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ISMP
An ECRI Affiliate

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

Drug, supply, and equipment 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 the July 2023 ISMP/ECRI survey on *Drug, Supply, and Equipment Shortages*. Most respondents confirmed that during the 6 months prior to the survey, shortages continued to be a daily struggle, involved an increasing number of lifesaving drugs without viable alternatives, and lasted longer than ever before. Their responses suggested that providing safe and appropriate drugs, supplies, and equipment has become extremely challenging and led to numerous instances of unsafe practices, compromised care, and potentially harmful errors. Many of the respondents clearly communicated their struggles to address shortages which are occurring at an alarming rate, making it nearly impossible to provide safe, high-quality patient care in a fiscally responsible manner. Respondents also expressed concerns about the potential for drug shortages worsening after the recent tornado damage to the Pfizer plant in North Carolina. Details from the survey follow.

Respondent profile

Nearly 200 respondents completed our survey, including pharmacy administration (e.g., director, manager, supervisor) (32%), supply chain/procurement (17%), clinical/staff pharmacists (8%), pharmacy technicians (7%), nurses (7%), pharmacy purchasing agents (6%), health technology management/clinical engineers (5%), hospital administration (4%), physicians and other prescribers (2%), and risk managers (1%). We also heard from individuals in other positions who respond only to supply or equipment shortages (e.g., anesthesia lead, backorder analyst, purchasing liaison, cardiac catheterization laboratory manager, respiratory therapist, director of pulmonary services, neurosurgery team lead) (7%), and others who respond only to drug shortages (e.g., ambulatory surgery staff, medication access liaison) (4%). Respondents practiced in various healthcare settings including community hospitals (49%), teaching hospitals (24%), critical access hospitals (7%), pediatric hospitals (4%), cancer care hospitals (2%), and other settings (e.g., ambulatory surgical centers, health systems, rehabilitation hospitals, ambulatory clinics, outpatient infusion centers, prison hospitals) (14%). Most (93%) respondents practice in the United States, but we also heard from some international professionals (7%).

Care areas affected by drug, supply, and equipment shortages

Over half (60%) of all respondents reported that more than 20 drugs, single-use supplies, or durable medical equipment were involved in shortages during the 6 months prior to the survey. Respondents reported shortages impacting the following areas: surgery/anesthesia (74%), emergency care (64%), pain management (52%), cardiology (45%), hematology/oncology (44%), infectious disease (39%), and obstetrics/gynecology (37%). Many other service lines also experienced shortages, including gastrointestinal/nutrition (32%), allergy/asthma (26%), neurology (24%), endocrinology (22%), psychiatry (15%), as well as others (e.g., radiology, intensive care, respiratory, urology, endoscopy, home infusion, nutrition, ophthalmology, pediatrics) (26%).

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SAFETY briefs

Limitations of the most recent posaconazole formulation. On May 31, 2021, the US Food and Drug Administration (FDA) approved posaconazole (**NOXAFIL POWDERMIX**) delayed-release oral suspension (30 mg/mL) by Merck for prophylaxis of invasive *Aspergillus* and *Candida* infections in severely immunocompromised patients. The product is indicated for pediatric patients 2 years and older who weigh 40 kg or less. This formulation was developed as a more tolerable, weight-based dosing alternative than the oral tablets and is said to provide more reliable bioavailability, given the poor gastrointestinal absorption of the immediate-release 40 mg/mL oral suspension that is approved for adolescents 13 years and older.

However, several aspects of the delayed-release Noxafil PowderMix may limit its use in the acute care setting. The product is only available as a kit containing eight 300 mg single-use packets of Noxafil PowderMix and a 473 mL bottle of mixing liquid. Each packet should be mixed with 9 mL of the liquid, and once mixed, it must be administered within 1 hour (www.ismp.org/ext/1131). The package insert states to use the custom-designed syringes included in the kit (**Figure 1**, page 2). The manufacturer told us that

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Help ISMP update its list of high-alert medications

It has been 5 years since we last surveyed readers and updated ***ISMP's List of High-Alert Medications in Acute Care Settings***. Please take a few minutes to complete our survey and submit your responses by **October 20, 2023** at: www.ismp.org/ext/1228. We would appreciate your opinion about possible deletions or additions to the list. Thank you for taking the time to provide your perspective on this important topic!

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Actions to address drug, supply, and equipment shortages

Respondents described utilizing numerous resource-intensive actions to reduce the impact of shortages on patient safety and to ensure patients received the appropriate treatment. These actions included the following:

Secure and maintain products. At least 90% of respondents reported adding back-up inventory for critically important drugs, supplies, or equipment for those in short supply, changing periodic automatic replacement (PAR) levels, and/or purchasing a more expensive product from the vendor. Respondents reported that these actions have significantly increased costs. In addition, more than one-third (35%) disclosed that they have purchased an alternative product in short supply from a secondary gray market.

