

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

NRFit: A global “fit” for neuraxial medication safety

Introduction



In an effort to prevent tubing misconnections that could result in harmful, sometimes fatal, wrong route errors, the International Organization for Standardization (ISO) developed the ISO 80369 engineering standards to specify the design of small-bore connectors for various clinical applications that are dissimilar.¹ The new ISO 80369 standards employ forcing functions to ensure that small-bore connectors and tubing used for a specific route of delivery will not fit into small-bore connectors used for different applications, including for intravenous (IV), enteral, and neuraxial medication administration, thus reducing the risk of misconnections. The transition to the new ISO 80369-compliant connectors can improve patient care by greatly minimizing the risk of adverse events.

Implementation of the new ISO standards began in 2016 with enteral connectors (ISO 80369-3), which the Global Enteral Device Supplier Association (GEDSA) named ENFit. More than 80% of California hospitals have transitioned to ENFit because its use is mandated in that state. However, fewer hospitals have adopted ENFit across the rest of the US. Many are in the planning stages, realizing that full adoption is a complex process that takes several months. According to GEDSA, approximately 25% of all US hospitals have adopted the ENFit system. GEDSA is a nonprofit trade association comprised of manufacturers, distributors, and suppliers worldwide, which was formed to help introduce the ISO standards in medical device connectors (<http://gedsa.org/>). ISMP joins GEDSA and other supporting organizations listed on its website, including ECRI, The Joint Commission, and the American Society for Parenteral and Enteral Nutrition, in strongly recommending widespread implementation of ENFit, the only ISO-compliant option for enteral administration.

The next phase of implementation of the ISO standards began last year with neuraxial connectors (ISO 80369-6), commonly referred to as NRFit. Does your organization have plans in place to transition to the new neuraxial connectors? The information that follows is intended to help you learn more about NRFit and how to adopt this life-saving strategy in your organization.

What is NRFit?

Medical device connectors for neuraxial applications are changing from Luer connectors to ISO 80369-6-compliant connectors, which are incompatible with the Luer system, thus preventing misconnections.² Similar to ENFit, NRFit is the name selected by GEDSA to use for these ISO-compliant neuraxial connectors. While the ISO 80369 standards only

continued on page 2 — [NRFit](#) >



Figure 1. Most ISO 80369-6-compliant devices will incorporate the color yellow and include a NRFit logo.



Figure 2. Luer syringe (left) tip extends beyond the collar. NRFit syringe (right) tip is flush with the collar.

SAFETY briefs



Use brand names to help differentiate tacrolimus formulations.

An order for oral tacrolimus extended-release (ASTAGRAF XL) 3 mg daily was to be dispensed from a hospital outpatient pharmacy using three 1 mg extended-release capsules for each dose. However, the pharmacist accidentally selected tacrolimus 1 mg immediate-release (PROGRAF) capsules instead of Astagraf XL. All tacrolimus products were in the same drop-down menu because the hospital's computer system displayed all strengths of an active ingredient in a single list. Also, immediate-release and extended-release tacrolimus products are available in similar 0.5 mg, 1 mg, and 5 mg strengths, which may increase the potential for confusion between the two dosage forms. In this case, the patient noticed a difference in the capsule appearance compared to prior refills and reported it to the pharmacy. The error was then discovered.

ISMP reviewed multifactorial causes of tacrolimus medication errors, including confusion with the various strengths and formulations, look-alike names, preparation errors, and more in our August 10, 2017 newsletter (www.ismp.org/node/182). To prevent errors similar to the one described above, we recommended displaying the brand name of tacrolimus extended-release formulations (i.e., Astagraf XL, ENVARUS XR) on medication ordering and verification screens to help differentiate them from immediate-release tacrolimus (i.e., Prograf, generics). As an aside, when prescribing immediate-release tacrolimus, use only the brand or generic name, without modifiers such as “IR” for immediate-release.



Name confusion with rapid-acting insulins.

