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ISMP
An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Smart infusion pump investigations after an unexplained over-infusion

Problem: For more than 20 years, ISMP has advocated for the use of smart infusion pump technology with drug libraries and dose error-reduction systems (DERS) when administering intravenous (IV) infusions. The ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice* #8 (www.ismp.org/node/160), calls for organizations to maintain compliance of greater than 95% for the use of DERS. The goal of using DERS is to prevent user-related medication errors, including over- and under-infusion that can cause harm to patients. But what if a practitioner adheres to the manufacturer's instructions and ISMP *Best Practices* and programs the smart pump using DERS, and the patient's medication infusion finishes much sooner than expected? Then, what if the infusion pump log data is analyzed by the organization's smart pump team, then sent to the vendor for further investigation, and "no issues" are found, while the log indicates that the practitioner programmed the pump correctly? This is exactly what happened in one organization that recently experienced several events within a 2-month period while using BD Alaris infusion pumps.

*In one case, a patient was prescribed an IV dexmede**TOMID**ine infusion (800 mcg/200 mL) at a dose of 140 mcg/hour (35 mL/hour) to treat agitation. Two nurses independently double checked the smart pump programming. Approximately 15 minutes after the infusion started, a nurse responded to an "air in line" alarm on the pump and found that the dexmede**TOMID**ine infusion bag was completely empty. The patient received the entire 800 mcg dose at a rate of approximately 800 mL/hr. At this point, the patient had agonal breathing and was unresponsive to painful stimuli. The nurse contacted the prescriber and was instructed to monitor the patient closely. Shortly after, the patient required intubation. No further patient outcome information was reported.*

In a second case, a morphine sulfate infusion (100 mg/100 mL) was ordered for a patient at a dose of 16 mg/hour (16 mL/hour). Less than 1 hour after the infusion was started, the nurse entered the patient's room and noticed the morphine infusion bag was empty. The nurse confirmed that the pump was programmed at 16 mg/hour, which should have infused the morphine over 6 hours.

BD conducted laboratory testing of the returned pump modules and could not confirm or replicate the over-infusions. However, the company was able to verify that the practitioners programmed the pumps at the intended rates. Of note, the administration sets were not returned to BD for analysis.

Incidents such as these can have devastating outcomes for patients, including death in the worst-case scenario. An unexplained smart infusion pump incident can be a logistical nightmare for practitioners that can erode end-users' trust in infusion pump technology. When programming errors are ruled out and an error cannot be replicated with laboratory testing, practitioners are left uncertain about what led to the incident and what actions to take to prevent a recurrence. Such events can also leave practitioners wary of device use altogether, choosing instead to run infusions by gravity if they believe they can have better control of the infusion rate.

Safe Practice Recommendations: While the reported cases involved BD Alaris infusion pumps, several principles outlined below also apply to pumps from other vendors. When investigating an over- or under-infusion incident, review the ISMP ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps*** (www.ismp.org/node/972), and

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SAFETY brief

Communicate Paxlovid expiration date extension to patients. In January, the Administration for Strategic Preparedness and Response (ASPR) and the US Food and Drug Administration (FDA) announced (www.ismp.org/ext/1153) authorization of an extension of the expiration date for the Pfizer antiviral therapy, **PAXLOVID** (nirmatrelvir and ritonavir tablets co-packaged). The expiration date was extended to 24 months based on the earliest manufacturing date of the two components. This extension was communicated to practitioners, but it appears it is not reaching patients.

The FDA received reports of patient confusion and concern about expiration dates that differ between what is printed on the pharmacy prescription label or changed on the outer carton, and what is printed on the blister package labels inside. In one case, a patient reported that the original outer carton label

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ISMP Survey on the 2022-2023 *Targeted Medication Safety Best Practices for Hospitals*

ISMP is conducting a short survey to get a sense of the current level of implementation of the 2022-2023 ***Targeted Medication Safety Best Practices for Hospitals***. We would very much appreciate your participation in this survey. Please complete this survey online by **June 30, 2023**, by visiting: www.ismp.org/ext/1164. ISMP plans to present the results of this survey during the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition in December 2023. The findings will also be described when introducing the **new** 2024-2025 ***Targeted Medication Safety Best Practices for Hospitals*** early in 2024.

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consider the following recommendations, many of which have been previously published by our affiliate, ECRI.[1-6]

Respond to recalls. Designate an individual(s) to monitor for recalls related to infusion pumps and consumables (e.g., administration sets, medication reservoirs, syringes used in pumps). Sequester or destroy/return all recalled products.[1] Share any warnings (e.g., medical device corrections) or recalls related to infusion devices used with end users (e.g., nurses, anesthesia providers), including recommended actions. Consider using an automated recall management software system, such as one offered by ECRI (www.ismp.org/ext/1167), to track and respond to recalls.

