Drug Shortages: Shortchanging Quality and Safe Patient Care

Abstract

Drug shortages are a public health crisis that has persisted for many years in the U.S. health system. The daily struggle of shortage management by healthcare providers has led to negative downstream effects on patients, including instances of unsafe or compromised practice and potentially harmful medication errors. A total of 448 medication error event reports associated with drug shortages were submitted to the Pennsylvania Patient Safety Authority from July 2004 through June 2018. Nearly three-quarters (71.0%; n = 318) of events reached the patient. Drug shortage reports involved 173 individual drugs, representing 57 different drug classes, with the most commonly reported drugs being analgesics, followed by antibiotics, electrolytes, and antidotes (e.g., reversal and rescue agents). The total number of reports was distributed evenly among the prescribing, dispensing, and administering nodes of the medication use system. High levels of frustration and tension among providers facing shortages that lack clearly defined or communicated management strategies are apparent from the reports. Organizations may use the data in this article and the revised Drug Shortage Assessment Checklist to inform proactive efforts, standardize protocols in drug shortage situations, prevent similar errors from occurring, and strengthen our national culture of safety.

Introduction

Drug shortages, declared an "urgent public health crisis" by the American Medical Association (AMA) in 2018, have challenged the provision of optimal patient care and appropriate drug therapy for more than two decades. Between 2011 and 2013, U.S. hospitals were forced to expend an estimated annual average of $229.7 million on unusually costly generic products and alternative therapies. Surveys of healthcare providers conducted by the Institute for Safe
Medication Practices (ISMP) from 2001 to 2017 indicate that shortages are long-standing and lingering issues in the national and global landscape of healthcare.\textsuperscript{3,5} Shortages are caused by a multitude of factors, and circumstances can rapidly deteriorate under the acute stress of isolated natural disasters and changes in the economy.\textsuperscript{5,6}

In 2017, the U.S. Food and Drug Administration (FDA) recognized 39 new drug shortages, with additional challenges ascribed to destroyed drug manufacturing facilities in Puerto Rico during a devastating hurricane season.\textsuperscript{7} But the status of U.S. drug shortages has been only exacerbated, and not caused, by these recent natural disasters. The need for comprehensive solutions to this ongoing crisis was emphasized by AMA Board Member William E. Kobler, MD, who stated, "The fact that drug shortages worsened when major hurricanes struck drug production facilities on Puerto Rico highlights the need to evaluate and plan for hazards that pose a threat to critical infrastructure for manufacturing pharmaceutical and medical products."\textsuperscript{1}

The availability of a drug product can be affected by any combination of factors throughout the supply chain, which involves many stakeholders. Members of the supply chain include raw material producers, manufacturers, regulators, wholesalers, vendors, purchasers (e.g., healthcare organizations), and, finally, healthcare providers. Some factors contributing to shortages include the complex nuances of the drug product market, manufacturing and quality issues, manufacturer business decisions, production delays, restricted distribution, and inventory practices.\textsuperscript{6}

Shortages impact the prescribing, dispensing, and administering nodes of the medication use system within healthcare facilities and destabilize systems built for medication safety. The daily struggle by healthcare providers to manage shortages has led to negative downstream effects on patients, including instances of unsafe or compromised practice and potentially harmful medication errors. ISMP surveys have revealed many frustrations and unsafe conditions faced by physicians, nurses, and pharmacists.\textsuperscript{3,6} Respondents also reported many examples of medication errors due to shortage situations, including peripheral nerve blocking agents (e.g., bupivacaine with EPINEPHrine 1:200,000) compounded at the wrong concentration.\textsuperscript{5}

Data from the Pennsylvania Patient Safety Reporting System (PA-PSRS) are used to inform changes in clinical practice with the intent of reducing the risk and severity of future patient safety events.\textsuperscript{9} Pennsylvania Patient Safety Authority analysts reviewed medication errors associated with drug shortages submitted through PA-PSRS from July 2004 through June 2018 and in this report identify the reasons these events took place, discuss the use of best practices, and provide system-based risk reduction strategies and recommendations.