Searching by generic name for rapid-acting insulins may result in dispensing the incorrect product. Medication errors have been reported due to mix-ups between

continued on page 2 — [SAFETY briefs](#) >

> **NRFit** — continued from page 1

address the shape and size of new connectors, there appears to be an industry trend to use yellow for NRFit devices. Thus, most neuraxial connectors compliant with ISO 80369-6 include yellow and a NRFit logo (**Figure 1**, page 1).²

The NRFit connector diameter is 20% smaller than the Luer connector diameter. NRFit syringes have a smaller collar and tip, although the inner diameter of the tip is the same as a Luer tip.² The NRFit tip is flush with the collar, while the Luer tip extends beyond the collar (**Figure 2**, page 1).² These design features make it unlikely that a medical device intended for neuraxial applications will fit together with medical device connectors used for other clinical applications, such as respiratory, enteral, urological, limb cuff, or IV routes of administration.

Why was NRFit developed?

ISO 80369-6 and NRFit connectors were developed because of numerous wrong-route errors (e.g., inappropriate medications, enteral feedings, or air being administered neuraxially), some with catastrophic outcomes, that have occurred around the world.³ ISMP alone has received dozens of reports of non-epidural medications (e.g., potassium chloride, antibiotics, vinca alkaloids) inadvertently administered into the epidural or intraspinal space, and of regional anesthetic solutions (e.g., fenta**NYL** and bupivacaine, ropivacaine) inadvertently administered by the IV route. While some of these wrong route errors produce few or short-lasting cardiac and neurological deficits, others can result in permanent cardiac and neurological deficits, including paraplegia and death.

Neuraxial administration of IV medications and vice versa has been particularly concerning, but we have also heard about other types of neuraxial wrong-route errors. For example, an anesthetic agent intended for IV administration was administered into the cerebrospinal fluid via an external ventricular drain.³ There have also been numerous reports of antibiotics inappropriately administered into the cerebrospinal fluid. These wrong-route errors continue to occur despite repeated warnings about the risk as well as implementation of other strategies such as special packaging and application of auxiliary warning labels. The risk of unintentional cross-connections is high when using a universal Luer connector. The introduction of NRFit will help reduce the incidence of misconnections by creating unique non-Luer connectors for neuraxial applications.

Why adopt NRFit?

Implementation of the NRFit connector provides a way to reduce the risk of neuraxial misconnections, which can be devastating to patients, families, and healthcare practitioners. Simply put, patients expect healthcare practitioners to put their safety first, and transitioning to NRFit will clearly improve patient safety. Also, the legal system expects healthcare providers to take all reasonable steps to mitigate the risk of wrong-route errors. Non-adoption of NRFit may expose practitioners and organizations to legal challenges if wrong-route events take place that could have been prevented by NRFit.³

Is NRFit adoption mandatory?

A mandate to adopt ISO 80369-6 connectors (NRFit) varies by jurisdiction. Currently, California is the only US state to mandate its use.⁴ However, many accrediting and regulatory bodies strongly recommend transitioning to ISO-compliant connectors as they become available, and many manufacturers and suppliers have adopted, or plan to adopt, the same new global standard connector system.

When will NRFit devices be available?

Currently, B Braun and Smiths Medical offer an extensive line of NRFit devices in the US. This includes a variety of ISO-compliant NRFit epidural and spinal needles, filters and filter straws, catheter connectors, and syringes (loss-of-resistance [LOR], slip, and lock). There will be no adapters for the syringes since they are all supplied with the application-specific NRFit connectors. Smiths Medical also offers the CADD-Solis infusion

