Sentinel Event Alert

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Optimizing smart infusion pump safety with DERS

Many medication errors can be prevented through safe medication practices;[1] however, sometimes these errors — including those involving "smart" infusion pumps — are caused by a combination of human and technical risk factors, including fatigue, distraction, and drug library overrides, deficiencies or misuse. For example, a health care professional working on a busy hospital floor mistakenly enters an incorrect flow rate into a smart infusion pump's flow rate field while programming a medication infusion outside the drug library, resulting in a serious injury to the patient.

Smart infusion pumps combine computer technology and drug libraries to limit the potential for dosing errors. Hospitalized patients commonly receive intravenous (IV) medications and fluids via smart infusion pumps, and errors involving the pumps occur each year.[2] A study published in 2016 found that bypassing the smart infusion pump or the drug library accounted for about 10% of the total number of errors or policy violations relating to infusion administration.[3] Smart pump errors can result in harm to patients that could be avoided by using built-in dose error reduction software (DERS).[4]

According to the Institute for Safe Medication Practices (ISMP), DERS refers to the integral computer software in smart infusion pumps intended to aid in prevention of infusion programming-related errors and warn users of potential over- or under-delivery of a medication or fluid by checking programmed doses/rates against facility-configurable preset limits specific to a medication/fluid, and to a clinical application (e.g., epidural administration) and/or location (e.g., neonatal intensive care unit, medical/surgical unit).

Most United States hospitals have invested in smart infusion pumps[5] with DERS, which have demonstrated their safety potential and have been on the market for 15 years. Still, many errors occur because health care organizations and clinicians are not optimizing the use of DERS technology.[2]

This *Sentinel Event Alert* describes actions health care organizations can take to reduce the risk of errors caused by the misuse of smart infusion pumps, especially errors that can be avoided by the optimal use of DERS, which is expected practice according to ISMP.[5] The Joint Commission recognizes that safe medication management cannot be accomplished with technology alone. Please share this alert within your organization; the alert is directed to clinicians using smart infusion pumps in all health care settings, especially nurses, physicians, pharmacists and anesthesia providers, and including clinical leadership, biomedical engineers, and patient safety and risk officers.

Implementing DERS can improve safety

DERS-equipped infusion pumps can store medication limits by care area, unit, location or patient population, with both hard and soft stops.[2] Hard stops are upper or lower limits set in the drug database that require the clinician to reprogram the pump to a value within DERS limits or to program the pump as a basic infusion outside the DERS. Soft stops are upper or lower limits that provide a warning prior to hitting the hard limit; the programming must be confirmed before the infusion can continue.[7]

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel and adverse events and high-risk conditions, describes their common underlying causes, and recommends steps to reduce risk and prevent future occurrences.

Accredited organizations should consider information in a *Sentinel Event Alert* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or reasonable alternatives.

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The Joint Commission

Smart infusion pumps with DERS are designed to reduce errors by keeping medication infusions within generally accepted ranges. The capability of DERS to store drug library information — such as hospital-defined dose/concentration/rate limits and clinical advisories — helps to avert errors and warn clinicians about potentially unsafe drug therapy.[5] In other words, technology is only one of the tools that complements the design of a safe medication management system.

Among the most common programming errors associated with smart infusion pumps are medication errors due to dose-rate confusion; mistakes with a decimal point, weight or unit of measure; and selecting the wrong drug or dosing method in the drug library.[2]

By connecting wirelessly to electronic health record (EHR) systems, many smart infusion pumps can be auto programmed for a clinician's review and pharmacist's verification before starting an infusion.[8] Integrating smart infusion pumps with an organization's EHR system results in benefits including a more complete and accurate library, which helps ensure DERS use when manual programming of a pump is required.[9,10,11] A 2013 ECRI study that determined that 28% of infusion errors could have been prevented with DERS also found that 75% of the reported problems could have been averted with smart pump-EHR integration. This integration also helps to ensure that:

- The right concentration, dose, rate, and weight/body surface area are programmed, since these parameters are sent directly from the EHR.
- All infusions programmed with smart pump integration have a matching entry in the DERS library.[9]

Smart infusion pumps can provide useful ongoing data for analysis to improve safety performance; these data help health care organizations to measure alert types and frequency, actions taken in response to alerts, the frequency of alert overrides, and compliance with using the drug library.[2]

Actions suggested by The Joint Commission

Barriers to optimizing the use of smart infusion pumps include limitations in infusion pump capabilities, alarm fatigue, availability of pumps, programming workflow, associated risks with secondary infusions, pump data analysis,[5] and persistent deficiencies related to library use and updates.[2] These deficiencies include omitting certain drugs and fluids (solutions) from the library and failing to engage the library for available drugs and fluids.[6] Additional barriers are related to usability and include confusing programming navigation, toggling between multiple screens, unintuitive selection keys and menus, and poor ergonomics that do not support human factors and the end-user.[12]

While understanding that the capabilities of smart infusion pumps and DERS vary within each organization, The Joint Commission suggests the following general actions that use a systems approach to help overcome these barriers and optimize the safe use of smart infusion pumps with DERS.