**Methods**

Safety analysts queried the PA-PSRS database for medication errors and adverse drug reaction reports containing terms such as "shortage," "back order," and "out of stock" that occurred from the beginning of data collection in July 2004 through June 2018. The query yielded 915 reports. After reading the reports, analysts excluded 467 reports that did not concern potential or actual medication errors associated with shortages (e.g., wasting of narcotics, failure to "read back" orders). A total of 448 reports were included in the final analysis.

Reporting facilities provided the medication names, patient care area, event type (e.g., dose omission), event description, and PA-PSRS harm score,\textsuperscript{10} (adapted from the National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] harm index).\textsuperscript{11} If the medication name field was left blank, an analyst adjusted the field when the medication name was provided within the free text of the event description field. In addition, reported details and summary case narratives were reviewed for common themes and contributing factors associated with the events reported and categorized by analysts into one of three nodes of the medication-use process—prescribing, dispensing, and administering.
Results

When stratified by PA-PSRS harm score, the majority (71.0%; n = 318 of 448) of drug shortage events reached the patient (harm score category, C to I; Figure 1).

Figure 1. Harm Scores for Medication-Related Events Due to Drug Shortages (N = 448)

![Harm Score Chart]

Note: Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018.

The reported event did not reach the patient (harm score category, A, B1, or B2) in 29.0% (n = 130 of 448) of the submitted cases. These events are commonly referred to as good catches, because the hazard or event was intercepted by a healthcare provider before reaching the patient.12

The following are examples of good catch reports related to drug shortages submitted through PA-PSRS:*

Shortage in corticosteroids per pharmacy, staff received [methylPREDNISolone] 125 mg vials for the patient's 80 mg ordered dose instead of 40 mg vials. Patient received correct dose, no harm.

Etomidate 20 mg was ordered, [automated dispensing cabinet (ADC)] listed 40 mg/10 mL as stock, but bin stocked with 20 mg ampules. Etomidate has been on national shortage / backorder. Supply has been sporadic, the incorrect size was placed in [ADC] so that floor would not be without medication. [ADC] has since been changed to match the size currently available.

Patient was ordered D50 [dextrose 50%]. When accessing [ADC], D50 was listed as out of stock. Another staff member reported that she used the last one two days ago. Dose was obtained from ICU [intensive care unit] (instead of accessing the crash cart).

[Leadership] indicated there was a nationwide shortage of D50; ER was unaware.

Nearly all reports (96.9%; n = 434 of 448) were submitted as medication errors, with a much smaller percentage (3.1%; n = 14 of 448) categorized as adverse drug reactions. The top event types selected by PA-PSRS reporters are listed in the Table, with the most frequently selected event types including "Medication error—other," "Medication error—dose omission," and "Medication error—prescription/refill delayed."

Table. Top 5 Most Common Event Types Reported by Healthcare Facilities (N = 448)

<table>
<thead>
<tr>
<th>EVENT TYPE</th>
<th>NO. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication error—other</td>
<td>120 (26.8)</td>
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</tbody>
</table>

Table generated by the Pennsylvania Patient Safety Reporting System.

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_DrugShortages.aspx
| Medication error—dose omission                  | 69 (15.4) |
| Medication error—prescription/refill delayed  | 51 (11.4) |
| Medication error—wrong dose/under dosage      | 35 (7.8)  |
| Medication error—wrong drug                    | 27 (6.0)  |

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018.

The number of reports submitted per year can be seen in Figure 2. The least number of reports in a calendar year (1.8%; n = 8 of 448) was submitted in 2006. The year with the greatest number of submitted reports was 2012 (16.5%; n = 74), with the most frequently cited medication shortage in 2012 involving the opioid analgesic nalbuphine (25.7%; n = 19 of 74). In 2017, the most commonly reported medication shortage involved morphine (13.4%; n = 9 of 67).

