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ISMP An ECRI Affiliate

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

Safety considerations for challenges when using smart infusion pumps

Smart infusion pumps are critical in helping prevent potentially harmful medication errors. It is important for nurses to utilize the safety features within the smart infusion pump to guide clinical practice. Organizations must customize their smart infusion pump drug libraries and tailor each to their needs. However, drug library customization requires a dedicated multidisciplinary team comprised of physicians, pharmacists, nurses, and information technology (IT) staff to review the literature, compare the parameters in the drug libraries with actual clinical practice, and determine safeguards for each infusion in the drug library within each clinical setting. It is essential for organizations to continually ensure that the library content is up to date and that the most recent version has been downloaded and is active on all of their smart pumps. Unfortunately, ISMP has received reports related to safety risks and limitations that healthcare practitioners face when trying to optimize drug libraries and implement important safeguards to prevent catastrophic programming errors.

No Universal Maximum Dose

Several medications, including opioids, benzodiazepines, and anticoagulants, do not have a universal maximum dose published in the official prescribing information; instead, they have widely variable doses based on the medication's indication, patient-specific parameters, tolerability, or clinical response. Without a maximum dose built into the smart pump library, a programming error, including programming doses or rates 10-fold or greater than intended (e.g., entering 200 mg instead of 20 mg, 19 units/hour instead of 1.9 units/hour) could lead to significant patient harm. For example, if a heparin protocol does not include a maximum dose, the team that builds the smart pump drug library will need to achieve consensus to choose one set. While the smart pump team may try to capture most dose scenarios, they may not know where to draw the line for patients who receive doses that are higher or lower than typical doses for clinically appropriate reasons. If a smart pump issues a hard stop for a dose outside the limits but the dose is still clinically appropriate for the patient, the practitioner will likely need to revert to a risk-prone process of manually programming the heparin infusion without engaging the dose error-reduction system (DERS).

Wide Dosing Parameters or Variable Rates

Medications with wide dosing parameters or variable rates of infusion pose added challenges when building dose range limits in drug libraries. The smart pump team may have difficulty building effective safeguards while accommodating the variable doses and infusion rates for medications titrated to patients' clinical responses, used for different indications, or based on the patients' tolerability. The following examples highlight these challenges.

Clinical response. Titratable medications, such as vasopressors, require prescribers to order an initial rate of infusion, titration parameters including the frequency of titration, the maximum dose or rate of infusion, and an objective clinical measure to guide changes. If the smart pump team setting the minimum and maximum dose limits does not consider the full range of the titration across all patients, the result is possible nuisance alerts or unnecessary hard stops for the practitioner programming the pump.

Indication. For mechanically ventilated patients in the intensive care unit (ICU), the typical dose of a ketamine continuous infusion for analgesia, sedation, agitation, or chronic pain is much lower

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SAFETY wires

Prefilled glass syringes incompatible with certain needlefree connectors. Due to drug shortages of certain vials or prefilled syringes of emergency medications, including atropine and naloxone injection, some hospitals have been providing prefilled glass syringes instead. However, certain needlefree syringe connectors for intravenous (IV) lines, called Luer-activated valve (LAV) connectors, are incompatible with prefilled glass syringes. We first reported this issue in July 2021 after receiving reports of naloxone injection failures when attached to MicroClave needlefree syringe connectors (www.ismp.org/node/25848). Now with the current drug shortages, the problem has increased. ISMP and the US Food and Drug Administration (FDA) have received multiple reports from practitioners who have been unable to inject a medication into an IV line once the prefilled glass syringe has been connected to the needlefree system. Evidently, inserting the glass syringe tip can cause the pin in the MicroClave needlefree access system to break off in the syringe tip, preventing delivery of the medication. In some events, a piece of plastic was found lodged inside the syringe tip (nozzle), effectively blocking the flow of medication **(Figures 1** and **2**).

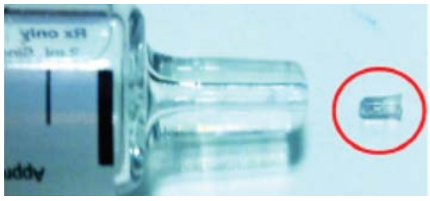

Figure 1. After connecting a glass syringe to the LAV connector, the pin from the connector became clogged in the syringe tip.

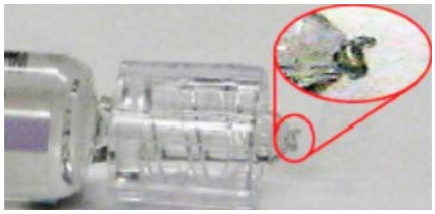

Figure 2. Pin from the LAV connector removed from the syringe tip.