1. **Leadership assigns responsibility by identifying a multidisciplinary project team or department (such as the pharmacy and therapeutic committee) responsible for smart infusion pump interoperability, including DERS, the oversight of drug library revisions or additions, infusion protocols, smart infusion pump maintenance and related issues.**[5]

2. **Define a process to create, test, regularly engage with, and maintain a drug library.** If a drug library is not designed and maintained well, DERS cannot operate optimally (i.e., garbage in, garbage out). Establish an interdisciplinary team to create, test and maintain a drug library, and to update it periodically at a frequency to be determined by the organization. ISMP recommends quarterly updates.[5] Perform independent double checks (i.e., performed separately by two different people) when building the library for every drug entry in the library, including drug name, dosing units, concentration, dose limits and associated clinical alerts.[5] Create a rapid approval process for any new formulary additions, with appropriate checks and balances to ensure all safety considerations are incorporated in the abbreviated process.

    - Standardize the nomenclature for drug name, dose/dosing units (e.g., weight-based versus non-weight-based dosing; mcg/kg versus mg/kg), and dose rate (mg/kg/min versus mg/kg/hr) in the drug library. Ensure that this

nomenclature is consistent across the medication use process, including the EHR system, pharmacy infusion labels, and pharmacy IV workflow systems.[5]

- Establish subsets within the library tailored to specific clinical contexts or patient populations (such as pediatrics or oncology patients), hospital areas, or nursing units (such as critical care).[5] These subsets are often referred to as "care areas." If possible, check the library's drugs, doses and ranges against other similar hospitals or organizations. When transferring patients to a different clinical unit, ensure the drug library care area/profile is appropriate for the receiving unit.[5]

- Standardize and limit the number of drug concentrations for continuous and intermittent infusions available in the drug library and ensure they are consistent within the EHR and pharmacy IV workflow systems.[5] Adoption of this safe practice will limit user selection mistakes in the drug library and help prevent overdosing errors.

- Engage the library when using smart infusion pumps to receive alerts when infusions are programmed outside dose limits or administration rates specific to medications and patient populations.[6]

- When updating drug libraries, work closely with the medical engineering and information technology departments, and smart infusion pump vendors to assure complete updates of all smart infusion pumps actively used within the organization. Identify and segregate infusion pumps that may not be operational during an update until the library becomes updated and ready for use. Recognize that medication shortages and drug substitutions may necessitate the reprogramming of pumps to reflect appropriate parameters.

- Limit the availability of custom concentrations (also known as wildcards) for continuous infusions, leaving them for medications/cases where it is absolutely necessary. Where custom concentrations are necessary, consider adding hard stops at least for low concentrations.[5,13,14]

3. **Train and assess competency of all clinical staff, including nurses and other clinicians who travel to various care settings.** Conduct initial training and annual competency assessment sessions for all personnel using smart infusion pumps to educate them about the risks of omitting certain drugs and fluids (solutions) from the library, failing to engage the library for available drugs and fluids, and overriding the DERS alerts.[6] Make them aware of differences between pumps, if more than one kind is used by your organization.

   Develop procedures and train staff on how to ensure the correct programming and verification of infusion parameters, including independent double checks, when a drug is not in the library, a non-standard concentration must be used, or if auto-programming is not possible.[15] Follow your organization's own policy regarding training and timeframes for it.

4. **Make the optimal use of DERS expected practice.**[5] Administer all IV medication and fluid infusions via programmable infusion pumps using DERS. Exceptions may include gravity infusions (administering a fluid infusion at a rate greater than the infusion pump allows) with clinical applicability.[5] The use of DERS is not a requirement, however, of a Joint Commission standard.

   Use smart infusion pumps that default directly to DERS programming, make it obvious when the infusion pump is operating outside DERS,[5] and can wirelessly update the drug library and transmit data. Have reliable wireless connectivity wherever smart infusion pumps will be in use.[5]

5. **Monitor alerts, overrides, equipment or software recalls, and adverse event and close call reports.** Set organizational expectations and goals for the use of DERS. Monitor DERS and use smart infusion pump data analytics to measure compliance and improve medication safety.[5,6]

   - Monitor the frequency and types of alerts, actions taken in response to the alerts, and safety feature overrides,[6] including bypasses of the drug library.[15] Frequent

alerts may signal the need to evaluate dose limits or ranges.