**Figure 2. Medication Related Events Due to Drug Shortages, by Quarter (N = 448)**

![Graph showing the number of reports by quarter from 2004 to 2018.](image)

**Note:** Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018.

A total of 173 unique drugs were reported to the Authority, which analysts subcategorized into 57 drug classes (Figure 3). The most commonly cited drug classes included analgesics, antibiotics, electrolyte supplements (e.g., potassium chloride, calcium chloride), and antidotes (e.g., reversal agents, rescue agents, rapid sequence intubation [RSI] medications).
Medications that pose an increased risk of patient harm when involved in medication errors, also known as high-alert medications, were involved in nearly one-half (46.2%; n = 207 of 448) of reports. The most common high-alert drug classes included opioid analgesics, injectable benzodiazepines, and parenteral electrolyte supplements (e.g., potassium chloride, sodium bicarbonate).

Analysts categorized each report into one of three nodes of the medication use system—prescribing, dispensing, or administering—then further categorized each report into node-specific event subtypes (Figure 4).

Figure 3. Top 10 Drug Classes Involved in Medication-Related Events Due to Drug Shortages (N = 448)

DRUG CLASS

- Analgesics*: 81 (18.1%)
- Antibiotics: 55 (12.3%)
- Electrolyte supplements*: 39 (8.7%)
- Antidotes*: 27 (6.0%)
- Benzodiazepines*: 19 (4.2%)
- Hormones: 15 (3.3%)
- Diuretics: 14 (3.1%)
- Anticoagulants*: 11 (2.5%)
- Total parenteral nutrition*: 11 (2.5%)
- Intravenous/irrigation fluids: 10 (2.2%)
- Vasopressors*: 10 (2.2%)

Note: Data reported through the Pennsylvania Patient Safety Reporting System. Events occurred from July 2004 through June 2018. Percentages in the table are based on N = 448. The number of events (n = 292 of 448) represented in the table correspond to the top 10 medication classes involved in drug shortage-related medication errors.

* Drug classes that may include high-alert medications.
Prescribing

There were 126 reports describing events that occurred during the prescribing node. The most common (44.4%; n = 56 of 126) event subtype related to the prescribing node was wrong drug or product selection. Delays in care may occur when a prescriber orders a drug that is unavailable because of a shortage and follow-up is required by the pharmacist or nurse to contact the prescriber and determine a suitable alternative. In addition, there are times when a prescriber attempts to order an appropriate alternative drug, but that alternative has not been entered into the electronic health record’s (EHR) drug library, leading to a delay in therapy. Following are examples of actual or potential therapy delays reported through PA-PSRS:

MD [medical doctor] ordered Bactrim™ [sulfamethoxazole and trimethoprim] 160 mg IV. Paged attending. IV form on national backorder. Attending verified resident meant to order PO [by mouth]. Resident changed order to PO form.

Patient had previously exhibited an acute oculogyric crisis after receiving Haldol™ [haloperidol]. This was an acute crisis that could have been life threatening. The Physician provided a verbal order to the charge RN [registered nurse] forCogentin® [benztropine mesylate] 2 mg IM STAT. RN contacted the pharmacy and was informed that the medication was on back order and was not available and recommended IM [intramuscular] Benadryl™ [diphenhydramine]. Physician attempted to order the medication through CPOE [computerized physician order entry] and Benadryl 50 mg IM PRN [as needed] was not an available option—so the physician wrote the order as a written order on the chart. IM Benadryl was not available in the [ADC]; however, one dose was located in [an ADC on another unit]. There was a delay in providing emergent care that was needed for the patient.

Other event subtypes in the prescribing node included errors occurring during therapeutic substitution (23.0%; n = 29 of 126), limitations on prescribed quantity or duration (15.1%; n = 19), wrong dose or concentration (13.5%; n = 17), and errors due to inaccurate order sets that were not updated with the alternative drug (4.0%; n = 5).