continued on page 3 — **NRFit** >

> **SAFETY** briefs cont'd from page 1

Novo Nordisk's **FIASP** and **NOVOLOG**, as well as the company's authorized generic for Novo**LOG**, all of which are insulin aspart. However, Fiasp has niacinamide in the formulation, which makes it even faster acting than Novo**LOG**. We warned about such errors last year in our August 1, 2019 newsletter (www.ismp.org/node/10323). Now, the same problem exists with Lilly's newly marketed **LYUMJEV**, **HUMALOG**, and the company's authorized generic for Huma**LOG**, all of which are insulin lispro. Lyumjev (pronounced LOOM jehv), which officially is insulin lispro-aabc (a 4-letter suffix is given to newly approved biologicals), contains treprostinil and other ingredients that make the product faster acting than Huma**LOG**. These products have different onsets of action after subcutaneous injection and are not substitutable. Fiasp and Lyumjev are injected at the beginning of a meal or within 20 minutes after beginning to eat. Other insulin lispro products (e.g., Huma**LOG**) are given within 15 minutes before a meal or immediately after a meal; other insulin aspart products (e.g., Novo**LOG**) are given 5 to 10 minutes before a meal.

Computer listings should always include the brand name for these insulins, and container labels should include both the brand and generic names. A pharmacist who recently reported the potential for mix-ups also recommended including niacinamide in parentheses with Fiasp listings, and treprostinil in parentheses for Lyumjev listings. Safety would be improved if the manufacturers and the US Food and Drug Administration (FDA) examined ways to better communicate product differences. Also, patients should be made aware of the differences between insulins and be able to identify that the correct insulin has been dispensed by their pharmacist.



Humate-P potency data shift on label leads to confusion. HUMATE-P (anti-hemophilic factor/von Willebrand factor complex [human]) is indicated for the treatment and prevention of bleeding in adult patients with hemophilia A (classical hemophilia). It is also indicated in adult and pediatric patients with von Willebrand disease (VWD) for treatment of spontaneous and trauma-induced bleeding and prevention of excessive bleeding during and after sur-

continued on page 3 — **SAFETY** briefs >

> **NRFit** — continued from page 2

pump (**Figure 3**) and the Portex regional anesthesia portfolio with NRFit connectors, as well as NRFit epidural administration sets (yellow lines, without injection ports), infusion pump accessories including extension sets, a spinal introducer, and syringe caps.

Additionally, BD is pursuing the development of a full portfolio of NRFit devices for neuraxial procedures for spinal and epidural anesthesia.⁵ Several other manufacturers are listed on the GEDSA *Stay Connected* NRFit Product and Supply Resources webpage (www.ismp.org/ext/513). However, some of these manufacturers may supply countries outside the US or offer limited devices with NRFit connectors. While each manufacturer may follow its own device and market launch timeline, the goal remains the same—to align to a common neuraxial connector across the globe to improve patient safety.⁶

Does NRFit work?

A study conducted in the United Kingdom in 2014 explored the clinical usability and cross connectivity of NRFit connectors.⁷ Specifically, the researchers tested whether the NRFit connectors functioned as well as Luer connectors, and whether they allowed clinically relevant cross connections with other small-bore connectors. Overall performance was found to be good, with connectors rated as easy or very easy to use. Leakage did not occur, and procedural times and number of attempts were generally similar between Luer and NRFit devices. Any concerns raised were usually device related, rather than connector related. The study also confirmed that clinically important cross connections do not exist between NRFit connectors and existing connectors. The study concluded that NRFit connectors were suitable for clinical use, were practical for implementation, and may provide an engineered solution to the problem of neuraxial—IV wrong-route errors.



Figure 3. CADD cassette with yellow NRFit (non-Luer) connector and cap for epidural use.

Will NRFit prevent all neuraxial misadministrations?

