

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

Hidden medication loss when using a primary administration set for small-volume intermittent infusions



While covering for a colleague during patient rounds in an adult medical unit, a pharmacist noticed two empty 50 mL minibags of **ZOSYN** (piperacillin and tazobactam) hanging on a patient's intravenous (IV) pole, each attached to a primary administration set. Each primary administration set (BD Alaris pump infusion set) holds about 25 mL of residual volume in the tubing. The implication for this 49-year-old patient with pneumonia was that he had only received about half of the total volume contained in each 50 mL bag, and therefore only half of the Zosyn dose with each intermittent infusion. Additionally, while an extended infusion time of 4 hours had been prescribed for each Zosyn dose, each intermittent infusion was completed in about 2 hours since only half of the volume infused while the other half remained in the tubing. Later, in the room of a 57-year-old patient with cellulitis, the pharmacist found an empty 50 mL minibag of clindamycin, again attached to a primary administration set filled with a residual volume in the tubing, meaning that this patient, too, had only received about half of the dose. Such significant underdoses could have a clinical impact on patient outcomes.¹

Background

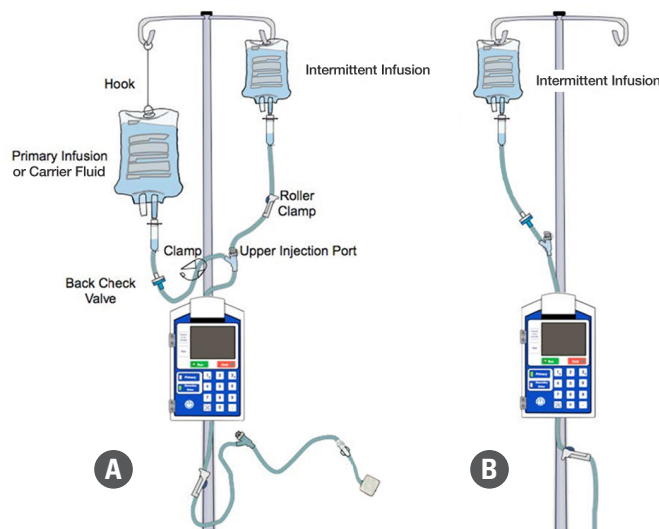
Medications administered via an intermittent IV infusion (e.g., antibiotics, electrolytes) are typically diluted in a small volume of 0.9% sodium chloride or 5% dextrose in water. If the patient has a compatible primary solution already infusing, these intermittent infusions are often administered through a short secondary administration set attached to a Y-site on the primary administration set, thus minimizing medication loss in the residual volume left behind in the tubing. If the primary solution is not compatible with the intermittent solution, or if the primary solution's rate of infusion cannot be altered (e.g., heparin) to accommodate the intermittent infusion, a carrier fluid (sometimes called a 'chaser bag' or 'flush bag') may be ordered. A carrier fluid is a small bag (50 to 250 mL) of compatible fluid that is used as a primary infusion to allow administration of the intermittent infusion via a secondary administration set (A in Figure 1). After the intermittent infusion is complete, the carrier fluid is infused (approximately 25 mL) to flush residual drug from the tubing.

cont'd on pg 2 — [Hidden loss](#) >

Figure 1. Two methods of administering small-volume intermittent IV infusions:

A (left, recommended): Using a secondary administration set attached at the Y-site (upper injection port) of a carrier fluid or primary infusion administration set (minimizes drug loss).

B (right, NOT recommended): Using a primary administration set connected directly to the patient's vascular access device (leads to significant drug loss).



SAFETY briefs



Anatomy of a conventional vs. liposomal DOXOrubicin mix-up. Since 1996, we have warned about accidental administration of DOXOrubicin liposomal injection (DOXIL) instead of the conventional form, DOXOrubicin injection solution or lyophilized powder (ADRIAMYCIN). Dosing guidelines for the liposomal and conventional formulations differ significantly. Conventional DOXOrubicin is used to treat a greater variety of cancers and it can be given at higher doses than the liposomal form, which has slower plasma clearance. Mix-ups have sometimes resulted in harm and even death, so the two forms should never be interchanged on a milligram (mg) for mg basis.

