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ISMP

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

Drug shortages continue to compromise patient care

An exhaustive account of frustrations, difficulties, misspent resources, and safety concerns came across loud and clear from respondents who participated in our August through October 2017 national survey on drug shortages. Most respondents to the survey confirmed that drug shortages during the 6 months prior to the survey continue to be a daily struggle, involving an increasing number of lifesaving drugs without a viable alternative, and lasting longer than ever before. They suggested that providing safe and appropriate drug therapy has become extremely challenging during shortages and has led to numerous instances of unsafe practices, compromised care, and potentially harmful errors.

Many respondents noted that the state of drug availability in the US is unacceptable. Some believed that inadequate planning during recent drug company mergers has led to many of the recent drug shortages. Others left angry comments blaming the drug manufacturers for limiting supplies to increase demands and bolster profits, noting that products in short supply that return to the market are often more costly than before the shortage. But most of the respondents clearly struggled to understand why the drug shortages continue to occur at an alarming rate that makes it nearly impossible to provide safe, high-quality patient care in a fiscally responsible manner. Details from the survey follow. Please note: Some responses to this survey occurred before, and some after, Hurricane Maria hit Puerto Rico in September 2017, which significantly worsened certain drug shortages.

Respondent profile

Nearly 300 respondents completed our survey on drug shortages, including pharmacy directors (37%), pharmacy managers or assistants (26%), pharmacy purchasing agents (21%), clinical/staff pharmacists (8%), pharmacy technicians (3%), medication safety officers (2%), and others (3%). Almost all respondents practiced in a hospital setting, including community hospitals (56%), teaching hospitals (21%), critical access hospitals (9%), and specialty hospitals (3% pediatrics, 3% long-term acute care, 4% other).

Drugs involved and frequency of shortages

Over half (55%) of all respondents reported that more than 20 drugs were involved in shortages during the 6 months prior to the survey. However, differences were seen among respondents from various practice settings. For example, 19% of respondents from critical access hospitals reported experiencing shortages with more than 20 drugs during this time, compared to 73% of respondents from teaching hospitals and 62% from community hospitals. Most were affected by at least one drug shortage daily, particularly those from specialty (80%), community (77%), and teaching hospitals (73%).

Shortages were reported across all treatment categories. Over two-thirds of respondents reported shortages that impacted emergency care (87%), anesthesia care (85%), pain management (81%), infectious disease treatment (71%), and cardiovascular care (68%). More than half of the respondents experienced shortages that impacted parenteral nutrition (55%), while one-third involved obstetrics/gynecology (33%) and hematology/oncology (33%) service lines. Vital drugs that impacted many other service lines were also reported, including neurology (18%), allergy/asthma care (15%), psychiatry (10%), endocrinology (10%), and ophthalmology (5%). Five percent of respondents reported intravenous (IV) fluids in short supply, affecting all service lines (which worsened after Hurricane Maria).

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Mix-ups between AuroMedics levoFLOXacin and levETIRAcetam. Given the current scope of product and intravenous (IV) fluid shortages, many facilities are using commercially available premixed IV products as much as possible to decrease the number of IV solutions that must be compounded. Some of these products

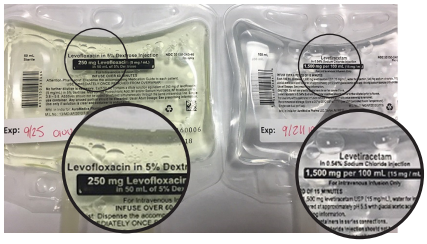

Figure 1. Once the overwrap is removed, the bags of levo**FLOX**acin (left) and lev**ETIRA**cetam (right) look very much alike.

are being used for the first time in hospitals. Two examples include levo**FLOX**acin and lev**ETIRA**cetam. These premixed IV products may only be available from one manufacturer through the organization's usual purchasing group or wholesalers.