NRFit connectors will help prevent inadvertent neuraxial administration of non-neuraxial medications, solutions, enteral feedings, and air because Luer (or ENFit) connectors will not fit into the NRFit devices. Additionally, neuraxial medications prepared in NRFit syringes and/or administered via NRFit administration sets will not fit into Luer (or ENFit) connectors, helping to prevent intravascular administration of neuraxial medications. However, please keep in mind that wrong-route errors are still possible if the wrong medication is selected for preparation in a NRFit syringe, or if the wrong bag or bottle of medication or solution is spiked with a NRFit administration set. In these cases, the wrong medication or solution could still reach the patient via the neuraxial route because it has been prepared in, or administered through, a NRFit syringe or administration set. Similarly, a medication vial or bag intended for neuraxial administration can be selected or spiked with an IV administration set and administered via the wrong route. In addition to using NRFit, differentiation of these vials, bags, syringes, and administration sets via labeling, label color, and storage location remain key in your safety roll out.

While NRFit is a high-leverage risk-reduction strategy in its own right, organizations should layer it with other strategies to reduce the risk of wrong-route errors. For example, whenever possible, bags or bottles of neuraxial medications (e.g., fentaNYL and bupivacaine) should be stored or dispensed with NRFit administration sets (attached by a rubber band to the bag, or spiked and primed if immediate administration is anticipated), along with an auxiliary label that notes, “Requires NRFit tubing.” For infusions, tubing should be traced from the source to the patient access site, and auxiliary labeling of the

continued on page 4 — **NRFit** >

> **SAFETY briefs** cont'd from page 2

gery. A hospital notified us that some cartons of Humate-P had labels that were misaligned during the printing process. The units used to dose Humate-P for von Willebrand disease (VWF:RCo) and factor VIII units for hemophilia A treatment were shifted down one line on some boxes (**Figure 1**). This could easily lead to dosing errors if the von Willebrand Factor (VWF:RCo) potency was mistaken as factor VIII (FVIII) potency. A pharmacist discovered the labeling misalignment before a dosing error was made.

This is not a recently discovered problem. CSL Behring alerted customers to this misalignment in October 2019, saying that, although positioned incorrectly, the printed potency values on the carton are correct. Also, the information printed on the vial labels inside the carton is positioned correctly

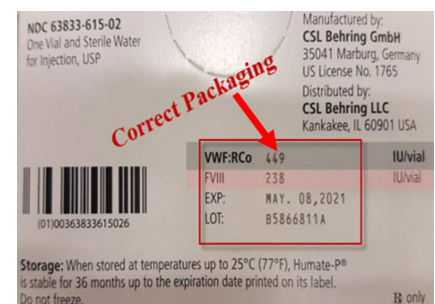
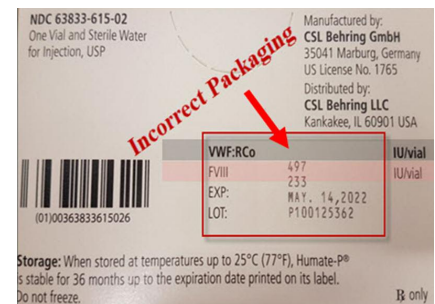


Figure 1. Information is condensed downward by one line on the carton label on the top but printed correctly on the carton label on the bottom.

(although the carton label is often used to determine the vials needed for the prescribed dose before actual compounding). Nevertheless, the appropriate dosing units can still be confused as this packaging is still in use. CSL Behring did not request a return of the cartons. Instead, the company asked users to refer to the vial label for dose calculations. Please search your inventory, and if these mislabeled cartons are available, mark the label in a way that clarifies the units associated with each factor. The company told us that the labeling problem is now resolved.

> **NRFit** — continued from page 3

site (e.g., “epidural”) closest to the patient should be strongly considered. Some hospitals also require an independent double check before administering all epidural infusions or injections (outside the operating room). For neuraxial administration via syringe (or cerebral spinal fluid withdrawal), parenteral syringes with a Luer connector should never be used. Also ensure that IV lipid emulsion rescue is readily available wherever regional anesthetics are administered, and that standardized protocols and/or coupled order sets are in place that permit emergency administration in cases of inadvertent IV administration of regional anesthetics.

How do organizations adopt NRFit?