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Supported by an educational grant from Fresenius Kabi and Ivenix

FRESENIUS KABI IVENIX INFUSION SYSTEM

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than the dose of this medication infusion used for refractory status epilepticus based on a goal of electrographic suppression. If only one option exists in the smart pump library for ketamine, which has up to a 10-fold difference in safe dosage ranges based on its indication, a practitioner who makes a programming error may not receive an alert.

Tolerability. Prescribers may incrementally increase the rate of certain chemotherapy and immunosuppressants based on the patient's tolerability, rather than titrating to a clinical endpoint. For example, when used for certain indications, ri**TUX**imab has an initial infusion rate with incremental increases every 30 minutes unless hypersensitivity or an infusion-related reaction occurs.

For each of these situations, practitioners who make programming errors will either not receive clinically important alerts if the dose limits are too wide, or will receive nuisance alerts or hard stops if the dose limits are too narrow. Nuisance alerts that happen regularly contribute to alert fatigue and unsafe workarounds that can result in administering the medication infusion without engaging the DERS.

Large Dosing Differences in Opioid-Naïve and Opioid-Tolerant Patients

Patients may require a continuous opioid infusion or patient-controlled analgesia (PCA) for a variety of indications, including pain management or end-of-life care. There are large differences in opioid doses, rates, and concentrations used to treat opioid-naïve patients compared to opioid-tolerant patients. Like the scenarios described above, if there is only one option for each opioid medication infusion, nuisance alerts may fire for opioid-tolerant patients if the dose range limits are too narrow, or clinically important alerts may not fire for opioid-naïve patients if the upper limits are too high.

Bolus Doses Inappropriately Administered from Continuous Infusions

When patients receive a continuous infusion, practitioners may be required to directly administer a bolus dose of the same medication from the continuous infusion. This is only safe if the smart pump has a bolus dose feature that administers the correct dose and volume for the bolus dose at the correct rate, and then *automatically* resumes the continuous infusion at the earlier rate. Without prebuilt bolus options, an unsafe workaround occurs when a practitioner simply increases the rate of infusion to administer the bolus dose, and then must *remember* to manually return the infusion to the prior rate settings after the bolus dose has been administered. A second issue seen with bolus doses is when the volume of the bolus consumes a large amount of the infusion provided. This may cause confusion and delays as the infusion will finish sooner than expected. Consider these error-prone scenarios:

A prescriber ordered a bolus dose of 3,200 units of heparin for a 40 kg child receiving a heparin infusion via a syringe pump. To administer the bolus from the 100 units/mL infusion, it would require administration of 32 mL, more than half of the current syringe volume. The nurse assumed the pharmacy would dispense a more concentrated heparin syringe for the bolus dose. However, the pharmacy did not dispense a separate bolus dose because the heparin order set in the electronic health record (EHR) did not specify how to administer it, and pharmacy staff did not realize the bolus dose would consume more than half of the volume in the syringe already infusing, which could result in a delay in care.

A prescriber ordered an opioid bolus dose for a patient receiving an opioid infusion, but the bolus exceeded the maximum hard limit in the drug library. As a result, the practitioner bypassed the bolus dose feature and administered the bolus by increasing the rate of the continuous opioid infusion. Fortunately, this at-risk behavior did not adversely affect the patient, and the practitioner remembered to decrease the opioid infusion rate after the bolus dose had been administered. Unfortunately, this sent the wrong message to the practitioner, that taking this risk was an

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FDA released an alert (www.ismp.org/ext/1046) on November 22, 2022, regarding LAV internal pins breaking after practitioners attached prefilled glass syringes. This problem has involved glass syringes from Aurobindo Pharma, Dr. Reddy's Laboratories, and most recently, Accord Healthcare (atropine sulfate prefilled glass syringes). As FDA points out, incompatibility can delay therapy, particularly in emergent and urgent situations, and potentially result in serious harm. FDA has requested LAV connector manufacturers to update the labeling on their products to warn practitioners that connectors with an internal pin may not be compatible with prefilled glass syringes. For now, FDA recommends:

- Inform staff that compatibility issues may occur when using prefilled glass syringes with LAV connectors with an internal pin.
- Review the instructions on LAV connectors used in your organization to determine if they have an internal pin and/or contact the manufacturer to confirm.
- Stock medications that come in plastic prefilled syringes or vials (when possible), or purchase connectors that do not use an internal pin.
- If your facility uses LAV connectors with an internal pin and medications packaged in prefilled glass syringes, establish and implement a plan to ensure the safe administration of these drugs.