Schedule preventive maintenance. Develop a process for clinical/biomedical engineering to routinely inspect infusion pumps. Review manufacturers' recommended cleaning practices and products for properly cleaning the devices and ensure the correct cleaning procedures are being followed.[2]

Check for visible damage. Damage (e.g., cracking, loose parts) on an infusion device can impact its ability to control medication flow or communicate with other modules. Clinical/biomedical engineering should inspect the pump door, hinges, and all modules for cracks, gaps, or misalignment, as these could impact the infusion and allow uncontrolled medication flow.[3] Be sure to view the device from the front, top, and sides. Check that screws are properly tightened and that all parts appear intact. Any cracks or damage should be fixed promptly. Educate staff to never use a device that has a crack or obvious structural damage, as reliability could be in question. Develop a process for practitioners to label such devices for clinical/biomedical engineering to repair and immediately take them out of circulation.

Educate staff how to set up the device. During orientation and annual competency assessments, the nurse educator should teach staff how to insert the administration set into the infusion pump according to the manufacturer's instructions. To prevent a misconnection at the time of set up, ensure practitioners trace the infusion line from the infusion bag, through the pump channel, and to the vascular access device. The BD Alaris pump module administration set can be loaded into the pump incorrectly without subsequent alarms if the manufacturer's instructions are not followed (www.ismp.org/ext/1173). Errors related to loading the administration set include inadvertently enclosing extra infusion tubing into a pump channel and stretching infusion tubing such that the blue fitment is above the pump door, both of which can impact the ability of the pump to control the flow.[4] Provide manufacturers' tip sheets and quick reference guides to all clinical areas that use the device and consider attaching them to the pumps.

Close the roller clamp. While the device's anti-free-flow protection mechanism is intended to eliminate free-flow events, it should not be solely relied upon. If the door latch has been compromised, the anti-free-flow protection may not engage when the door is opened.[5] The anti-free-flow protection is a secondary protection mechanism; the roller clamp is the primary method of preventing flow. During times when the practitioner does not intend to administer an infusion to a patient, ensure the roller clamp is closed to prevent an inadvertent bolus dose from being delivered to a patient.[5] Only unclamp the roller clamp when starting or restarting the infusion.

Monitor infusions for unintended flow. Periodically check throughout the infusion that the remaining infusion volume approximately corresponds to the expected delivery time. Check that there is no flow in the drip chamber whenever the pump is off, paused, or not programmed to be infusing. For critical medications, consider more frequent monitoring.

Identify and respond to potential medication errors. If a practitioner suspects a significant discrepancy between the expected rate and how fast or slow an infusion was administered, confirm the infusion was programmed correctly (e.g., correct medication, concentration, dose-rate). Note

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expiration date was removed and a date of 02/2024 was written on the box. The patient noticed an expiration date of 04/2023 on the medication blister packages. Not knowing about the approved date extension, the patient thought that expiration date tampering had occurred! Other patients reported that they had ingested expired Paxlovid, not knowing the expiration date had been extended.

When counseling patients about Paxlovid, it is important that pharmacists also address the expiration date change. Also, Pfizer can provide an auxiliary label to be affixed on the Paxlovid carton to inform patients about the FDA-authorized expiration date change, mentioning that the expiration date listed on blister packages inside the carton is sooner than what is now authorized and relabeled on the outer carton. Pharmacists and patients can check the former expiration dates and new dates, listed by the batch number found on the outer carton, via this website: www.ismp.org/ext/1154.

Special Announcements

Quarterly ISMP Resources and Services Highlights

What does ISMP have to offer you? Check out our quarterly highlighted educational webinars and workshops, professional development opportunities, and **FREE** medication safety tools. The spring edition is now available as a convenient webpage, visit: www.ismp.org/node/61994.

Free FDA webinar

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a **FREE** webinar, ***FDA Drug Topics: How to Avoid Medication Errors with Pen Injectors*** on **May 23, 2023**. Participants will be provided with important safety information on how to prevent errors when using these devices to administer medications. ISMP President Emeritus **Michael Cohen** will be one of the speakers. For details, visit: www.ismp.org/ext/30, and to register for the program, visit: www.ismp.org/ext/31.