Following are examples of errors that occurred during therapeutic substitution:

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_DrugShortages.aspx
Chemo [chemotherapy] orders for patient written by MD, for [methotrexate], including pre and post hydration orders. Physician did not recognize that orders contained Sodium bicarbonate. This medication is on critical shortage and is being omitted from [methotrexate] bag; hydration is being replaced with sodium acetate. Physician did not closely look at orders before signing them.

Order for Niferex™ [iron polysaccharide] 220 mg TID [three times daily] written (660 mg Elemental Iron). Physician was thinking of Ferrous Sulfate Elixir 220 mg po TID (132 mg of Elemental Iron), liquid Niferex on backorder so pharmacist substituted Ferrous Sulfate Elixir.

Prescribers may also be unaware that the pharmacy department has set limitations on ordering drugs on shortage, such as limiting duration or quantity dispensed or requiring some form of approval by the prescriber before the medication can leave the pharmacy. Following are examples of events where the pharmacy placed restrictions on ordering drugs on shortage:

Order for bicarb [sodium bicarbonate] drip was rejected by overnight pharmacy staff citing reasons of "does not meet approval criteria." Drug had been on shortage (requiring approval), but has resolved recently since supply on-hand.

IV Fluid of D5/0.45% [dextrose 5% in 0.45% normal saline] w/KCl [potassium chloride] 20 mEq/L entered by RN as per protocol. Potassium level was 4.6. When I called RN to clarify if this IVF with K [intravenous fluid with potassium] was correct she said she was just re-ordering previous day's IVF because it had been discontinued. (IVF was d/c'd [discontinued] d/t [due to] 24 hr Duration as per IV shortage policy.)

**Dispensing**

There were 173 reports submitted describing events that occurred during the dispensing node. The most common event subtype related to dispensing was administration delay due to pharmacy's prior removal of a floor stock item from the ADC, medication cart, or drug box (35.8%; n = 62 of 173). Nearly one-half (43.5%; n = 27 of 62) of reports in this event subtype involved delayed procurement of antidotes or rescue agents, including those used in code situations. Following are example reports in which treatment with a rescue agent was delayed due to changes in dispensing:

Patient's blood glucose registered 18 [mg/dL] on glucometer. RN repeated test additional times to confirm blood glucose. Tried to get Dextrose 50% from [ADC], but none available. No Dextrose available in crash cart. Pharmacy sent 2 syringes. But medication currently restricted due to [manufacture] backorder.

DOPamine infusion [was empty]. Went to [ADC] to get med. Out of Stock. Called Pharmacy for DOPamine stat. Since med not immediately available in [ADC], DOPamine pulled from crash cart. Med arrived from Pharmacy [10 minutes later]. Pt experienced drop in [blood pressure] before rebounding when med resumed.

Other event subtypes in the dispensing node included significant delay in dispensing therapy due to pharmacy compounding workflow changes (30.1%; n = 52 of 173), wrong product dispensed or product mislabeled (21.4%; n = 37), incorrect or change in products stocked in ADC pocket (6.9%; n = 12), and intentional or unintentional stocking of expired product (5.8%; n = 10).

Additional examples of events that occurred within the dispensing node include the following:

The patient was ordered Valium® [diazepam], and there was a delay in pharmacy filling the medication [the ADC] with valium for [almost an hour]. The nurse spoke to pharmacy about the delay. It was discovered that the delay is due to a national shortage of diazepam that requires additional compounding in the pharmacy.

Patient with frequent episodes of bradycardia. Order received to keep external defibrillator and atropine at bedside. Pharmacy notified of need for Atropine. Dose provided noted to have expired. When Pharmacist notified, informed nurse that all they had was expired [because] medication is on back order.
Due to an ongoing nationwide drug shortage, the pharmacy has not been able to obtain the single dose vials or ampules of nalbuphine 10 mg/mL that we usually use and would prefer to use. Intermittently, larger 10 mL vials of nalbuphine became available. The pharmacy has been drawing from the 10 mL vial into smaller vials (1 mL doses) with limited dating. When the 10 mL vial first became available it was a concentration of 20 mg/mL, so it was necessary to dilute with normal saline to the 10 mg/mL we wanted. [At month's end] the clerk was able to get another box of 10 mL vials. The clerk did not remember that it was 20 mg/mL before and didn't specifically mention to anyone that the new one was 10 mg/mL. The pharmacists and techs continued to use the old formula with dilution, so it is likely that [over the next couple of weeks] vials labeled 10 mg/1 mL were only 5 mg/1 mL.