Similarities in the two preparations may lead to confusion as these products are available in the same concentration (2 mg/mL), and the vial volumes can also be similar. For example, both are available in 10 mL (20 mg) and 25 mL (50 mg) containers (Figure 1 shows similar 10 mL cartons). The label on liposomal products prominently notes, "Liposomal Formulation—Do Not Substitute," which is meant to convey that the liposomal formulation is not substitutable for the conventional formulation. Unfortunately, this is not always seen or understood,

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

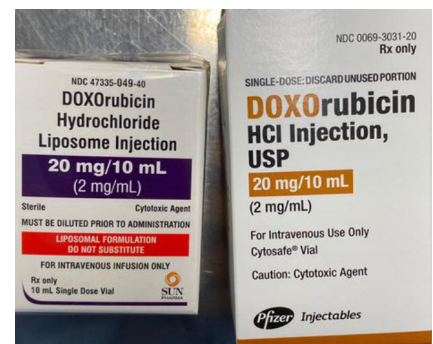


Figure 1. Liposomal (left) and conventional (right) DOXOrubicin products are both available in 20 mg/10 mL (2 mg/mL) containers. Note the warning, "Liposomal Formulation—Do Not Substitute," on the liposomal product, which may not always be seen or understood.

> **Hidden loss** — continued from page 1

However, when the patient has a vascular access device (e.g., saline lock) placed without a continuously infusing compatible primary solution or carrier fluid, unfortunately, intermittent infusions are often administered using a longer primary administration set (via pump or gravity) connected directly to the patient's vascular access device (**B** in **Figure 1**, page 1). This may lead to significant underdosing because the residual volume that exists in the length of the primary administration set may not be administered to the patient.¹

Nurses may separately flush the tubing of the intermittent infusion to promote administration of the full dose; however, the flush volume would have to be as large as the residual volume left in the primary administration set (e.g., 25 mL). We have also observed the unsafe practice of nurses adding a small volume of extra diluent to small-volume intermittent infusion bags prior to administration to account for the residual volume left in the administration set, risking both errors and contamination. Nevertheless, there would still be medication left in the tubing, which could then be administered to the patient at a later time if the next infusion is administered via the same administration set. Hypothetically, the medication left in the tubing could become contaminated or unstable over time, particularly if it required refrigeration or protection from light prior to administration.¹

Scope of the Problem

The pharmacist who observed the small-volume intermittent infusions attached to primary administration sets wondered how often this was occurring. To determine the scope of the problem, he requested monthly reports on the organization's smart pump technology, including data that showed whether nurses had used primary or secondary administration sets to administer 50 mL infusions. He then determined the number of 50 mL intermittent IV infusions administered to adults correctly as a secondary infusion, excluding chemotherapy (administered via short administration sets). This was divided by the total number of 50 mL intermittent infusions administered as either primary or secondary infusions.

He found that only 28.5% of the 50 mL intermittent infusions had been administered as secondary infusions. The pharmacist then looked at smart pump data from other hospitals within his health system and found that only 35.7% of the 50 mL intermittent infusions had been administered as a secondary solution. Across the entire health system, this represented about 360,000 small-volume (50 mL) intermittent infusions annually that were likely administered to patients at significantly lower doses than prescribed due to using a primary administration set. Based on ISMP's observations in other organizations and the literature,^{1,2} the scope of this problem is much larger than only within this health system.

Contributing Factors

To understand why nurses were administering small-volume intermittent infusions via primary administration sets, the pharmacist gathered an interdisciplinary team of nurses, pharmacists, and prescribers, who found the following contributing factors:

Unclear policies/procedures. As with many organizations around the country, the health system found that its organizational and departmental policies and procedures provided few details regarding how to administer small-volume intermittent infusions. A quick search of the literature also found that best practices for administering small-volume intermittent infusions are few; even the Infusion Nurses Society's *Infusion Therapy Standards of Practice* document is silent on the issue of whether to administer small-volume intermittent infusions as a primary or secondary infusion.^{1,3}

Lack of awareness. There was a lack of awareness among nurses, pharmacists, and prescribers regarding the significant loss of medication in the tubing when administering intermittent infusions using primary administration sets. Although the risk of medication loss has been widely reported when locating infusion pumps with extension tubing outside patient rooms during the recent pandemic, the issue had not been considered when administering small-volume intermittent infusions using a primary administration set.