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ISMP now accepting Fellowship applications

ISMP is now accepting applications through ***March 31, 2018***, for two unique 2018-2019 yearlong Fellowship programs commencing mid- to late-summer 2018. The **ISMP Safe Medication Management Fellowship** offers a pharmacist, nurse, or physician an opportunity to learn from the nation's experts in medication safety. The **FDA/ISMP Safe Medication Management Fellowship** offers a healthcare professional an opportunity to work with medication safety experts at ISMP for 6 months and the US Food and Drug Administration (FDA) Division of Medication Error Prevention and Analysis for 6 months. All candidates must have at least 1 year of postgraduate clinical experience and relocate to the area. For details, visit: www.ismp.org/sc?id=3064.

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Advanced notification about shortages

Few respondents reported consistently receiving advanced notifications from drug manufacturers, wholesalers, distributors, group purchasing organizations, or the US Food and Drug Administration (FDA) about impending drug shortages (12%), their causes (13%), or their duration (11%). However, improvements were observed in our 2017 survey when compared to a similar survey we conducted in 2010 (www.ismp.org/sc?id=3080). In 2010, 84% of respondents said they *never* or *rarely* received advanced notifications about shortages, their causes, or duration. In 2017, notifications about drug shortages were more frequently reported, although 38% still said they *never* or *rarely* received this information.

Interdisciplinary tension

Approximately two-thirds (62%) of all respondents reported that patients, medical staff, hospital leadership, nurses, and/or staff from other clinical departments *frequently* or *always* expressed frustration with pharmacists or pharmacy staff members because of drug shortages. Few differences were seen among respondents from different settings.

Actions to address drug shortages

Respondents reported taking many resource-intensive actions to reduce the impact of drug shortages on patient safety and to ensure patients receive the required treatment.

Secure and maintain products. Most respondents reported actions that have significantly increased drug costs because of drug shortages. At least 90% of respondents reported adding back-up inventory for critically important drugs in short supply, changing par levels, purchasing excess inventory from a wholesaler, and/or purchasing a more expensive brand, generic, or therapeutic alternative product from a wholesaler. More than half of the respondents purchased more expensive products from a new distributor (67%) or an outsourcer (58%). Fifteen percent admitted to purchasing drugs in short supply at great cost from a secondary gray market, which represents a decrease when compared to a 2011 survey (www.ismp.org/sc?id=3081) in which half of the respondents admitted to purchasing medications from the gray market. To secure a needed medication, respondents also said they borrowed or purchased it from another health system, purchased it directly from the manufacturer or in different strengths/concentrations, or compounded it.

Limit or extend drug use. Ninety-four percent of respondents reported rationing or restricting drugs in short supply. Examples included establishing criteria for using products, restricting access to drugs via override in automated dispensing cabinets (ADCs), and providing kits for emergency drugs. Thirty percent of all respondents said they have used a drug in short supply outside its specific labeling to help extend its use, such as keeping expired products (without FDA-extended dating) in code carts.

Communicate and educate. Almost all respondents (97%) reported devoting resources to keep the medical staff informed about drug shortages. A vast majority had also established regular meetings with pharmacy staff to address the shortages (79%) and devoted resources to staff education about the safe dosing of alternative drugs (80%).

Adverse patient outcomes

A majority of respondents felt that drug shortages had compromised patient care. Most (71%) were unable to provide patients with the recommended drug or treatment for their condition due to shortages, and nearly half (47%) thought that this resulted in patients receiving a less effective drug. Also, three-quarters (75%) of respondents stated that patient treatments had been delayed because of drug shortages. One example involved a delay in treating sepsis and acidosis using sodium bicarbonate that may have contributed to a patient's death. An additional 5% of respondents reported other types of adverse outcomes related to drug shortages, such as increased pain or discomfort during a procedure due to the unavailability of a required analgesic or sedation agent.

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AuroMedics Pharma provides levoFLOXacin in 250 mg/50 mL, 500 mg/100 mL, and 750 mg/150 mL bags, as well as levETIRAcetam in 500 mg/100 mL, 1,000 mg/100 mL, and 1,500 mg/100 mL bags. Some hospitals that started using these products have been complaining that once the overwrap is removed, the bags look very much alike. One hospital alone reported "numerous mix-ups" between the two products. Both drug names start with L-E-V, and there is a shared 500 mg/100 mL strength. Additionally, the font size used on the label is very small and difficult to read (particularly in comparison to other manufacturers' products). The strength for each product is printed within a black background, which is also hard to read. A mix-up was even reported between a 250 mg/50 mL bag of levoFLOXacin and a 1,500 mg/100 mL bag of levETIRAcetam (**Figure 1**, page 1).