The images used in this article are from the FDA alert (www.ismp.org/ext/1046).

QuVa Pharma two-sided labels for IV bags. We are pleased to share that intravenous (IV) bag labels by QuVa Pharma, a 503B outsourcing facility, will have significant improvements so that practitioners can view product information from both sides of the bag (www.ismp.org/ext/1043). The oxytocin IV bag (**Figure 1**, page 3) will be the first product with these new labels to be released in early 2023, with additional IV bags with these labels

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acceptable practice. Sooner or later, someone will forget to decrease the infusion rate to the continuous infusion rate which can lead to an overdose.

Untimely Library Updates

Some organizations lack the resources and/or expertise for ongoing maintenance, updating, and testing of the software and drug library for all smart infusion pumps. Smart infusion pumps are limited by the software version and drug library installed on the devices, making it imperative to regularly update the drug library in every device. For example, after changing a standard concentration of a medication infusion due to a drug shortage or formulary change, if organizations do not update the libraries on all the pumps, the practitioner may select an incorrect concentration resulting in a programming error. Or, if the practitioner cannot find the new concentration, it may delay patient care.

Frontline nurses should be represented on the organization's smart infusion pump team and offer insight when considering the following recommendations to address the described smart infusion pump challenges:

Establish and approve dose limits. Establish and/or evaluate minimum and maximum dose limits for each medication infusion and bolus dose that requires infusion via a smart infusion pump. Determine if the dose limits should be weight-based or non-weight based, aligning the dose limits with organizational protocols, dosing references, literature, and clinical practice. Engage end users (e.g., nurses, anesthesia providers) when deciding if medication infusions and bolus doses should have more than one drug library entry due to wide dosing parameters or variable rates. For example, consider providing two library options for opioid infusions and bolus doses based on the patient's opioid status (naïve versus tolerant). Also consider the full range of titration when setting dose limits for titratable infusions. Smart infusion pump dosing limits should not cause nuisance alerts or prevent the programming of incremental doses when administering typical doses. Once the drug library parameters have been determined, require approval by an interdisciplinary committee before updating or creating the drug library. Also determine and communicate a process for practitioners to request changes to the set limits.

Use the EHR to drive safe practice. Because smart pump dose alerts or hard stops detect and/or prevent catastrophic programming errors and serve only as a final layer of protection against administering overdoses, establish dose range checking in the EHR to notify prescribers and pharmacists up front if it is likely that a medication infusion dose has been prescribed outside of a safe dose range. Also, configure the EHR to notify prescribers and pharmacists that a medication infusion requires a change in concentration if the dose falls outside of the capability of the organizational pumps (e.g., less than 0.1 mL/hour for a 50 mL syringe). Require all titratable medication orders to include the medication name; route; initial or starting rate; incremental units the in which the rate can be increased or decreased; frequency of dose titrations; maximum rate of infusion; and an objective clinical measure to guide changes. Ideally, match medication names in the smart pump with the names on the medication label, and in the medication administration record (MAR) and EHR.

Create drug libraries. Once the dose limits and hard stops have been established and approved, set soft dosing limits in the smart pump drug library that reflect the maximum expected dose and rate prescribed as well as a buffer for patients who may require more or less than the typical default doses and rates. Set hard dosing limits as a forcing function to prevent catastrophic errors, while considering patients who may clinically require atypical doses, to prevent end users from programming the infusion without engaging the DERS. Incorporate a process to double check the drug library build prior to releasing it onto the pumps.

Limit multiple indication-based options. If different indication-based library entries are needed

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to follow later this year. The front of the IV bag label contains the required drug/dosing information, barcode, and important warnings, while the back of the label contains the drug name and concentration in large font so practitioners can see it when looking through the IV bag solution from the back side. The new label will help differentiate oxytocin bags from hydrating solutions and magnesium infusions as suggested in the ***ISMP Targeted Medication Safety Best Practices for Hospitals***, Best Practice #17 (www.ismp.org/ext/986).

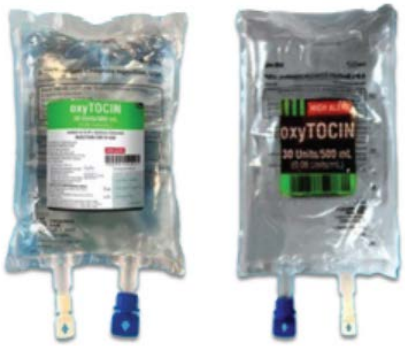

Figure 1. Practitioners can view the new and improved oxytocin IV bag label from the front (left) and back (right) sides of the IV bag.