continued on page 3 — **Hidden loss** >

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

as noted in a recent case reported to us in which two patients received liposomal instead of conventional **DOXO**rubicin. A technician was asked to prepare two infusions of conventional **DOXO**rubicin, but the inventory was low so there were not enough vials to complete the orders. The technician found additional vials but did not realize that these contained liposomal **DOXO**rubicin. When the technician scanned the barcodes on the vials, she received an alert stating, "Wrong medication scanned." The warning was overridden, an at-risk behavior that had become common practice due to alert fatigue. Since pharmacists were not required to review overrides, the error was not noticed. One order was compounded with a mixture of liposomal and conventional **DOXO**rubicin and the other order was compounded with liposomal instead of conventional **DOXO**rubicin. Unfortunately, the pharmacist did not catch the error during final verification. The preparations were dispensed and administered.

The next day, the same pharmacist realized that there was no more conventional **DOXO**rubicin in stock and was concerned that orders from the previous day may have been compounded incorrectly. He compared the lot numbers in the compounding record to the lot numbers on file for conventional and liposomal **DOXO**rubicin and confirmed his suspicion. Both patients required close monitoring for several days. No harm was evident, but the cycle of chemotherapy was suspended for both patients.

Since the incident, the pharmacy has taken a number of steps to prevent this from happening again, including separating vials of liposomal and conventional **DOXO**rubicin. Liposomal **DOXO**rubicin is now stored in a lidded container with a prominent sticker noting, "**DOUBLE CHECK: LIPOSOMAL DOXORUBICIN. DO NOT CONFUSE WITH CONVENTIONAL DOXORUBICIN.**" This was done for the liposomal formulation since it is less commonly used. Staff will be educated about the differences between the two forms, including during orientation. Dispensing technology will soon require a second individual's review of scanning overrides, and a pharmacist must now perform an independent double check for all drugs and diluents prior to admixture.

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

> **Hidden loss** — continued from page 2

Failure to prescribe carrier fluids. When choosing a medication administration method that minimizes the residual volume left behind in the tubing, nurses had limited options if the prescriber ordered an intermittent infusion without a corresponding order for a carrier fluid, or if the prescriber discontinued a compatible continuous infusion while the patient still required intermittent infusions. There were no triggers or reminders for prescribers to order a carrier fluid (and saline flushes), and due to safety and scope-of-practice concerns, nurses were not permitted to hang a carrier fluid without an order.

Recommendations

Results of a recent study suggest that the best practice to minimize medication loss is to administer small-volume intermittent infusions through a secondary administration set with a compatible primary infusion.¹ Thus, the pharmacist worked with the interdisciplinary team he had established in his health system and was able to increase the administration of small-volume (50 mL) intermittent infusions as secondary infusions from 35.7% to 77.8% by implementing the following strategies:

Add carrier fluids to order sets. The health system added an appropriate carrier fluid to order sets used for prescribing small-volume intermittent infusions. This contributed to an increase in orders for carrier fluids which enabled nurses to administer intermittent infusions as a secondary infusion and flush the residual volume through the tubing to ensure the patient received the full medication dose. Additionally, pharmacists now have the authority to enter carrier fluid orders without contacting the prescriber. This is particularly important if the patient already has a primary infusion that should continue to be administered at the prescribed rate of infusion. Take, for example, a septic patient who is receiving normal saline at 150 mL per hour. If the patient is also receiving piperacillin/tazobactam in 50 mL over 4 hours three times a day, stopping the saline infusion for 12 hours each day would not be optimal. Instead, a separate compatible carrier fluid, which the pharmacist can now enter, should serve as the primary infusion for the secondary intermittent infusion. At the conclusion of the intermittent infusion, the nurse can then infuse a set amount (approximately 25 mL) of the carrier fluid through the primary tubing.¹

Educate staff. The health system increased staff awareness of the significant loss of medication in the residual volume left in the tubing when administering a small-volume intermittent infusion, particularly a 50 mL minibag, as a primary infusion. For nurses, the health system engaged nurse educators, created an educational document on the topic, and came up with a catchy slogan: **If the bag is the small kind, put it on a secondary line.** They also created a pop-up warning on automated dispensing cabinet screens to administer small-volume intermittent infusions with a secondary set. The pharmacy also affixed labels to minibags stating, “Infuse via secondary set” for the first few months.