ISMP has contacted the manufacturer and suggested redesigning the labels using a larger font size and tall man letters. Printing the strength within a black background should also be eliminated, as it acts to draw one's eyes away from the drug name. To improve the likelihood that an error will be recognized, we recommend placing any pharmacy-applied label just below the drug name and strength on premixed bags, rather than on the reverse side unless there is insufficient room for the label on the front of the bag. This way, both the title (base solution and/or drug name), as listed by the manufacturer, and the pharmacy label, can be easily scrutinized to make sure they correlate.

In the reports we received, nurses have also prevented mix-ups by scanning the manufacturer's barcode, not the pharmacy label barcode. Scanning a pharmacy label barcode would not detect the wrong drug if the label was affixed to the wrong bag. We recommend placing the pharmacy label in such a way as to not cover the manufacturer's barcode. However, with the AuroMedics products, not covering the barcode or the expiration date and lot number presents quite a challenge. Errors could also be detected if these products were scanned before being dispensed from the pharmacy for individual patients, or scanned upon

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Adverse impact on organizational resources

Although not directly queried in the survey, more than one-third of all respondents took the time to provide comments voicing their anger and frustration with the extensive human and financial resources that have been required to manage drug shortages. Many said they needed full-time staff to manage drug shortages and felt the tasks associated with this process had cut into the time normally devoted to patient care and medication safety, introducing risk, and contributing to errors. Many respondents also provided examples of how recent drug shortages have led to unsafe practices that have increased the risk of an error. Examples included:

- Dispensing medications in vials to patient care units so they can be prepared and administered via IV push administration; these medications were previously available in premixed containers or mixed in the pharmacy in small-volume containers
- Administering IV push medications rapidly when they should be administered more slowly via a syringe pump
- Diluting or reconstituting medications in saline flush syringes on patient care units due to shortages of normal saline
- Compounding products in the pharmacy and in the operating room that were previously available as premixed solutions or injectables
- Providing medications in concentrations that differ from what was typically used for direct injectables, or for compounding products according to standardized formulas, which are then no longer accurate

Errors due to drug shortages

Similar to our 2010 survey, nearly a quarter (21%) of all respondents in our 2017 survey were aware of the occurrence of at least one medication error related to a drug shortage in the 6 months prior to the survey. Respondents provided descriptions of close to 100 errors; most (67%) were associated with the wrong dose or concentration. Examples are provided in **Table 1** (page 4). Comments by some respondents who were not aware of errors due to drug shortages suggest they may occur but are not being reported.

Breaches in drug purchasing or allocation policies

Approximately one in six (17%) respondents were aware of breaches in drug purchasing or allocation policies. The most frequently cited breaches included using drugs supplied in emergency carts or kits for non-emergencies, unauthorized drug purchases, buying excessive amounts of drugs associated with impending shortages, hoarding of drugs, removing a drug in short supply from an ADC via override despite restrictions, using single-dose vials as multiple-dose vials, and purchasing sterile products compounded from non-sterile ingredients from compounding pharmacies without evaluating the risk. Despite these breaches, improvements were observed when compared to our 2010 survey in which more than half of respondents reported breaches such as the hoarding of drugs.

Conclusions

Our national survey suggests that the impact of drug shortages continues to take an enormous toll on healthcare providers and patients. The staff hours alone spent on planning for the shortage; educating staff; restocking and barcoding the alternative products; dealing with secondary market vendors; prescribing, preparing, and administering unfamiliar alternative products; and fielding questions consumes a large portion of the health professionals' time, stealing valuable resources from clinical activities. Overall, survey respondents conveyed a real sense of crisis, frustration, and anger associated with the ongoing drain of resources and threats to patient safety that the shortages impose.

Numerous organizations and governmental agencies have been working steadily to provide oversight regarding the availability of pharmaceutical products, develop more effective early warning systems for impending shortages, keep clinicians informed about shortages and potential alternatives, and reduce the overall adverse effects of drug short-

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placement and removal from an automated dispensing cabinet (ADC). Even keeping the 2 drugs far apart from one another, rather than stored in bins close by, would help.