**Administering**

There were 149 error reports submitted describing events that occurred during the administration node. Actions during this node are typically performed by nurses and involve procuring the medication or administering it to the patient. The most common (36.2%; n = 54 of 149) event subtype was wrong dose administered due to unfamiliarity with concentration changes in pharmacy-specific compounded products or products from different manufacturers. The following are examples of wrong dose errors reported during administration:

- **Norepinephrine** 4 mg/250 mL premix in MAR [medication administration record]. Norepinephrine 8 mg/250 mL infusing. Found with bag change. During report double-concentrated because of shortage.

- Nurse did not look at the concentration of the med and patient received a total of 6 mg of HYDROmorphine instead of 3 mg as ordered. Contributing factors: HYDROmorphine shortage results in different concentrations being placed in [ADC]. Warning in [ADC] was not read carefully by nurse [because] dose ordered was 0.5 mg and our usual concentration has been 1 mg vials.

- MD ordered Lasix™ [furosemide] 40 mg IV for an ED [emergency department] patient. RN prepared medication from dispensing system from 40 mg selection. RN thought they were 20 mg vials due to prior shortage of 40 mg vials. RN [administered] 2 vials that were 40 mg. Patient without any issues or side effects.

Other event subtypes included skipped or missed doses while waiting for future drug shipments to arrive (31.5%; n = 47 of 149), improvised and unsafe compounding practices (14.1%; n = 21), administration of the wrong drug (10.7%; n = 16), and administration of incomplete therapy (7.4%; n = 11).

Additional examples of errors during the administration node include the following:

- Pharmacist called unit to report that patient had an RN [on a previous day] who documented liquid multivitamin given. Pharmacist stated that this medication was falsely documented given because the medication has not been available in the hospital for weeks due to being on backorder.

- Pt. had D5 NSS [dextrose 5% in normal saline solution] maintenance fluids running instead of D5 LR [dextrose 5% in lactated Ringer solution] infusing. Noted at change of shift during report. Nightshift RN stated physician wanted D5NSS ordered, however due to hospital shortage of this fluid did not order. However, D5NSS was hung and infusing when order in computer has D5LR. Maintenance fluid bag of D5NSS was not scanned. Dayshift RN upon assuming care of pt. scanned and hung D5LR per order.

- IVIG [intravenous immune globulin] therapy with recommendation for IVIG 50 grams IV. Pharmacy was able to provide only 35 grams due to national shortage. Physician was notified.

* The details of the PA-PSRS event narratives in this article have been contextually deidentified to preserve confidentiality.

**Discussion**

http://patientsafety.pa.gov/ADVISORIES/Pages/201903_DrugShortages.aspx
Nearly three-quarters of reports concerning drug shortages involved events that reached the patient. Three nodes of the medication use system (i.e., prescribing, dispensing, administering) are equally affected by drug shortages, with the number of submitted error reports similar among all three.

From July 2004 through June 2018, the number of reports submitted through PA-PSRS involving drug shortages has increased, with 2012 including the greatest number. FDA, in a 2012 report, referred to that period as the "height of the shortage crisis," because shortages tracked by the agency quadrupled from 61 in 2005 to more than 250 by 2011. Actions taken by FDA and other stakeholders in the years since 2012 have led to a reduction in the number of new tracked shortages each year, with 26 announced in 2016. Unfortunately, the number of new shortages increased again in 2017 after a devastating hurricane season and because, at the same time, a major manufacturer closed certain operations for remediation and upgrade. The overall trend indicates that the crisis has continued despite fluctuations from year to year, including a recent increase in number of active shortages.