Storytelling. The health system also employed a simple but fundamental strategy to create change by conveying compelling stories about errors and the desired change strategy to draw attention to the problem and encourage action. Using actual examples of patients who had likely received only half of the prescribed doses, the stories were shared at departmental and committee meetings, in educational programs, and in “Tip of the Week” documents, which included repetition of the slogan encouraging small bag administration via a secondary administration set.

Lessons Learned

The health system plans to continue working to improve the rate of administering small-volume intermittent infusions as a secondary infusion (improvement has continued at a slower pace since the coronavirus disease 2019 [COVID-19] pandemic). However, they wanted to share with others the lessons they have learned so far:

See the problem firsthand. Do not rely on policies and procedures to illustrate what normally happens when small-volume intermittent infusions are administered. Take the time to observe intermittent infusion administration to understand “real life” practices.

continued on page 4 — **Hidden loss** >

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



Administer adenosine rapidly for cardioversion.

Adenosine injection is often used to restore normal sinus rhythm in patients with paroxysmal supraventricular tachycardia. To be effective, doses must be administered as a rapid intravenous (IV) bolus injection over 1 to 2 seconds. It is typically given via a peripheral venous access site as close as possible to the patient's torso. In addition, adenosine must be followed immediately by a rapid 0.9% sodium chloride flush. Experienced nurses often attach the adenosine syringe and sodium chloride flush syringe to a stopcock to expedite administration. Such a rapid sequence of injections is unlike many other medications administered via IV push. This is due to the drug's very short half-life (less than 10 seconds) and the need to carry the drug to the heart as quickly as possible before rapid metabolism inactivates it. Manufacturer syringe and vial labels mention that the drug is intended for rapid IV use; however, some practitioners may be unaware of this fact. We recently received a report in which adenosine injection was administered too slowly during an advanced cardiac life support (ACLS) event, resulting in a failure to convert the patient to normal sinus rhythm.

Retrieval of adenosine from an automated dispensing cabinet (ADC) is often accomplished via override (e.g., during a code), so many safeguards built into orders may not appear on the medication administration record (MAR). Thus, an auxiliary label affixed to adenosine, reminding staff to administer the drug via rapid IV push, may be an important reminder. Prescribers can also remind staff to give adenosine by rapid IV push when giving verbal orders during an emergency. Pharmacy staff, especially those stationed in the emergency department or responding to codes, must be aware of, and educate others about, the requirement for rapid injection at a site as proximal to the patient's torso as possible, and that the medication must be rapidly flushed and cleared from any tubing. Adenosine for cardioversion is available as a 3 mg per mL solution in 6 mg (2 mL) and 12 mg (4 mL) single dose vials, and in 6 mg (2 mL) prefilled syringes. These should not be confused with adenosine 60 mg/20 mL vials, which are used as a stress agent as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

continued on page 4 — **SAFETY** briefs >

> **Hidden loss** — continued from page 3

Use data to measure the problem and progress. Historically, practitioner reporting has been used to identify and measure patient safety problems, which provides, at best, an incomplete assessment of whether a problem exists and whether changes have resulted in improvements. More accurate ways of measuring safety problems—through automated technology and direct observation, for example—should be used to identify the scope of suspected safety problems and to monitor progress to determine if improvement efforts have been successful.

Foster collaboration across professions. The importance of fostering teamwork across the professions should not be underestimated. For example, collaboration between prescribers, pharmacists, and nurses may overcome any reluctance to allow post-infusion flushing with a small amount of a compatible carrier fluid. Collaboration across professions is also critical to resolve questions that might arise. How will the organization manage fluid-restricted patients who receive multiple small-volume intermittent infusions? How can an organization minimize instances when a nurse forgets to unclamp the secondary infusion (since the pump may not alarm if the carrier fluid is infusing)? Would it be feasible to program smart infusion pumps to only allow administration of small-volume intermittent infusions as a secondary infusion (may be a concern with interoperability)?

Tell stories to humanize the problem. Storytelling is a familiar form of communication that resonates with all—the contextual details and the exposed humanity in stories educate us, touch us, and inspire us to take action. Storytelling is an efficient vehicle for helping practitioners to understand, remember, and accept new ideas.