Limit or extend product use. Eighty-six percent of respondents reported rationing or restricting drugs, supplies, or equipment in short supply. Examples included establishing criteria for product use, restricting access to drugs in patient care areas, and rounding doses down or up to the nearest vial size (e.g., chemotherapy). Forty-two percent of all respondents said they have used drugs, supplies, or equipment in short supply, outside of its specific labeling to help extend its use (i.e., extending the beyond-use-date, reusing a single-use device).

Communicate and educate. Most (84%) respondents reported providing resources to educate clinical staff about safe dosing of alternative drugs, or properly utilizing alternative supplies and/or equipment. Nearly all (92%) reported that they regularly inform medical staff about products in short supply. Many (77%) have also established regular meetings with pharmacy staff and central supply/materials management (82%) to manage the shortages.

Adverse patient outcomes

A majority of respondents reported that drug, supply, or equipment shortages compromised patient care. Nearly one-third (32%) of the respondents were unable to provide patients with the recommended drug or treatment for their condition, and more than one-fifth (21%) thought this resulted in patients receiving a less effective drug. Also, nearly half (49%) of the respondents stated that patient treatments had been delayed. Some examples follow:

- Interrupted, modified, or delayed chemotherapy regimens (e.g., reduced doses, treatment withheld if non-curative intent)
- Removal of dextrose 50% injectable syringes from patient care areas leading to a delay in treating hypoglycemia, resulting in patient harm
- A shortage of endotracheal tubes, especially in pediatric sizes, and certain pulmonary artery catheters have been concerning, almost to the point of impacting the ability to provide adequate clinical care
- Manufacturing defects in microbore tubing has led to shortages and delays or disruptions of medication doses
- Rescheduling, postponing, or canceling surgical cases due to lack of supplies needed for procedures
- Shortage of medical equipment spare parts has delayed equipment repair and interrupted patient care requiring patients to be transferred to other facilities

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during development, powder flakes would clump and block part of a conventional oral syringe tip. There is also a concern that during administration, aggregation of the suspension at the tip of the syringe can lead to potential dose loss. The notched tip on the custom syringe provides an opening that allows the entire admixed dose to be administered and not remain in the syringe or syringe tip. To ensure accurate dosing, no other syringe types should be used. The syringes do not come with caps as the product is intended to be used immediately (within the hour). Also, each kit only comes with two syringes of each size (3 mL and 10 mL), and they are not available for individual purchase. Both of these facts will preclude the pharmacy from preparing patient-specific doses of the medication for use in patient care units. In addition, many hospitals have already converted to ENFit systems for patients with enteral feeding tubes; however, these notched syringes are not compatible with ENFit connectors. The single-use packets are not available for individual purchase, so if more than eight doses are required, another kit would need to be purchased and dispensed.

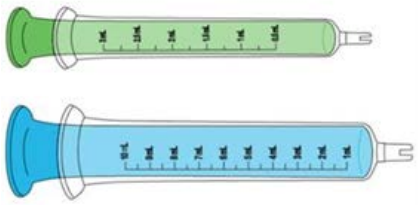

Figure 1. Oral syringes with special notched tips are provided in the Noxafil PowderMix kit and must be used to prepare and administer this product.

Organizations should consider carrying only one of the oral suspensions on the formulary. If deciding to switch from the 40 mg/mL immediate-release suspension to the Noxafil PowderMix, develop a comprehensive pro-active concentration change plan (www.ismp.org/node/32208). However, keep in mind the implications discussed may make it difficult to use the Noxafil PowderMix in the inpatient setting given the inability to use ENFit syringes (or oral syringes), the limited number of custom-designed syringes in the kit, the lack of syringe caps for the syringes, and the short timeframe from preparation to administration. Precluding the pharmacy to prepare patient-

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- Various forms of lidocaine are unavailable to be given, requiring the use of more opioid analgesia

Five percent of respondents reported other types of adverse outcomes related to shortages, such as increased central line-associated bloodstream infection (CLABSI), surgical site infection (SSI), and catheter-associated urinary tract infections (CAUTI).