Leaving the AuroMedics bags in their overwraps until the time of use can also prevent mix-ups, as the overwraps use various colors for the different strengths. The pharmacy label can be attached to the product via rubber band or tape so it can be affixed to the bag immediately before use. However, even that would not help with AuroMedics lev**ETIRA**cetam 1,500 mg and levo**FLOX**acin 750 mg, each of which share the same orange color on the overwrap (**Figure 2**).

Figure 2. Despite the different strengths, the 1,500 mg bag of lev**ETIRA**cetam (left) was mixed up with the 750 mg bag of levo**FLOX**acin (right).

Confusing dose with administration time. A dispensing error occurred in the pharmacy that involved misinterpreting the "hang time" of 1500 (3 p.m.) as the dose needed for a vancomycin intravenous (IV) piggyback. In fact, the pharmacist stated that he has often caught himself interpreting the time printed on the patient's label as the dose (**Figure 1**). The mistake has also happened to a pharmacy technician. Since the error, pharmacy has asked its information technology department to modify the label format to display the time in a format with a colon between the hour and the minutes, so the label reads 15:00 instead of 1500. It may also be helpful to use a larger, bold font for the dose.

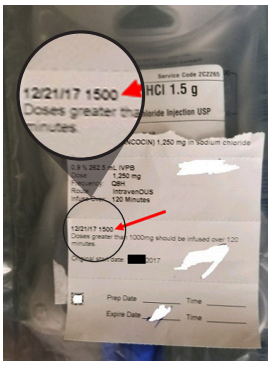

Figure 1. Scheduled administration time (arrow) was mistaken as a dose of "1500" mg.

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Table 1. Examples of medication errors associated with drug shortages reported by survey respondents

Pharmacy had to compound **EPINEPH**rine with lidocaine, resulting in the wrong concentration.
EPINEPHrine 1 mg per mL vial was used to prepare and administer an IV dose; drug was not diluted, and the wrong dose was administered.
Dispensed e**PHED**rine instead of **EPINEPH**rine to the operating room; **EPINEPH**rine was unavailable in stock in its usual location.
Used a multiple-dose vial with a preservative to prepare an epidural infusion when preservative-free bupivacaine with **EPINEPH**rine was unavailable.
Anesthesia staff tried to make their own bupivacaine with **EPINEPH**rine 1:200,000 by adding **EPINEPH**rine to plain bupivacaine, resulting in variable concentrations.
DOPamine infusion unavailable and prepared at the wrong concentrations, resulting in both under- and overdoses.
DOPamine 800 mg per 250 mL bag selected in error and administered when 400 mg per 250 mL bags were unavailable.
Potassium chloride small volume infusion was prepared at the wrong concentration and administered.
Wrong concentration of sodium acetate injection was added to an automated compounder; several patients received the wrong dose in their parenteral nutrition.
When sodium acetate was unavailable and there was a severe restriction on sodium bicarbonate, the pharmacy used potassium acetate in an IV solution; the final product contained 150 mEq of potassium per liter but was fortunately not administered to the patient.
1 mL **LOR**azepam vials (2 mg per mL) were not available; pharmacy received 10 mL vials (2 mg per mL), which were entered into stock as 10 x 1 mL vials.
1 mL vials of morphine 10 mg dispensed when 2 mg vials were unavailable; 10 mg IV administered in error.
HYDROmorphone 1 mg administered instead of 0.5 mg because the 0.5 mg syringes were unavailable.
Ordered **HYDRO**morphone prefilled syringes from a different manufacturer; nurse gave the medication orally because the syringe looked like an oral syringe, although it was clearly labeled for IV use.
Selected an ampul of **SUF**entanil instead of fenta**NYL** and administered it during a fenta**NYL** shortage.
A patient received no treatment when a drug known to be unavailable was ordered verbally, and the nurse did not notify the pharmacy about the order or request an alternative.

ages. For example, the American Society of Health-System Pharmacists (ASHP), ISMP, and other organizations recently met to develop a Congressional call to action to address the causes of drug shortages (www.ismp.org/sc?id=3039). The work is slow but ongoing.