References

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- 2) Cousins D. Patients are being underdosed: we need new guidance on small-volume drug infusions. *Clinical Pharmacist.* 2018;10(12). doi: 10.1211/CP.2018.20205779.
- 3) Gorski L, Hadaway L, Hagle M, McGoldrick M, Orr M, Doellman D. Infusion therapy standards of practice. *J Infus Nurs.* 2016;39(suppl 1):S1-S159.

Handling monoclonal antibodies from Lilly and Regeneron can be confusing

Since supply hurdles are expected with the two new monoclonal antibodies that were granted emergency use authorization (EUA) by the US Food and Drug Administration (FDA) last month (bamlanivimab and casirivimab/imdevimab), those administering these drugs may not know which will be available at any given time. So, it is important to understand the differences in how these products are prepared and stored, as it can be confusing. The products are intended for patients who test positive for coronavirus disease 2019 (COVID-19) and are at risk of progressing to serious disease and/or hospitalization. They are not for patients already hospitalized with COVID-19.

Lilly's bamlanivimab 20 mL vial must be removed from refrigeration and brought to room temperature for about 20 minutes before preparation. The *Fact Sheet* (www.ismp.org/ext/584) calls for 20 mL (700 mg) to be added to a 250 mL 0.9% sodium chloride injection bag after first removing 70 mL of saline, for a final volume of 200 mL. The bag should then be inverted gently by hand 10 times to ensure mixing. Some may have read about alternate methods of preparation. However, it is critical to always follow the instructions for preparation in the current *Fact Sheet*, which is continuously updated, so check for updates frequently.

The infusion is administered over a minimum of 60 minutes (200 mL/hour). If immediate administration is not possible, the diluted bamlanivimab solution can be stored for up to 24 hours at refrigerated temperature (2-8°C [36-46°F]) and up to 7 hours at room temperature (20-25°C [68-77°F]), including infusion time. After infusion, the residual medication must be flushed through the tubing with normal saline. FDA has received several reports in which this was not done, resulting in patient's not receiving up to 30 mL of a 200 mL dose.

continued on page 5 — **Monoclonal antibodies** >

> **SAFETY** briefs cont'd from page 3



Keep topical fluorouracil far away from pets. Many know how truly devastating it is to lose a pet. ISMP was recently reminded by a concerned veterinarian about a medication error that is fatal to our furry family members, even after just licking their owners! The topical chemotherapeutic agent fluorouracil (**CARAC, EFUDEX, FLUOROPLEX, TOLAK**), often used to treat skin disorders such as actinic keratosis or basal cell carcinomas, is extremely toxic to dogs and cats. Despite receiving emergency veterinary treatment after coming into contact with fluorouracil, mortality rates within 24 hours are high for dogs and cats. When even small amounts of fluorouracil are ingested, the urea cycle is disrupted, resulting in toxic hyperammonemia. Exposure often happens when a pet licks the owner's skin where the medication was applied or chews the fluorouracil container. Clinical symptoms rapidly develop, causing gastrointestinal tract, bone marrow, and nervous system abnormalities. Neurologic signs of fluorouracil toxicity include altered mentation, tremors, ataxia, and seizures. There is currently no reversal agent available for pets when fluorouracil is ingested. The remaining treatment options are generally palliative to reduce symptoms (www.ismp.org/ext/574).

Additionally, the product labels on fluorouracil do not alert or educate users about this risk. We have communicated with the US Food and Drug Administration (FDA) and USP about this issue with the hope that a path is set to address drug toxicities specific to pets. FDA has posted additional information about the problem at: www.ismp.org/ext/600. We have also notified the major drug information vendors to ask them to prominently include this information in patient instructions. In the meantime, we urge providers to bring this topic up at safety committees in the hope that practitioners who prescribe fluorouracil creams and solutions will discuss this risk with their patients and the need for safe storage if pets are nearby. We also urge pharmacists to reinforce this information while providing medication counseling to ambulatory patients. Remind patients to safely store medications up and away and out of sight of children and pets. ISMP is interested in knowing of any safety strategies that you have implemented so we can disseminate information to the public. Please contact us at: ismpinfo@ismp.org.

> **Monoclonal antibodies** — continued from page 4

Regeneron's product is available as a combination of two different drugs—casirivimab and imdevimab. The *Fact Sheet* (www.ismp.org/ext/597) notes that each is provided in a separate single dose vial, which must be brought to room temperature over 20 minutes before preparation. Ten mL (1,200 mg) of **each** drug (drawn into separate syringes) are mixed together in 250 mL of 0.9% sodium chloride after first removing 20 mL of saline from the bag.