Avoid tearing the metal flange on the monkeypox (mpox) vaccine vial. With the mpox outbreak, we are fortunate to have smallpox and mpox vaccine injection (**JYNNEOS** [US], **IMVAMUNE** [Canada], **IMVANEX** [Europe]). However, this vaccine comes in vials that have a closure typically used for oral preparations, where you tear off the metal flange and remove the stopper to pour out the liquid.

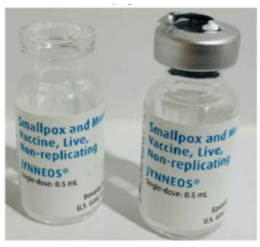

Figure 1. With improper removal of the yellow cap from the Jynneos vial, the entire metal flange and stopper can come off (left), or the metal flange can tear leaving sharp edges (right).

The mpox vaccine is a parenteral injection and needs to be opened carefully. Unless you are aware of how to properly open these vials, you might tear the flange leaving an exposed sharp edge, or if the stopper is removed, it can affect sterility (**Figure 1**). We contacted Bavarian Nordic

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for certain medication infusions, determine if the infusion is only used for a single indication in a specific location, and limit the drug library for that location to only one option, when possible. Otherwise, let end users know about the infusions that have multiple indication-based options. If possible, clearly include the indication in the drug name selection on the pump and test how the different options appear on pump search screens (e.g., will users need to scroll to a second page to see the second indication based on alphabetical search).

Test the drug library. Test the drug library to ensure that soft and hard stops will capture a variety of prescribing and programming errors. Specifically test hard stops to ensure they will capture and prevent 10-fold under- and overdose errors. For medication infusions with two options in the drug library based on the indication, make it obvious to the end users which option to select, or this could lead to unintended downstream effects or programming errors. For example, if oxytocin has a peripartum option with a lower dose range limit for induction and a postpartum option with a higher dose range limit for bleeding, have end users review the naming convention used for each indication of oxytocin in the drug library as well as the associated workflow to ensure it is intuitive to select and switch between the two options.

Differentiate opioid status. In alignment with the ISMP ***Targeted Medication Safety Best Practices for Hospitals*** (www.ismp.org/node/160), verify and document a patient's opioid status (naïve versus tolerant) before prescribing and dispensing continuous infusions of opioids. Default order entry systems to the lowest initial opioid starting dose. Review the literature and analyze organization-specific prescribing and pump data to build order sets with dosing guidance that differentiate opioid-naïve versus opioid-tolerant patients. During opioid prescribing, automatically link products with the corresponding concentration that pharmacists will dispense. Design the drug library options and limits to reflect the order sets and to be intuitive for end users. Consider whether your patient population warrants having a separate palliative or end-of-life care drug library. Additionally, instead of relying on end users to select the correct opioid concentration from a menu of multiple options, consider establishing entries defined by a dose threshold (e.g., morphine less than or equal to 5 mg/hour or greater than 5 mg/hour), with specific concentrations restricted to opioid-tolerant patients.

Limit bolus doses from a continuous infusion. Only allow practitioners to administer a bolus dose from a continuous infusion if your infusion pump has a bolus feature that *automatically* resumes the continuous infusion rate once that bolus dose has been administered, **and** if your drug library includes bolus dose range limits. For large volume bolus doses or when several medications are running through the same infusion line, consider dispensing and administering the bolus dose separately.

Communicate how end users should administer bolus doses. On the EHR/MAR, clearly show the route and rate of administration of the bolus, and whether the pharmacy will dispense a separate bolus (or verify a bolus dose from an automated dispensing cabinet [ADC]), or the practitioner should administer the bolus from the continuous infusion via a bolus infusion feature. If the pharmacy dispenses a separate bolus dose (or verifies removal from an ADC), specify on the EHR/MAR whether it will be in a syringe or a bag/bottle, which might require a different infusion pump or channel and a separate administration set. If dispensing a bolus dose in a syringe for pediatric patients, electronically determine the syringe size based on the volume of the dose and the required rate of infusion.

Track all smart pumps. Provide the necessary resources to track all smart infusion pumps, regardless of the location in the organization, to ensure timely software and drug library updates as well as ongoing biomedical inspections and maintenance. Some infusion pump vendors provide a central server to help track infusion pumps by serial number; others use radio frequency identification (RFID) tags on the devices to track the approximate physical location of infusion pumps, both of which can be used to help find missing infusion pumps that need to be inspected or updated.