Multiple resources are available to organizations that must manage this complex problem, guided by pharmacy leadership, including the following:

- ASHP Resource Center: www.ashp.org/shortages and www.ismp.org/sc?id=3076
- FDA Drug Shortages Page: www.ismp.org/sc?id=3071
- US Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response: www.ismp.org/sc?id=3072
- ISMP newsletter on managing drug shortages: www.ismp.org/sc?id=241
- ASHP and University of Utah guidance on small-volume parenteral solutions shortages: www.ismp.org/sc?id=3073
- Centers for Disease Control and Prevention guidance on vaccines in short supply: www.ismp.org/sc?id=3074
- American Society for Parenteral and Enteral Nutrition guidance on shortages with parenteral nutrition components: www.ismp.org/sc?id=3075

Preparation, standardization, communication, and monitoring is paramount to safely manage drug shortages. Although it may be impractical to prepare for every potential drug shortage, proper planning can minimize the adverse effects on both patients and providers. Also be sure to update and standardize any processes associated with alternative medications and communicate information to clinicians about the steps taken to limit or extend products in short supply. Utilize error and adverse event reporting systems, as well as focus group meetings, discussions during pharmacy rounds, or other means, to learn about hazardous conditions, close calls, and adverse events associated with drug shortages so actions can be taken to limit further risk and harm.

ISMP welcomes 3 new Fellows

ISMP welcomes **Vivek Brahmbhatt, PharmD**, a **2017-2018 FDA/ISMP Safe Medication Management Fellow**, and **Kayla Cierniak, PharmD, MS**, also a **2017-2018 FDA/ISMP Safe Medication Management Fellow**. Vivek and Kayla will spend 6 months at the US Food and Drug Administration (FDA) and 6 months at ISMP. Prior to the Fellowship, Vivek was a clinical pharmacist for Kindred Hospital in Mishawaka, IN, and Kayla completed a PGY1 residency at University Hospitals Ahuja Medical Center, in Beachwood, OH.

ISMP also welcomes **Barbrakaryne N. Nchinda Fobi, PharmD, MPH**, our first **ISMP International Medication Safety Management Fellow**, sponsored by Baxter International Inc. Originally from Cameroon (Central Africa), Barbra worked in PA for UPMC Pinnacle Hanover and CVS prior to the Fellowship. She will be spending 2 years with ISMP.

Special Announcements

Just Culture certification course

Attend a **Medication Safety Focused Just Culture Certification Course** on **February 21-22** in **Phoenix, AZ.** Register with discount code **ISMP2018** to receive $200 off. For details, visit: www.ismp.org/sc?id=3040.

Free ISMP webinar

January 18: ***Introducing ISMP's New Targeted Best Practices for 2018-2019***. For details, visit: www.ismp.org/sc?id=349.

To subscribe: www.ismp.org/sc?id=382

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP Medication *Safety Alert!* Acute Care (ISSN 1550-6312)

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit our website at: www.ismp.org/MERP or www.ismp.org/VERP.