NRFit must be introduced in a healthcare organization in a planned and coordinated manner, starting with a small team of clinicians who are committed to transitioning from the Luer connector to NRFit for intrathecal and epidural procedures. While every organization will have a different process for implementing the change, all will require a well-informed, properly prepared cross-functional team composed of organizational leaders, anesthesia providers, other physicians who perform neuraxial procedures (e.g., spinal taps), nurses who assist with neuraxial procedures, and pharmacists who prepare neuraxial medications. The team should start by communicating with the organization’s supplier of neuraxial devices, requesting NRFit samples when available, familiarizing themselves with all the product-specific changes, practicing new connections with all the products affected by the NRFit connector, and developing an anticipated timeline and checklist for the organization-wide transition.

The next step for the team is to conduct a failure mode and effects analysis (FMEA) to identify before transition what could possibly go wrong. Risks may arise anywhere in the process due to staff unfamiliarity with the NRFit connector design changes, incorrect use, and supply chain issues. Potentially serious problems should be identified, anticipated, and addressed prior to transition.

Additionally, before transitioning to NRFit, all practitioners who will be involved in neuraxial procedures should receive hands-on education about the new NRFit connectors and the importance of this change. Organizations will also need to evaluate and update current procedures, related order sets, and pharmacy preparation and dispensing processes, adjusting them as needed to include the new NRFit devices. GEDSA offers a NRFit Connector Transition Checklist for Nurses and Clinicians (www.ismp.org/ext/514) to guide this process, offering recommended activities that support:

- S—Supplier Communication** to understand the timeline for NRFit availability
- T—Training** of clinicians regarding the importance of transitioning to NRFit
- E—Education** about how to use NRFit products
- P—Process** of updating current procedures, order sets, and pharmacy preparation
- S—Supply Management** of NRFit and legacy inventory

Please keep in mind that some devices, including long spinal needles, may be used in your facility for non-neuraxial applications, such as amniocentesis and joint injections.⁶ If this is the case in your organization, long needles with a Luer connector will still be required after transition to NRFit. Some manufacturers have expressed an interest in marketing such devices to meet clinical needs, so please contact your current suppliers to ask them about long needles with Luer connectors if you believe you will need them in the future after transition to NRFit.

It is also recommended that your organization’s transition team regularly visit the GEDSA *Stay Connected* website (<http://stayconnected.org/>) to remain apprised of any joint communication initiatives on behalf of the industry and to avoid any confusion as the new, safer connectors are introduced in the market.

References

- 1) International Organization for Standardization (ISO). ISO 80369-1:2018. Small bore connectors for liquids and gases in health-care applications—part 1: general requirements. 2018. www.ismp.org/ext/515
- 2) Global Enteral Device Supplier Association (GEDSA). NRFit connector changes (video). NRFit new design overview. Stay Connected. www.ismp.org/ext/100
- 3) Eldor J. To NRFit or not to NRFit? *J Health Sci Dev.* 2019;2(1):9-13.
- 4) California Assembly Bill No. 444, Chapter 198. August 13, 2015. www.ismp.org/ext/519
- 5) BD ISO 80369-6 ISO-compliant NRFit products. March 18, 2020. YouTube. www.ismp.org/ext/517
- 6) GEDSA. Neuraxial-specific 80369-6 frequently asked questions. Stay Connected. www.ismp.org/ext/518
- 7) Cook TM, Wilkes A, Smith PB, et al. Multi-centre clinical simulation evaluation of the ISO 80369-6 neuraxial non-Luer connector. *Anaesthesia.* 2019;74(5):619-29.

Special Announcement

FREE international ISMP webinar
ISMP is presenting a **FREE** international webinar on **August 18 (7:00 a.m. EDT), *A Look Behind the Scenes: Global Progress in Patient Safety and Prevention of Harmful Medication Errors.*** The program is intended for an international audience. During the past 20 years, a lot has happened to improve medication safety around the world. Join us in looking back at some of the progress that has been made and looking forward to areas that still require improvement. To register, visit: www.ismp.org/node/18844.