- Encourage staff to report conditions that require workarounds,[15] such as a drug not being in the library or a lack of smart pumps.

- Investigate medication errors and close calls to determine any root cause or process gap that may have contributed to it, or if it was related to improper use of the safety software.

- Track, trend and report these findings as part of the organization's event reporting process.

- Stay attuned to adverse event reports, hazardous conditions and recalls relating to smart infusion pumps issued by internal and external sources, including the U.S. Food & Drug Administration (FDA) and ISMP.

- Share monitoring information and smart infusion pump data with the committee or department responsible for oversight of DERS (mentioned in suggested action #1).

6. **If your organization has the capability, connect your smart infusion pump fleet with your EHR system.** Use smart infusion pumps capable of bi-directional communication with your EHR system. Establish a multidisciplinary project team to guide the planning and implementation of this interoperability. Connecting your smart infusion pump fleet with your EHR system enables auto-programming, which can reduce manual programming errors.[5]

7. **Identify and address human and environmental factors — such as understaffing, variation in pumps that can create confusion in controls, workflow distractions, and low lighting or glare — that contribute to smart infusion pump programming errors in your hospital.**[12]

8. **Keep the smart pump fleet safe from security threats and during downtime.** Protect smart pumps from cybersecurity threats including malware, hacks, breach of personal health information, and loss or disruption of equipment and services.[16,17] Discontinue the use of pumps with significant cybersecurity vulnerabilities and transition to the use of an alternate system.[18] Develop downtime procedures to guide workflow when interoperability or wireless capability goes down.[5]

Related Joint Commission requirements

The Joint Commission has several standards and elements of performance (EPs) in the Joint Commission's accreditation manual for the hospital program that address medication administration safety and supporting processes, including performance improvement. See the content of the applicable standards on the last page of this alert.

Resources

"Optimizing Safe Implementation and Use of Smart Infusion Pumps," Institute for Safe Medication Practices.

REMEDI is a not-for-profit collaborative community of pharmacists, nurses, researchers, vendors and others working to improve patient safety and health care quality through the development and exchange of infusion pump medication administration knowledge and best practices. The REMEDI science gateway currently includes a vendor-neutral infusion pump analytics and reporting package, allowing hospitals to perform self-analysis, benchmarking and comparison of DERS programming alerts, smart infusion pump compliance, and drug limit libraries with other hospitals.

Building a Smart Infusion System Drug Library. Prepared by Tim Hoh, Pamela I. Krueger, Baxter Healthcare Corporation, in collaboration with the Institute for Safe Medication Practices, Jan. 30, 2017.

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Related Joint Commission requirements.

HOSPITALS

Medication Management (MM)

MM.06.01.01: The hospital safely administers medications.

MM.06.01.01 element of performance (EP) 3: Before administration, the individual administering the medication does the following:
- Verifies that the medication selected matches the medication order and product label
- Visually inspects the medication for particulates, discoloration, or other loss of integrity (See also MM.03.01.05 EP 2; MM.05.01.07 EP 3)
- Verifies that the medication has not expired
- Verifies that no contraindications exist
- Verifies that the medication is being administered at the proper time, in the prescribed dose, and by the correct route
- Discusses any unresolved concerns about the medication with the patient's licensed independent practitioner, prescriber (if different from the licensed independent practitioner), and/or staff involved with the patient's care, treatment, and services

MM.08.01.01: The hospital evaluates the effectiveness of its medication management system.
Note: This evaluation includes reconciling medication information. (Refer to NPSG.03.06.01 for more information)

MM.08.01.01 EP 1: As part of its evaluation of the effectiveness of medication management, the hospital does the following:
- Collects data on the performance of its medication management system (See also PI.01.01.01 EPs 12 and 13)
- Analyzes data on its medication management system
- Compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management system

Note: This element of performance is also applicable to sample medications.

MM.08.01.01 EP 5: Based on analysis of its data, as well as review of the literature for new technologies and best practices, the hospital identifies opportunities for improvement in its medication management system.

Performance Improvement (PI)
PI.01.01.01: The hospital collects data to monitor its performance.

PI.01.01.01 EP 12: The hospital collects data on the following: Significant medication errors. (See also LD.03.07.01 EP 2; MM.08.01.01 EP 1)