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ISMP
An ECRI Affiliate

Nurse AdviseERR®
Educating the Healthcare Community About Safe Medication Practices

# Smart infusion pump investigations after an unexplained over-infusion

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. 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.

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 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

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## SAFETY wire

**Safety mechanism needed for Evenity syringe needle to prevent needlestick injuries!** We continue to receive reports of needlestick injuries involving **EVENITY** (romosozumab-aqqg), risking transmission of blood-borne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) to healthcare providers and patients. Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or for patients who have either failed or are intolerant to other available osteoporosis therapies. The manufacturer, Amgen, supplies the medication in a carton containing two prefilled syringes (both syringes are needed to administer the total dose of 210 mg subcutaneously) and is labeled to be administered by a healthcare provider (**Figure 1**).


**Figure 1.** A dose of Evenity requires the administration of two subcutaneous injections. The manufacturer, Amgen, packages two prefilled syringes in one carton. The syringe needles do not have safety guards, so the potential for needlestick injuries is high.

In one case, a nurse in an outpatient infusion setting experienced an accidental needlestick injury while administering Evenity to a patient. The needles on Evenity syringes lack a safety device; they are not retractable or even removable, so the nurse was unable to change the needle to one that has a safety guard. Other organizations have reported the same concern about accidental needlesticks with this product, which we wrote about in our September 2022, issue (www.ismp.org/node/38617). All the reports noted the lack of a safety guard and suggest adding one.

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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 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.** During the infusion, periodically check that the remaining 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 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

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It should be noted that the Occupational Safety and Health Act (OSHA) of 1970 requires compliance with OSHA standards to institute safety measures in workplaces where there is occupational exposure to blood or other potentially infectious materials. Under the standard, as revised by the *Needlestick Safety and Prevention Act*, employers are required to evaluate, select, and use engineering controls (e.g., sharps with engineered sharps injury protections or needleless systems) to eliminate or minimize exposure to contaminated sharps (www.ismp.org/ext/1104). Technically, if an injectable does not allow the use of an engineering control such as a needle with a safety guard, then the product should not be used in that facility. Using injectables without safety needles when providing patient care puts organizations at risk, especially with products like Evenity that have labeling stating it should be administered by a healthcare provider.

Some people may think an accidental needlestick is a low-risk situation for a healthcare professional—that it won't happen here or won't cause an infection. Although the actual risk of disease transmission may be low, needlestick injuries can still happen and disease transmission certainly can occur and be devastating. Organization protocols detail steps that address needlestick injuries and have an associated cost, take up precious resources, and cause downtime for nurses and other healthcare workers. There is also a need for postexposure prophylaxis for HBV and HIV, along with associated pretreatment laboratory testing (www.ismp.org/ext/1105).

OSHA requires that employers maintain a log of all work-related needlestick injuries where there may be contamination with another person's blood or other potentially infectious material. As mentioned in our September 2022 issue, ISMP is aware of other marketed prefilled syringe products without needle safety guards. We do know of another product, **LUPRON DEPOT-PED** (leuprolide acetate for depot suspension), that is labeled "must be administered by a healthcare provider" and it has a safety needle (www.ismp.org/ext/1117).

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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, 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 to the right >

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Much of this safety issue could be avoided if all prefilled syringes had engineering controls that protected people, not just healthcare professionals, against needlestick injuries. ISMP asked the US Food and Drug Administration (FDA) and manufacturers to address this concern with a requirement for ALL prefilled syringes to have a safety guard. We also spoke with Amgen directly about the need for a needle safety guard for Evenity and hope they will consider adding one. Alternatively, companies can make prefilled syringes without an affixed needle so that a safety needle can be placed on the syringe before use. This would allow conformance with the OSHA requirement and help protect people against injury from an uncovered needle after administration.

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