To subscribe: www.ismp.org/node/10



ISMP Medication Safety Alert! Acute Care (ISSN 1550-6312) © 2020 Institute for Safe Medication Practices

(ISMP). Subscribers are granted permission to redistribute the newsletter or reproduce its contents within their practice site or facility only. Other reproduction, including posting on a public-access website, is prohibited without written permission from ISMP. This is a peer reviewed publication.

Report medication and vaccine errors to ISMP: Call 1-800-FAIL-SAF(E) or visit our website at: www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters’ wishes regarding the level of detail included in publications.




Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO, ML. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.

References appear in the right column at the top ^


ISMP Medication Safety Alert!® ActionAgenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the April – June 2020 issues of the *ISMP Medication Safety Alert!* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number (S = supplement) to locate additional information. **Please note: many problems published in the COVID-19 Special Edition newsletters have not been included unless they are still relevant today.** Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the *ISMP List of High-Alert Medications* (www.ismp.org/node/103). The Action Agenda is also available for download in a Microsoft Word and Excel format (www.ismp.org/node/18837) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: www.ismp.org/nursing-ce.

Key:  — ISMP high-alert medication

| Issue No. | Problem | Recommendation | Organization Assessment | Action Required/Assignment | Date Completed |
|--|---|--|-------------------------|----------------------------|----------------|
| Double concentration (2%) propofol now available | | | | | |
| (9 - S, 12)  | Due to shortages of propofol 1% (DIPRIVAN and generics, 10 mg/mL), Fresenius Kabi received an emergency use authorization from the US Food and Drug Administration (FDA) to import Fresenius PROPOVEN 2% (propofol 20 mg/mL) emulsion in 100 mL vials. If the double concentration of this imported product is overlooked, overdoses may occur. | Alert practitioners to the double concentration. Post a wall chart (www.ismp.org/ext/479) and distribute Fact Sheets (www.ismp.org/ext/480 ; www.ismp.org/ext/481) about how the product differs from propofol 1%. Apply warning stickers to each carton and vial. Update drug databases and smart pump libraries to reflect the double concentration. Affix a barcode if the international barcode does not scan. | | | |
| Prepare for vials of neuromuscular blocking agents without cap warnings | | | | | |
| (11)  | Due to a drug shortage, Gland Pharma Limited is allowed to manufacture and market vecuronium and rocuronium vials without the usual, required warning on the vial cap, "Warning: Paralyzing Agent." The vial and carton labels will remain unchanged. The absence of the cap warning may lead to potentially fatal drug selection errors with look-alike vials. | Alert staff about the absence of the usual warning statement on the vial caps. Affix auxiliary labels noting, "Warning: Paralyzing Agent," to vial caps, store the vials lying down (not cap up) so labels are visible, and use barcode scanning during preparation and administration. For additional strategies, visit: www.ismp.org/node/247 and www.ismp.org/node/160 . | | | |
| Ventilator arms may break from the weight of 2 liter bags of sterile water | | | | | |
| (6 - S)  | Hanging a 2 liter bag of sterile water for humidification on the articulated arm of a ventilator may cause the arm to break due to the weight of the bag. Similar concerns have been reported with 1 liter bags of sterile water, which also may be inadvertently infused as intravenous (IV) fluids. | Use hard-sided sterile water containers to differentiate them from IV fluids. Avoid using 1 liter sterile water bags outside of the pharmacy because they look too similar to IV bags (www.ismp.org/node/160). Ventilator arms will not support humidification fluids, so use a pole labeled "For Respiratory Use Only." | | | |