Errors due to shortages

Nearly a quarter (24%) of all respondents were aware of at least one medical/medication error related to a drug, supply, or device shortage in the 6 months prior to the survey. Respondents provided descriptions of more than 40 errors. Some examples follow:

- Due to the albuterol 0.5% 20 mL vial shortage, albuterol nebulization solution (3 mL) was brought into the clean room to batch syringes for continuous nebulization. When preparing doses, **PULMOZYME** (dornasa alfa) nebulization solution was mistaken for albuterol nebulization solution, which was used in error.
- Ketamine was incorrectly changed from 100 mg/mL to 50 mg/mL in the computer system, resulting in patients receiving half the dose.
- A patient received the incorrect dose of oxy**CODONE** when a 10 mg tablet was selected and administered instead of what was intended–to split the tablet and only administer half.
- Due to the lidocaine multidose vial shortage, a single-dose lidocaine vial was procured but was inadvertently utilized as a multidose vial.
- In an effort to convert cefdinir to a strength available from pharmacy, an error was made in which the medication was changed to cephalexin.
- A patient received methotrexate preservative-free single-dose vials, but the label instructions were for a multidose vial which led to incorrect administration instructions being provided to the patient.

Other examples of shortage-related issues were provided that could potentially lead to errors. One respondent indicated that shortages of nasal atomizers may contribute to incorrect dosages due to different dead space volumes in available nasal atomizers. Another respondent mentioned that changing strengths and directions of medications to accommodate the shortage may not be adequately communicated to patients or caregivers resulting in wrong dose errors.

Adverse impact on organizational resources

Respondents also expressed their anger and frustration with the extensive use of human and financial resources required to manage shortages. They reported that the increased administrative and production workload has resulted in confusion, along with an overwhelming amount of information having to be filtered down to frontline staff. Some felt that this environment has likely contributed to additional errors. Some examples follow:

- When it comes to conserving supplies for the most critical needs, significant time and effort are placed on staff to monitor each specific vial amount in inventory. For example, staff started specifying which vial sizes of methotrexate and **CIS**platin were going to be used for each patient on a daily basis to minimize waste and ensure patients were able to receive their treatment on time.

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specific doses for nurses to administer removes a significant safeguard to ensure accurate dosing of medication in pediatric patients. If you are using the product despite these limitations, consider the following:

- Develop a plan to operationalize and coordinate the preparation, delivery, and administration of patient-specific doses, addressing all safety gaps identified.
- To prevent the risk of wrong route or dosing errors, educate nurses about the use of notched-tip syringes provided with the kit.
- Upon discharge, use the teach-back method to educate patients and/or caregivers how to properly mix the medication, calculate and draw up the correct dose using the notched-tip syringes, and how to administer the medication (www.ismp.org/ext/1111).

Confusing Fluzone high-dose packaging. We received a report about this year's **FLUZONE** (influenza) high-dose quadrivalent vaccine for adults 65 years and over by Sanofi Pasteur. The carton's primary display panel states it contains 10 single-dose prefilled syringes–five trays with two syringes sealed in one tray (**Figure 1**). The concern is that some may think both syringes are needed to administer a dose. If your organization purchases this vaccine, notify staff and ensure barcode scanning is used when dispensing and administering. Consider adding auxiliary labels to each tray noting that each dose requires only one syringe. If stored outside the carton, consider removing the syringes from each tray.

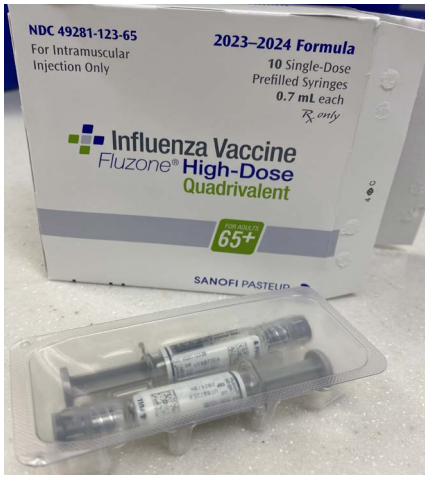

Figure 1. Fluzone carton contains 10 single-dose prefilled syringes—five trays with two syringes sealed in each tray.

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- Sterile compounding practices were changed to compensate for multiple doses coming from single-dose vials, and to compound from different strengths of drugs to get the required potency.

Conclusions

ECRI's Top 10 Health Technology Hazards for 2022 ranked supply chain shortages second among the top 10 risks facing healthcare organizations (www.ismp.org/ext/1221). Our survey results suggest that the impact of drug, supply, and equipment shortages continues to exert an enormous toll on healthcare providers and patients. A vast amount of effort is spent on planning for and managing shortages. This involves educating staff; stocking alternative products and adding barcodes into systems; dealing with secondary market vendors; prescribing, preparing, and administering unfamiliar alternative products; and fielding questions. All of this consumes a large portion of the health professionals' time, stealing valuable resources from other activities. Overall, survey respondents conveyed a real sense of crisis, frustration, and anger associated with the ongoing depletion of resources and threats to patient safety that these shortages impose.