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(Jynneos) and learned there are specific steps to follow to avoid damaging the flange (**Figure 2**). However, they did not explain why a parenteral vial has this closure system.

Figure 2. To use, flip off the yellow cap at the arrow (top) with your thumb at a 90-degree angle. Leave the yellow cap on the metal flange (bottom). Alternatively, flip the yellow cap all the way off but ensure the metal flange stays on the stopper/vial.

Paralytic cap warning is easily missed.

Cisatracurium is a neuromuscular blocking agent that causes paralysis and requires the patient to be mechanically ventilated. Vials of cisatracurium (20 mg/10 mL) from Teva display "Warning: Paralyzing Agent" in black print on a dark blue cap, making the warning difficult to visualize (**Figure 1**). The way the warning is printed on the cap likely violates USP General Chapter <7> *Labeling*. USP Chapter <7> requires printing the cautionary statement, "Warning: Paralyzing Agent" or "Paralyzing Agent" (depending on the size of the closure system), in black or white font, whichever provides the greatest color contrast with the ferrule or cap color, and in a way that is clearly visible under ordinary conditions of use.

Figure 1. Due to the dark print and cap color on the cisatracurium 20 mg/10 mL vial by Teva, practitioners can overlook the cautionary statement, "Warning: Paralyzing Agent," printed in black.

ISMP has notified the US Food and Drug Administration (FDA), USP, and the manufacturer about this problem and has recommended using white print on the dark blue cap so that practitioners can clearly see the warning statement. For now, organizations should consider

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Update drug libraries. Update drug libraries at least quarterly and establish criteria for off-schedule updates needed to address drug shortages, new drugs added to the formulary, new drug protocols, or concentration changes. Implement a standard process for communicating drug library content changes to end users, including the updated drug library go-live date, the modified information, and directions on how to ensure the infusion pump has the newest library version. Include the organization's name as part of the drug library name, so users can quickly identify whether an infusion pump is from an outside organization. Consider using the current month and year (e.g., September 2022) as a naming convention for library updates to inform the user that they are using the most current drug library. While we recommend the purchase or lease of smart infusion pumps capable of wireless drug library updates, some pumps require a physical connection to a computer to update the library. Whether you have wireless capability or a manual library update process, develop a method to track the update status of each pump and investigate pumps that have not been updated.

Review pump data. The smart infusion pump team should regularly monitor drug library usage and alerts, including overridden soft alerts, and adjust the dose limits as needed based on current practice and the literature. If a patient's dose falls outside a defined hard limit and the practitioner must administer the medication outside of the DERS, require an independent double check. Consider using a checklist/form to standardize and document the process, ensuring all necessary steps are followed. Use this checklist/form to communicate the outliers to the smart pump programming team and the pharmacy. Also if there are any safety reports related to the use of the smart pump, notify the smart pump team for follow-up.

Plan for interoperability. Implement bi-directional (i.e., auto-programming and auto-documentation) smart infusion pump interoperability with the EHR to reduce the risk of infusion pump programming errors. Employ the above recommendations to prepare for a smooth interoperability implementation. To learn more about infusion pump and EHR interoperability, see our ***Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps*** at: www.ismp.org/node/972.

Work with pump vendors. Collaborate with your smart pump vendor and provide feedback for consideration for future upgrades. For example, share how character limits in the drug library might affect the display of the medication name, potentially increasing the opportunity for error as well as increasing the difficulty in finding a medication in the library. Smart pump vendors must consider human factors to enhance the physical design of the pump and the drug library, and to improve the programming experience for end users.

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ISMP will soon be accepting applications, for our unique Fellowship program that will begin in the summer of 2023—the **ISMP Safe Medication Management Fellowship**. An ISMP Fellowship can help you grow in your career and make major contributions to medication safety worldwide. You will spend the entire year learning from our team of medication safety experts. For a brief description of our Fellowship program, candidate qualifications, program brochure and outline, and directions for applying, visit: www.ismp.org/node/871.

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purchasing this medication from a different manufacturer, or if already purchased, add an auxiliary label with "Warning: Paralyzing Agent" or "Paralyzing Agent" over the cap.

Expanded access to adult vaccines. Starting in 2023, the Inflation Reduction Law (www.ismp.org/ext/969) specifies that adult vaccines, recommended by the Advisory Committee on Immunization Practices (ACIP), will be available for free (without copays or out-of-pocket expenses) for Medicaid and Medicare Part D beneficiaries. For a complete list of the recommended vaccines, please visit ACIP's website at: www.ismp.org/ext/1053. Please share this information with your colleagues, your patients and their families to promote immunization.

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