© 2020 ISMP

| Issue No. | Problem | Recommendation | Organization Assessment | Action Required/Assignment | Date Completed |
|---|--|--|-------------------------|----------------------------|----------------|
| Education is “predictably disappointing” and should never be relied upon alone to improve safety | | | | | |
| (11) | Education alone is a weak, low-value, improvement strategy, despite being healthcare’s go-to response to a problem. Education relies heavily on human memory and vigilance, and ranks among the least effective interventions, far below high-leverage, system-based strategies such as forcing functions, barriers and fail-safes, and automation. Unless a knowledge deficit is uncovered, education does little to address human error or policy/procedure violations, or to change unsafe, complex habits. | A single strategy, particularly one as weak as education, is not enough to change behaviors and prevent errors. Instead, numerous high-leverage risk-reduction strategies that improve system reliability must be layered together, on top of education, to create a more robust safety system. This is important for organizations in their quest to attain highly reliable outcomes. A table of key safety strategies for improvement, including examples with high-alert medications, can be found at: www.ismp.org/node/635 . | | | |
| Labeling confusion with investigational use intravenous (IV) remdesivir vials | | | | | |
| (9 - S) | An adult protocol called for a loading dose of IV remdesivir 200 mg, followed by 100 mg doses. But <u>two</u> 100 mg vials were used to prepare each of the subsequent doses. Like many investigational drugs, the vials were not clearly labeled. Vials of lyophilized powder list the total amount of drug (100 mg) on the label. But one vial presentation of the injectable solution lists only the per mL amount (5 mg/mL) and total volume (21.2 mL). | Add a barcode label to each remdesivir container so that it can be scanned to verify the product prior to preparation. Consider adding an auxiliary label to injectable solution vials to note the total amount of drug (100 mg). Provide prescribers, pharmacy staff, and nurses with a remdesivir Fact Sheet (www.ismp.org/ext/483) or Pharmacy Guide (www.ismp.org/ext/484), which are available from the manufacturer. | | | |
| US Food and Drug Administration (FDA) removes syringe administration from vinCRISTine labeling | | | | | |
| (12)  | In 2019, ISMP called on FDA to eliminate vinCRISTine syringe administration in official product labeling. More than 130 deaths have occurred from accidental intrathecal injection of the drug via syringe—no cases have been reported with dilution of the drug in a minibag. In June 2020, FDA asked Pfizer to revise the product labeling. Pfizer complied, removing all references to vinCRISTine administration via syringe from the package insert. | To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRISTine should be diluted in a flexible plastic container and prominently labeled as indicated “FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.” The practice of dispensing and administering vinCRISTine via syringe should be eliminated. | | | |

© 2020 ISMP

| Issue No. | Problem | Recommendation | Organization Assessment | Action Required/Assignment | Date Completed |
|---|--|--|-------------------------|----------------------------|----------------|
| Leadership support is vital during the coronavirus (COVID-19) pandemic | | | | | |
| (8 - S) | As healthcare providers work in under-resourced environments and deal with the risk of infection during the COVID-19 pandemic, they look to leadership to support their well-being, health, and safety. In a survey, only half of the participants strongly agreed that their employers have communicated a clear plan of action for COVID-19; and only 1 in 3 are confident that they will be safe if they follow their organization's policies during this public health crisis. | Leaders can support staff by 1) creating a safe haven for staff to retreat, reflect, and talk to each other away from their work units; 2) creating an environment of trust, fairness, and compassion; 3) balancing critical information with positive updates to help staff maintain a positive mindset; 4) communicating transparently; and 5) being a visible leader in patient care units. ISMP encourages all leaders to review the full article for additional recommendations to support staff during this crisis (www.ismp.org/node/17459). | | | |
| Differences between human error, at-risk behavior, and reckless behavior | | | | | |
| (12) | Organizations often struggle with differentiating and responding justly to human error, at-risk behavior, and reckless behavior. Human error is inadvertent. With at-risk behaviors, often staff knowingly violate policies and procedures because they have lost the perception of risk associated with the violation or mistakenly believed it to be insignificant or justified. Reckless behavior is the conscious disregard of what is known to be a substantial and unjustifiable RISK (not just the conscious disregard of a policy). | In a Just Culture, human error is managed by consoling the individual and redesigning the system to make it more human-error proof. At-risk behavior is managed by coaching the individual to see the risk, system redesign, and a reward system that encourages safe behavioral choices. Reckless behavior is managed through disciplinary actions. The focus of safety programs should be the just and proactive management of at-risk behaviors, not just the management of inescapable human error and the rare reckless behavior. | | | |
| Keeping infusion pumps outside of COVID-19 patients' rooms | | | | | |
| (6 - S) | Many hospitals position infusion pumps outside of COVID-19 patients' rooms to conserve personal protective equipment (PPE) and reduce staff exposure. Hallways may become cluttered, tubing may become disconnected, patient verification during drug administration outside of the room is a challenge, medications take longer to reach the patient, and the tubing may pose a tripping hazard. | While recognizing that this is not ideal, hospitals must weigh the risk versus benefit of positioning infusion pumps outside of COVID-19 patients' rooms. A special report from ECRI guides the selection and use of long extension sets for this purpose (www.ismp.org/ext/400) and factors to consider (e.g., fluid viscosity). Never position pumps in the hallway for two patients occupying a single room. | | | |