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that the accuracy of an infusion pump flow rate varies due to a number of factors (e.g., head height differential between the primary and secondary infusion), but if a significant discrepancy is identified, notify the provider and discuss the best course of action. For example, consider the following: review programming settings and the volume infused; review the medication order; consider the need to pause the infusion and close the roller clamp to stop the medication flow; alert unit management and report the incident per facility policy; and document a detailed timeline of events including any issues (e.g., IV bag changes, administration set changes, use of secondary products, resistance of the door, how many times the administration set was removed from the pump, error alerts on the infusion pump screen and corresponding actions taken) that may have occurred.

Sequester the impacted device. Implement a policy to sequester the pump, involved module, and all other modules attached at the time of the incident, and follow an escalation process (e.g., notify clinical/biomedical engineering). Develop a form that practitioners can use to document detailed information about the issue and attach this to the device for investigation. To the extent possible, preserve how the pump was set up when the incident occurred. Do not detach the modules.

Save consumables. If an infusion pump is involved in an incident, the investigation may be hindered if consumables (e.g., IV bag and infusion set) are discarded. Educate staff about the importance of saving any consumables associated with a suspected infusion pump incident, when clinically acceptable.[6] If the medication is a controlled substance, ensure a secure chain of custody is maintained.

Extract infusion pump log data. If an error has been reported related to the use of a smart pump, notify the smart pump team for follow-up. Extract and review the usage logs for all pump modules; confirm the pump programming. When analyzing the event, pay particular attention to whether the door was opened during the time the event occurred and identify any unexpected alarms, which may aid in determining the root cause of the event.

Investigate. After sequestering the device, consumables, and event log data, analyze the information gathered about the incident and surrounding conditions. Review the documented timeline of events and any other incident report details. Interview involved personnel, check the product label, and test the device's operation. If there are concerns that an infusion could have been prepared with a different volume than what was prescribed, investigate the possibility of a dispensing error. Seek assistance from the manufacturer or a third-party consultant to support the investigation. Our affiliate, ECRI, provides this service along with ISMP support as needed.

Report events. Report any incidents to the smart infusion pump vendor, ISMP (www.ismp.org/node/18107), ECRI (www.ismp.org/ext/1162), and the US Food and Drug Administration (FDA) (www.ismp.org/ext/1163).

Collaborate with pump vendors. After investigating an event, follow up with your vendor to understand the results of their investigation and to determine if any changes in your organization's policy, processes, or education may be needed. Request your pump vendor conduct onsite visits and provide free training for persistent issues. Consider partnering with vendors to help educate practitioners on how to prevent and respond to common issues seen with the device.

Share internal and external information. Provide practitioners who use smart infusion pumps with ongoing information about errors that have occurred in the organization and/or have been reported by external organizations. Share lessons learned from past investigations and provide continuous education to staff on strategies to minimize these risks. Provide illustrative photographs of potential error scenarios as merited. Keep staff abreast of any emerging issues or recalls that may impact device operation.

References appear at the top of the right column >

References

1) ECRI. BD—Alaris Pump Modules: overinfusion may occur with the use of certain administration sets [ECRI Exclusive Hazard Report]. *ECRI Alerts*. May 2, 2019. Accession No. H0511.

2) ECRI. BD—Alaris Pump Modules: ECRI and ISMP members continue to report inter-unit interface (IUI) problems that may lead to cessation of infusion [ECRI Exclusive Hazard Report]. *ECRI Alerts*. March 20, 2023. Accession No. H0840.

3) ECRI. CareFusion—Model 8100 Alaris Infusion System Pump Modules: cracked or broken upper platen hinge may result in drug overdelivery [ECRI Exclusive Hazard Report]. *ECRI Alerts*. May 13, 2016. Accession No. H0319.

4) ECRI. BD—Model 8100 Alaris Pump Modules: ECRI Institute continues to receive reports of overinfusion because of administration set entrapment [ECRI Exclusive Hazard Report]. *ECRI Alerts*. April 11, 2019. Accession No. H0326 01.

5) ECRI. CareFusion—Alaris Pump Modules: damaged door components may fail to engage anti free flow mechanism, potentially leading to gravity flow [ECRI Exclusive Hazard Report]. *ECRI Alerts*. August 25, 2016. Accession No. H0337.

6) ECRI. Infusion Pumps—ECRI Institute recommends that facilities sequester consumables with pumps after an incident [ECRI Exclusive User Experience Network]. *ECRI Alerts*. August 22, 2019. Accession No. S0376.

Editors: Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Shannon Bertagnoli, PharmD; Ann Shastay, MSN, RN, AOCN; Kelley Shultz, MD. ISMP, 5200 Butler Pike, Plymouth Meeting, PA 19462. Email: ismpinfo@ismp.org; Tel: 215-947-7797.

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