed can result in errors that lead to subpar therapeutic outcomes.”

The FDA presents numerous examples of errors due to overriding soft dosing limits, often with alert fatigue involvement. For example, a nurse programmed nitroglycerin as 5 mcg/kg/min instead of the intended 5 mcg/min. The nurse bypassed soft limit alerts, leading to a 100-fold overdose. Error discovery only happened after the bag was complete. In another case, a nurse who intended to deliver total parenteral nutrition at a rate of 45.7 mL/hour gave 457 mL/hour despite a soft alert presentation.[3]

In addition to dosing limits, hospitals can set concentration limits that trigger alerts. If a soft concentration limit is not set, or the user overrides an alert, large overdoses can result. The literature provides an example.

In this case, a physician prescribed regular insulin, 12.5 units/hour. The pharmacy dispensed a standard bag of insulin 100 units/100 mL (1 units/mL). When programming the infusion device, the nurse failed to use the standard option and instead entered a custom concentration of 5 units/100 mL (0.05 units/mL). Consequently, the pump infused the insulin at 250 mL/hour, which led to infusion of the entire bag in 20 minutes.[6] As demonstrated in this example, not having enough limits, especially with high-risk medications, can lead to harmful errors.

Cumbersome Development and Update Process

Creating a drug library involves collaboration among multiple departments as members of a smart pump committee, with the goal of setting common doses and limits.

When several hospitals must come together to standardize and develop a single library that is used system wide, it can be even more difficult.

Additionally, once drug library content is entered, the remainder of the review process lacks automation and is time consuming and can be labor intensive. Typically, only one user (usually a pharmacist) can log into the library at a time, manually entering most of the information. Other individuals might assist in reviewing this information, but the pharmacist who enters the drug library limits may not have access to a pump to verify the data. Instead, nurse managers or reviewers will review the content against previously discussed content. Since this is a blind check, meaning they do not see the values displayed on the pump, it can be an error-prone process.

In some cases, after a pump update deployment, the defined dosing parameters for a specific medication do not meet the clinical practice needs of the end user, and require further refinement. Some hospitals use a dedicated pump to download and preview drug library changes; however, downloading unapproved content to a medical device can be dangerous if that device is kept in a non-secure location and away from the patient floors. This process can also be cumbersome if used within a health system (multiple hospitals).

In addition, a pump's drug library update calls for further interdisciplinary resources. Smart pump committees coordinate the update process, which involves medicine, pharmacy, nursing informatics, and biomedical engineering. This process can also be tedious, often taking several months per round of updates, depending on the size of the organization.

When wireless pump updates are not available, biomedical engineers have to locate each pump in the organization to facilitate upload of the latest updated library. It can take approximately 3 hours per device to locate, update, and redeploy.

> "Most drug libraries continue to be extremely labor intensive to develop, review, and update."

The frequency of updates largely depends on the size of the organization and can quickly add up in costs. Despite best efforts, the process is inefficient and renders some pumps with old software through months of use unbeknownst to end users. Some technologies rely on nurses to accept and power cycle smart pumps. In addition, when the update is not obvious, nurses might be oblivious of the update status. This may lead to administration of some infusions with outdated libraries exposing the patient to possible adverse events.

Underutilized Data and Missed Quality Improvement Opportunities

Smart pump libraries and related software record large amounts of crucial data related to dose limit warnings, clinician behavior, and user errors that are otherwise not available to an organization. This information may support significant improvements in clinical practice guidelines and drug library revision. For example, using this data, one pediatric hospital found that they were able to avert approximately 70 adverse events, resulting in a cost avoidance of over $3 million in three years.[7] However, smart pump data needs proper display to allow easier translation and issue identification. Some organizations do not dedicate sufficient resources to review the data as it stands, leading to missed improvement opportunities. These opportunities may involve adjusting the information presented on smart pumps through the revision of the drug library.

Conclusion

The wide variety of problems presented by smart pumps can have adverse impact on an organization's staff time, costs, and most important, patient safety. As mentioned earlier, there are numerous challenges with drug libraries such as:

- Bypassing drug libraries,
- Balancing limits and alert fatigue,
- Cumbersome drug library development,
- Long and inefficient update process,
- Underutilization of data and
- Missed quality improvement opportunities.

Fortunately, where there are challenges, there are possibilities to implement solutions that can help to improve efficiency and safety. These solutions will be explored in the next paper of this smart pump safety series.

References

1. Infusing Patients Safely. Priority Issues from the AAMI/FDA Infusion Device Summit. 2010 Accessed from: https://www.aami.org/docs/default-source/reports/aami_fda_summit_report.pdf
2. Top 10 Health Technology Hazards for 2017. A report from Health Devices Nov 2016. (cited April 20 2017) https://www.ecri.org/Resources/Whitepapers_and_reports/Haz17.pdf
3. Cummings K, McGowan R. "Smart" infusion pumps are selectively intelligent. *Nursing*. 2011;41(3):58-59.
4. Schnock KO, Dykes PC, Albert J, et al. The frequency of intravenous medication administration errors related to smart infusion pumps: a multihospital observational study. *BMJ Qual Saf*. 2017;26(2):131-140.
5. Smart Infusion Technology: Don't Bypass the Safety Catches (online). Pa Patient Saf Advis 2007 Dec (cited 2017 Apr 20) https://patientsafety.pa.gov/ADVISORIES/Pages/200712_139.aspx
6. Smart Pump Custom Concentrations without Hard "Low Concentration" alerts. ISMP Acute care Newsletter. 2012;2:23
7. Tu,K., Schearer, S. Burr, W., et. al. Improving patient safety by optimizing smart pump utilization in a pediatric hospital. https://www.ashp.org/-/media/assets/meetings-events/docs/sm12-poster-abstracts.ashx

FRESENIUS KABI

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.us/ivenix

3336-IVEN-02-02/23 v2.0