The list of medications involved in drug shortage reports submitted to the Authority is lengthy and diverse. Analgesics were most commonly involved in drug shortage–related errors, along with antibiotics, electrolyte replacements, and antidotes (e.g., reversal agents, rescue agents, RSI medications). Several reports showed nurses struggling to procure dextrose 50% to treat patients with severe hypoglycemia. It is unclear from the reporting details whether any of these patients were currently on insulin therapy. One report described a patient with a severe dystonic reaction to an antipsychotic medication, for which access to appropriate anticholinergic therapy was delayed. Hospital providers routinely treat patients who have acute, urgent conditions such as these for which therapy cannot be delayed, often scrambling for limited or risky options.

Other product shortages affected patient care in more subtle ways. The high number of reports of vitamin shortages mainly affected appropriate and safe therapy with parenteral nutrition (PN) admixtures. Pharmacists were often forced to omit vitamin and electrolyte replacements from PN compounds for both adult and pediatric patients. In 2013, ISMP survey data also found that shortages of PN components caused a wide range of patient harm, including deficiencies in serum electrolytes, increased risk of precipitate when substituting calcium chloride for calcium gluconate, and increased burden of cost from imported PN components.

There is increased risk of errors when a prescriber must change his or her practice to include use of less-familiar alternative medications, especially those that may be less efficacious, have less desirable adverse effect profiles, or require unusual or more involved (e.g., more frequent administration) dosing regimens. Selection of alternative therapies is time consuming and often results in delayed therapy.

In addition, therapeutic substitutions may be written into institutional policies and involve auto-conversion of a shortage drug to a predefined alternative. In some situations, the substitution may be done automatically by the EHR software. However, in other situations, the substitution requires order discontinuation and re-entry by another provider, typically the pharmacist. Human error can easily be introduced at this step. Another potential risk is that providers may be unaware of, or disagree with, automatic therapeutic substitutions currently approved at their facility.

Risk of medication errors increases when a pharmacy must alter standard dispensing practices and change the standard, protocol-based ways a medication is prepared, labeled, distributed, and stored. Shortages of both small- and large-volume parenteral base solutions have forced pharmacies to prepare drugs in nonstandard concentrations, leading to downstream issues with administration of many medications. To conserve use of small-volume parenteral products, many pharmacies have dispensed IV antibiotics in IV push form, so the high number of reports detailing errors with antibiotics was expected. Other errors were due to fluid shortages involving delivery of chemotherapy agents, a class of high alert medications, and investigational drugs.
In shortage situations, pharmacies may alter medication storage practices by stocking alternative products in ADCs or by completely removing items from ADCs that nurses are accustomed to easily locating. Changes in ADC stocking, especially in short-term situations without prior notice, can stress nurses. Frequent alterations in the concentration or formulation of products may cause additional confusion as providers and nurses try to keep track of the modifications.

For example, a nurse may become accustomed to the use of furosemide 20 mg vials in place of furosemide 40 mg vials after a prolonged shortage of the latter. When the furosemide 40 mg vials become available again and are stocked in the ADC, the nurse may not notice the change in concentration, as observed in the error example included above.

In response to shortages, hospitals have relied more heavily on 503A and 503B compounders to supply prefilled syringes. Unfortunately, these compounders may deviate from USP <7> labeling standards, with little FDA labeling oversight.17 As a result, nurses, as well as pharmacists and prescribers, contend with confusing dose expressions and look-alike labeling on prefilled syringes, which have resulted in wrong drug errors and 10-fold opioid overdoses.17,18

A common theme across ISMP surveys on drug shortages has been increased interdisciplinary tension and frustration among pharmacy staff and other providers.17 As one respondent commented in 2001: "There [are] always hard feelings between pharmacy and physicians when they must change their practices because we can't get a drug. Nurses feel caught in the middle and are upset about using alternative drugs with which they are unfamiliar." Analysts identified similar sentiments in the PA-PSRS data. Reporting expressed misdirected frustration with colleagues, such as "demanding tone" used by providers requesting shortage medications from pharmacy. Pharmacy personnel, in turn, may have added stress from extrinsic factors that interfere with their responsiveness to the routine medication supply and demand in the hospital.