© 2020 ISMP

| Issue No. | Problem | Recommendation | Organization Assessment | Action Required/Assignment | Date Completed |
|--|--|--|-------------------------|----------------------------|----------------|
| Standardizing critical care drug infusions | | | | | |
| (7-S)  | When programming a norepinephrine infusion via a smart pump outside of a patient's room, a nurse selected a weight-based (mcg/kg/minute) dosing option rather than the prescribed mcg/minute infusion rate. She also selected the maximum concentration in the library (32 mg/250 mL) instead of the prepared concentration (4 mg/250 mL). Nurses also suspected that the patient received bolus doses of the drug when flushing the line. | Standardize dosing units to either weight-based (mcg/kg/minute) or non-weight-based (mcg/minute) for norepinephrine. The American Society of Health-System Pharmacists (ASHP) <i>Standardize 4 Safety</i> initiative recommends using mcg/kg/minute dosing units for norepinephrine (www.ismp.org/ext/446). | | | |
| Incorrect use of a smart infusion pump in the operating room (OR) leads to milrinone overdose | | | | | |
| (9)  | An anesthesia resident started a milrinone infusion in the OR using a smart pump in "anesthesia mode." He entered the concentration as 200 mcg in 100 mL, when the Hospira premixed infusion he was hanging contained 20 mg in 100 mL. The bag label emphasized the per mL amount (200 mcg) rather than the total drug in the bag (20 mg). The error resulted in a rapid infusion and overdose, requiring patient monitoring in critical care. | The use of smart infusion pumps with an engaged drug library should be expected in the OR. Hands-on education about how to use smart pumps along with competency assessments should be implemented for all anesthesia providers. When possible, implement upper and lower hard limits for medication doses, concentrations, infusion rates, loading and bolus doses, and limit the use of "anesthesia mode." | | | |
| Subtherapeutic heparin infusions: Is your organization at risk of bypassing soft low-dose alerts? | | | | | |
| (10)  | In a large health system, most heparin infusions required weight-based dosing using a standardized, indication-based protocol. After a smart pump programming error resulted in a subtherapeutic heparin dose of 12 units/hour, analysis of aggregate pump data identified 25 similar cases within a 2-month period. When programming the pump, users had selected "non-weight based" heparin in error, often overriding the resulting low-dose alert. | Standardize to weight-based dosing to reduce the risk of administering heparin infusions as <i>units/hour</i> instead of <i>units/kg/hour</i> . If there are indications for which weight-based heparin dosing is not feasible, limit the non-weight-based programming choice to the care area/profile where it is needed. Establish a hard stop for heparin low-dose alerts. Implement smart pump interoperability or employ an independent double check for user-programmed heparin infusions. | | | |

© 2020 ISMP