ISMP Quarterly Action Agenda

ISMP 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 October-December 2017 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 to locate additional information. 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/sc?id=479). The Action Agenda is also available for download in a Microsoft Word format (www.ismp.org/sc?id=3082) 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/sc?id=480. **Key:** ⚠ — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
ISMP Targeted Medication Safety Best Practices (TMSBPs) for Hospitals 2018-2019					
(25) ⚠	The ISMP 2018-2019 TMSBPs for Hospitals include 2 revised and 3 new practices (www.ismp.org/sc?id=1750). The new practices include eliminating the prescribing of fentaNYL patches for opioid-naïve patients or acute pain, removing injectable promethazine from formularies, and proactive use of external risk and error information.	ISMP encourages hospitals that have not implemented the 2016-2017 TMSBPs to do so as a priority, while implementing the new 2018–2019 best practices. Hospitals can compare their level of implementation of the 2014-2015 and the 2016-2017 TMSBPs to other hospitals via survey data available at: www.ismp.org/sc?id=3063.			
Flow rate documentation errors with interoperable smart infusion pumps due to duplicate barcodes					
(24) ⚠	In a hospital with smart infusion pump interoperability, electronic documentation of an insulin infusion was being recorded intermittently at both 3 mL per hour (the correct rate) and 60 mL per hour. Investigation revealed that the pump channel barcode was associated with two *different* pump channels being used for two *different* patients. Both channels had been labeled with the same barcode after pump repair.	If you have implemented or plan to implement bidirectional smart infusion pump interoperability, conduct an independent double check when affixing barcodes to pump channels, verify the serial numbers and barcodes when pumps have been returned after repair, and ensure that internal serial numbers and information technology (IT)-applied barcodes all match before pumps leave the IT department.			
Damaged or dirty BD Alaris inter-unit interface (IUI) connectors can lead to device errors					
(24)	Alaris IUI connectors used to attach a pump channel to the PC unit (pump brain) or another channel can become dirty, cracked, or otherwise damaged, which can interrupt communication between the channel and the PC unit and cause errors or pump shutdown.	Cleaning instructions for the IUIs can be found at: www.ismp.org/sc?id=3050, and an inspection tip sheet is available at: www.ismp.org/sc?id=3049. Any dropped or damaged instruments should be sent to the biomedical engineering department for repair.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Ensure all staff are using the drug library built into smart infusion pumps					
(24) ⚠	An anesthetist programmed a dexmedetomidine infusion to deliver 0.15 mcg/kg/minute instead of mcg/kg/hour. Using a CareFusion Alaris smart pump, she selected "Guardrails Drugs" to program the infusion, but then chose the "DRUG CALC" function and entered the infusion rate instead of selecting the drug from the library. The pump did not indicate that the dose error reduction software (DERS) had not been activated.	Educate smart pump users (including anesthesiologists and anesthetists) about proper programming and how to engage the drug library. Confirm staff understanding via annual competencies and monitor compliance with the drug library. Consider requiring an independent double check of high-alert medication infusions that require manual entry of custom concentrations (e.g., investigational drugs).			
Errors related to horizontal barcodes on curved surfaces and multiple barcodes on packages					
(21, 22)	Pharmaceutical products are required to have a linear barcode, but pursuant to the Drug Supply Chain Security Act (DSCSA), many manufacturers are also including a 2-dimensional (2D) data matrix barcode. The presence of both linear and 2D data matrix barcodes can lead to confusion regarding which to scan, and the horizontal repositioning of linear barcodes around curved surfaces renders them unreadable.	Alert staff to the new DSCSA requirement to include a 2D data matrix barcode on certain product labels, and advise them which barcode to scan. Establish a process for incorporating new barcodes into the information technology database and linking them to the correct products. For a resource on managing the challenges associated with barcode verification systems, visit: www.bcmaresources.com/.			
Mix-up between protein C concentrate, human (CEPROTIN) and prothrombin complex concentrate, human (KCENTRA)					
(22)	A patient received prothrombin complex concentrate, which stops bleeding, instead of protein C concentrate, which assists with anticoagulation. The physician thought PCC was an abbreviation for protein C concentrate, not prothrombin complex concentrate.	Avoid the use of abbreviations for drugs, including PCC. Instead, include the full name of the products, protein C concentrate, or Ceprotin, and prothrombin complex concentrate, or Kcentra.			
STABILOX canister in SIMPLIST syringe package mistaken as a vial					
(21)	Simplist morphine syringe packages contain a StabilOx canister which improves product stability. A nurse called the pharmacy to ask how to use the "vial" (canister) in the package.	Educate nurses about the purpose of StabilOx canisters and instruct them to discard the canisters upon opening the packages.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Texting of medical orders can compromise patient safety					
(13, 23)	The debate regarding the texting of orders continues. Proponents have embraced the convenience and usefulness of texting orders. Still, results of an ISMP survey revealed high concern regarding potential risks associated with texted orders, such as data security, delays in carrying out orders, unintended autocorrections, misunderstood abbreviations, misspellings, incomplete orders, and patient misidentification.	Establish and communicate policies to avoid the texting of medication orders. The texting of orders is currently prohibited by certain regulatory and accrediting agencies. Safety issues need to be identified and resolved through advanced technology along with the development of industry-wide clinical guidelines to ensure standardized, safe, and secure texting processes can be implemented.			
Misuse of standard insulin pen needles by patients at home after hospitalization					
(21) ⚠	While hospital staff often use insulin pens with a safety needle that does not require removal of the needle cover prior to injection, patients often use a standard insulin pen needle at home, which has a needle cover that must be removed before injection. Some hospitalized patients who have been taught to inject insulin using a pen with a safety needle have tried to inject insulin at home without removing the needle cover on a standard needle, thus failing to administer the insulin. One patient developed ketoacidosis and died.	Teach patients how to administer the insulin with the pen they will be using at home and require a return demonstration. Verify which pen needle the patient will be using and tailor the training to that needle. Remind patients that a standard pen needle is different from what may have been used in the hospital. Review injection technique with the patient if blood glucose levels are elevated. A National Alert Network (NAN) communication offers further details (http://ismp.org/NAN/files/NAN-20171012.pdf).			
Improper use of the BD AUTOSHIELD DUO and NOVOFINE AUTOCOVER insulin pen safety needles					
(22) ⚠	A patient required 5 emergency department (ED) visits and a hospital admission for hyperglycemia and ketoacidosis caused by nursing home staff misuse of the BD AutoShield Duo insulin pen safety needle. Some staff did not press hard enough for the needle cover to retract, and others injected the insulin at an angle that did not allow the retraction mechanism to work. Similar problems are possible with the NovoFine Autocover safety needles.	Educate staff about the proper use of insulin pens and safety needles. Include a requirement to look for the red indicator on the BD AutoShield Duo and NovoFine Autocover post-injection to ensure that the needle has retracted properly. Patients rarely use safety needles unless a caregiver is administering the insulin. If this is the case, also educate the caregivers about proper use of the pen and safety needles.			