Complicating matters is that each of the Regeneron drugs may be made available either as 4 x 2.5 mL vials or as one 11.1 mL vial. That means if the 11.1 mL vials are not available, 8 vials (4 x 2.5 mL vials of casirivimab and 4 x 2.5 mL vials of imdevimab) will be needed to mix 10 mL of each drug in the infusion bag, thus increasing error potential. It also appears that some of the vial and carton labels arriving this week do not include drug names (**Figure 1**) or identify the specific antibody contained within, making it difficult to ensure that both casirivimab and imdevimab are added to the saline solution in the correct amounts. These labels appear to be investigational drug labels, listing a product code number rather than a drug name. Also, the manufacturer's barcode does not distinguish between the two drugs. These interim labels will soon be replaced with improved labels (www.ismp.org/ext/601). Meanwhile, pharmacy staff must look up the product code numbers in the *Fact Sheet* to identify these drugs and can affix barcode labels to the vials based on the National Drug Code (NDC) numbers in the *Fact Sheet*.



Figure 1. Imdevimab (left) and casirivimab (right) vial labels list only product code numbers, not drug names, and the manufacturer's barcodes do not differentiate the products. A pharmacy has affixed barcoded labels with drug names to the vials.

To complete preparation, the infusion bag must be inverted gently by hand 10 times to mix the solution. If immediate administration is not possible, store the diluted casirivimab and imdevimab infusion in the refrigerator between 2-8°C (36-46°F) for no more than 36 hours and at room temperature up to 25°C (77°F) for no more than 4 hours, including infusion time. As with bamlanivimab, the dose is infused over 60 minutes.

The slight differences between the drug presentations, preparation, and storage (**Table 1**) can cause confusion, as can the error-prone labeling; so, be aware and be prepared!

Table 1. Primary Differences Between New Monoclonal Antibodies

Product Features	Monoclonal Antibodies	
	bamlanivimab 700 mg/20 mL vials (Lilly)	casirivimab and imdevimab 120 mg/mL vials (Regeneron)
Dose for adults and children 12 years and older weighing at least 40 kg	700 mg	2,400 mg (1,200 mg of each drug administered together as a single infusion)
Vial size(s)	20 mL	11.1 mL or 2.5 mL
Volume of drug needed for dose preparation	20 mL	20 mL (10 mL of each drug)
Preparation instructions	Remove 70 mL from a 250 mL bag of 0.9% sodium chloride, and add 20 mL of drug for a final volume of 200 mL	Remove 20 mL from a 250 mL bag of 0.9% sodium chloride, and add 10 mL of each drug (20 mL total) for a final volume of 250 mL
Gently invert bag 10 times after adding drug	Yes	Yes
Minimum infusion time	60 minutes	60 minutes
Storage	Store up to 24 hours at 2-8°C (36-46°F) and up to 7 hours at room temperature 20-25°C (68-77°F), including infusion time	Store up to 36 hours at 2-8°C (36-46°F) and up to 4 hours at room temperature up to 25°C (77°F), including infusion time

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FREE FDA webinar

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a **FREE** webinar, **FDA Drug Topics: Project Facilitate: Oncology Expanded Access Program Update**, on **December 14**. This webinar will discuss the regulatory pathway by which an oncologist may obtain access to an investigational drug for patients with a life-threatening condition for which there is no acceptable treatment. For details, visit: www.ismp.org/ext/30, and to register, visit: www.ismp.org/ext/31.

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



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Coming in early 2021!

ISMP has developed and pilot tested a new self-assessment

tool that can help interdisciplinary perioperative teams in hospitals, ambulatory surgery centers, and other surgical sites pinpoint how currently designed systems, staff practices, and emerging challenges may impact perioperative medication safety.

Launch of the assessment tool is expected early in 2021, after the holidays!

ISMP Medication Safety Self Assessment[®] for Perioperative Settings



Start building your perioperative assessment team to:

- ✓ Identify opportunities for improvement
- ✓ Create organization-specific, safety-focused initiatives
- ✓ Compare your results with demographically similar organizations



Expected release:
Early 2021

This project has been funded by the US Food and Drug Administration (FDA) under contract # 75F40119C10120.