Numerous governmental agencies and professional organizations, such as the American Society of Health-System Pharmacists (ASHP), ISMP, and ECRI, have been working steadily to provide insight regarding the availability of pharmaceutical products, supplies, and equipment; developing more effective early warning systems for impending shortages; keeping organizations informed about shortages and potential alternative products; and reducing the overall adverse effects of shortages. ASHP has also recently joined a White House-sponsored roundtable discussing the national shortages of key cancer medications (www.ismp.org/ext/1218), completed and released their 2023 drug shortages survey results (www.ismp.org/ext/1224), and updated their drug supply chain recommendations focused on addressing drug shortages (www.ismp.org/ext/1219). We have also shared these survey results with the US Food and Drug Administration (FDA) in the hope that the agency will reach the right decision-makers.

Multiple resources are available to help manage this complex problem, including the following:

- ASHP resources: www.ismp.org/ext/828
- FDA Drug Shortages webpage: www.ismp.org/ext/830
- FDA Medical Device Supply Chain and Shortages webpage: www.ismp.org/ext/1216
- US Department of Health and Human Services Drug Shortages and Scarce Resources webpage: www.ismp.org/ext/831
- ISMP newsletter article on managing drug shortages: www.ismp.org/node/775
- Centers for Disease Control and Prevention Current Vaccine Shortages & Delays webpage: www.ismp.org/ext/1210
- American Society for Parenteral and Enteral Nutrition (ASPEN) Parenteral Nutrition Resources webpage: www.ismp.org/ext/1215
- ECRI Supply Chain Disruption in Healthcare webpage: www.ismp.org/ext/1220

Preparation, standardization, communication, and monitoring are paramount to safely managing drug, supply, and equipment shortages. Although it may be impractical to prepare for every potential shortage, proper planning can minimize the adverse effects for both patients and practitioners. Be sure to update and standardize any processes associated with alternative medications, supplies, or equipment. Communicate information to clinicians about the steps taken to limit or extend products in short supply. Refer to ISMP newsletters addressing the need to make a comprehensive proactive plan to mitigate risk when changing drug concentrations (www.ismp.org/node/32208) and on safety considerations during expedited product approval (www.ismp.org/node/71465). Utilize error and adverse event reporting systems, as well as focus group meetings, discussions during rounds, or other means, to learn about hazardous conditions, close calls, and adverse events associated with shortages, so actions can be taken to limit further risk and harm.

Special Announcements

Apply for a JUST CULTURE scholarship

The Just Culture Company, in cooperation with ISMP, will award three ***Judy Smetzer Just Culture Champion Scholarships*** to honor Judy Smetzer, BSN, RN, FISMP, a retired ISMP vice president. Applications are due by **September 28, 2023**. For details and to apply, visit: www.ismp.org/node/30840.

Virtual and in-person workshops on human factors in healthcare

Our affiliate, ECRI, will be offering two unique programs. The first virtual workshop, ***Improving Infection Prevention Practices Using Human Factors and Healthcare Safety Systems Design***, will be held over a two week period, **September 18-29, 2023**. Virtual sessions will be facilitated by ECRI subject matter experts in infection prevention, human factors engineering, and healthcare safety system design. The second in-person 2-day workshop, ***Advancing Patient Care Excellence through Human Factors Engineering***, will be held **October 11-12, 2023**. Participants will learn how to identify critical risks where the system may facilitate error. For details, visit: *virtual workshop*, www.ismp.org/ext/1229; *in-person workshop*, www.ismp.org/ext/1230.

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Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit 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.

Judy Smetzer Just Culture Champion Scholarships

Become a Just Culture Certified Champion

In cooperation with The Just Culture Company, ISMP will award three scholarships for the next calendar year to a team of three individuals from the same organization to participate in a 15-hour Just Culture certification course. For more details, visit: **ismp.org/node/30857**.

Candidate Qualifications

For a team to be considered for a scholarship, they must:

- Be working currently in the field of healthcare in any setting
- Have at least 5 years of fulltime post-graduate experience in healthcare
- Obtain a commitment to the Just Culture model from at least one executive leader in their organization

For more information and to apply, visit:
ismp.org/node/30840

Application Deadline: September 28, 2023

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These scholarships will be awarded in honor of **Judy Smetzer, BSN, RN, FISMP**, former vice president at ISMP who retired in 2022.