**Limitations**

Analysis by the Authority of events involving drug shortages is limited by the information submitted through PA-PSRS by reporting facilities. Error reporting programs in general are limited by the quantity and quality of reports, which are highly dependent on the complexity of the reporting system as well as the ability of each reporting facility to identify events and submit complete and accurate information. Although the narrative fields of the reports help analysts discern what happened during the event, they often do not contain details describing how the event deviated from the standard operation or which factors contributed to the event.

**Risk Reduction Strategies**

Providers are acclimated to the clinical troubleshooting required to work around drug shortages, in part because these deficiencies have persisted for many years.8 It may be best for clinicians to stop accepting drug shortages as standard practice because they are, in fact, public health crises. Hospitals can do little to prevent drug shortages, which is why institutions should employ emergency-management methods and disaster-response tools to manage their occurrence.19 This includes robust medication error reporting during shortages to identify risks associated with drug shortages.8 A collaborative and structured approach is essential; ISMP survey data indicate that less tension among healthcare providers during shortages was more likely when establishments had a formal process in place for handling them.3

Consider the strategies described below, which are based on a review of current literature, events submitted to the Authority, and observations from ISMP:
• Develop an ongoing strategy to prepare for drug shortages, standardize how shortages are approached, communicate to stakeholders updates on shortages (as well as changes in practice as a result of shortages), and monitor interventions that are implemented (i.e., choosing an alternative drug).  

• Establish the infrastructure necessary to manage drug shortages. Depending upon the size and nature of the institution, this may include forming an interdisciplinary drug shortage team and resource allocation committee. 

• Form a proactive process for approving alternative therapies in anticipation of potential drug shortages. This may include use of failure mode and effects analysis (FMEA) to identify changes necessary to implement the alternative and associated risks. 

• Exercise caution when purchasing and employing imported items or products supplied by 503A and 503B compounders. Labelling practices may deviate from USP standards and introduce additional risk of misinterpretation by providers. 

• Employ multiple communication methods to keep affected healthcare providers informed of the status of drug shortages in a timely manner. For example, communication through the EHR may be used to alert clinicians of a shortage situation at the point of prescribing and to suggest a therapeutic alternative. 

• Outline steps necessary to address ethical considerations that may arise because of drug shortages. 

• Remain transparent by disclosing relevant information regarding drug shortages to patients as well as current mitigation strategies being used to improve patient safety in these circumstances. 

• Use data and information from event reporting systems, federal agencies, professional organizations, focus group meetings, discussions during hospital rounds, and other means to learn about hazardous conditions, good catches, and other events associated with drug shortages so that actions can be taken to proactively mitigate future risks. 

A sample drug shortage checklist that is intended to identify options and risk reduction strategies that may be helpful when a facility anticipates or is faced with a drug shortage can be found here: http://patientsafety.pa.gov/pst/Pages/Drug_Shortages/checklist.aspx.

Conclusion

This analysis of reports submitted to the Authority found that errors and hazards related to drug shortages are nearly equally distributed among the prescribing, dispensing, and administering nodes of medication use. Over the span of the first 14 years of reporting medication errors to the Authority, reports concerning drug shortages submitted were sparse, indicating potential underreporting in this topic of concern. In an extensive list of medications reported, the most common medication shortages across the years have involved opioids, antibiotics, electrolytes, and antidotes (reversal and rescue agents). Nearly three-quarters of these events reached the patient.

Risk reduction strategies may include both an evaluation of how shortages affect each node and employment of emergency-management methods and disaster-response tools. Organizations can use this information, along with the revised Drug Shortage Assessment Checklist, to assess safety gaps in their current processes to minimize risk to patients and design systems to prevent similar errors from occurring in this ongoing public health crisis.
Notes