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Confusion with measuring the correct dose with a U-500 insulin pen					
(25) ⚠	A patient using a U-500 insulin pen showed a pharmacist how he turned the dose knob on the pen to "15" to deliver each prescribed dose of 75 units. He had previously used a U-100 syringe to measure each dose of U-500 insulin, stopping at the "15 units" marking on the syringe. But the U-500 pen delivers the actual dose dialed.	Hospital staff should use U-500 insulin pens, or U-500 insulin syringes and vials, when measuring and administering U-500 insulin. For patients, perform a medication history on admission to determine whether they are using a U-500 insulin pen at home, or a vial and syringe, and tailor the education to the devices being used.			
Differentiating insulin types by touch and separate storage					
(21) ⚠	A visually impaired woman who uses both rapid-acting and long-acting insulin pens stored them both in the refrigerator. She accidentally administered 50 units of the rapid-acting insulin at night. She woke up at 4 a.m. with a blood glucose value of 50 mg/dL.	Teach patients ways to differentiate insulin types by touch, such as applying adhesive tape or rubber bands to pens. Avoid storing insulin pens together; advise patients to keep long-acting insulins in the bedroom and rapid-acting insulins in the dining area.			
Compounding error with PROLASTIN-C (alpha1-proteinase inhibitor [a1-PI])					
(22)	A patient prescribed IV Prolastin-C 7,000 mg received 8,379 mg due to a compounding error. Although the package insert indicates that each vial contains 1,000 mg, the actual amount in each vial was 1,197 mg. Seven vials were used for the dose, along with 20 mL of diluent for each vial (140 mL), when only 6 vials (7,182 mg) were needed.	Before compounding, require pharmacy staff to check the actual amount of the active ingredients in any plasma-derived medication and calculate the volume needed. Develop clinical guidelines, order sets, and procedures to guide appropriate use. Only those with knowledge of plasma-derived products should prescribe these drugs.			
Confusion between IV RITUXAN (riTUXimab) and subcutaneous RITUXAN HYCELA (riTUXimab and hyaluronidase)					
(20) ⚠	The hyaluronidase component of Rituxan Hycela allows subcutaneous delivery of ri**TUX**imab in volumes that might not otherwise be feasible. But the large volume of Rituxan Hycela may cause staff to believe that the drug should be administered intravenously (IV), which may lead to an overdose. Rituxan Hycela has also been mixed up with IV Rituxan.	Educate staff about the two formulations and the recommended procedure for administering the large subcutaneous dose of Rituxan Hycela. Store these products in a way that will clearly indicate that they are different formulations. When dispensing Rituxan Hycela, include a warning, "For Subcutaneous Use Only."			