The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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Drug Shortages and Medication Safety Concerns

Across Canada, healthcare organizations and practitioners are struggling to cope with a new wave of drug shortages resulting from cuts in production at the Sandoz Canada plant in Boucherville, Quebec. Although drug shortages have become an ongoing global issue, the nature and extent of the current Canadian shortages are creating concerns. For many of the affected products, the options for alternative sources may be limited. Healthcare leaders and patient advocates have spoken out in the media about the possible impact on the quality and efficiency of patient care,[1-5] but the possibility of harmful medication errors arising from drug shortages may be less well recognized. A wealth of useful information, designed to assist hospitals and individual practitioners in coping with the shortages, has already been provided by professional organizations, licensing bodies, group purchasing organizations, and various levels of government. This Safety Bulletin does not attempt to duplicate information available through these sources but instead reviews the medication safety concerns associated with drug shortages and outlines preliminary recommendations and strategies to reduce the likelihood of harmful errors. Lists of additional resources and references are provided at the conclusion of this bulletin.

A recent survey conducted in the United States by the Institute for Safe Medication Practices (ISMP) revealed an association between drug shortages and harmful medication errors. In reporting on the survey results, ISMP noted that "Approximately one in three (35%) respondents reported that their facility had experienced a near miss during the past year due to a drug shortage. About one in four reported actual errors and one in five reported adverse patient outcomes during the past year due to drug shortages."[6] ISMP Canada has received calls from concerned practitioners with questions about the safety of specific conservation measures.

Various factors and circumstances have the potential to increase the risk of harmful medication incidents during drug shortages. In the following text, examples of safety concerns are presented in bold, followed by specific recommendations to reduce the likelihood of harmful errors.

When drug shortages occur without adequate advance warning, healthcare facilities may not have sufficient time to develop plans, identify therapeutic alternatives, and implement necessary safety measures. The need for a rapid response may also create challenges in establishing effective communication with staff and patients.

Recommendations

- Actively monitor for impending drug shortages, and develop action plans as far in advance as possible. For information on websites with public information about drug shortages in Canada, visit the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/shortage-rupture-eng.php).
- Assign responsibility for monitoring and managing drug shortages.[7] In particular, identify the team members who will be responsible for monitoring drug shortages; for communicating with suppliers, staff, and patients about shortages; for assessing the clinical and operational impacts of shortages; and for recommending potential solutions.
- Consult with front-line staff and clinicians before implementing changes that will affect practice. Ensure that pharmacists and other appropriate clinicians are involved in assessing clinical concerns and in developing strategies to reduce the impacts of the drug shortage on patient care.[8]
- Provide dedicated resources and a standard process for establishing guidelines for appropriate use of drugs that are in short supply and for identifying and approving therapeutic alternatives.[8] Clear guidelines can help to avoid inappropriate use and can support front-line practitioners in providing effective management of drug supplies.
- Conduct sustained and effective communication to ensure that healthcare practitioners are kept informed of changes. Consider providing information about the following aspects of the shortage:[8]
  - information about drugs that are in short supply, including their current availability and the anticipated duration of the shortage
  - guidelines or restrictions for use of products that are in short supply
  - information about recommended alternatives, including dosing, preparation, administration, and monitoring
  - potential for error with alternative agents and any additional steps required to enhance safety
- Ensure that patients and families receive relevant information about the impact of drug shortages on therapy. Keeping patients informed of changes to their

medications is essential to support their role in preventing harm from medication incidents.
- Carefully weigh the benefits and risks of strategies to reduce drug wastage. As much as possible, maintain standard policies and procedures during times of drug shortages.
- Communicate and collaborate with other practitioners and organizations when identifying and developing solutions. For example, members of the Canadian Society of Hospital Pharmacists have access to information and updates through an eForum on drug shortages.

The necessity of using alternative medications (or alternative concentrations, strengths or dosage forms of the same medication) may introduce additional complexity and opportunities for error into the processes of prescribing, preparing, administering, and monitoring medications. Standardization of products and concentrations may become difficult or impossible when the supply of drug products is unreliable. Healthcare organizations may have to temporarily abandon previously implemented standardization initiatives. Practitioners may be more prone to make errors when available products, concentrations, or dosage forms are unfamiliar. Of particular concern is the fact that current shortages are affecting high-alert drugs such as opioids, which are frequently reported as causing harm as a consequence of medication error. Substituting an opioid of a different strength or potency for an opioid that is in short supply may create opportunities for dangerous dosing errors.

Recommendations
- To the extent possible, have the pharmacy provide medications to care areas in patient-specific unit-dose or unit-of-use formats.[8]
- Avoid relying on front-line practitioners to make calculations and adjustments during drug preparation.
- When assessing pharmacy priorities for admixture and repackaging of medications during times of drug shortages, place a high priority on admixture or repackaging of high-alert and critically needed agents.
- To the extent possible, maintain standard concentrations of products.
- Whenever alternative medications or alternative concentrations or dosage forms of existing medications must be used, consider whether measures such as additional warnings or alerts, independent double checks, product segregation, staff training, or special patient monitoring are needed to reduce the risk of harmful medication incidents.[8] Such measures are of particular importance when drug shortages necessitate changes to the available selection, concentration, or dosage form of high-alert agents.
- Verify that each replacement product has the same characteristics and approved route(s) of administration as the item in short supply. If differences are noted, confirm that your practice is appropriate for the new product, and consider whether additional preparation or auxiliary labelling by the pharmacy is required.

Pressure to conserve drugs that are in short supply may lead to unsafe strategies and practices. For example, well-intentioned staff members may circumvent established policies and procedures in an effort to reduce wastage, or organizations may implement interim adjustments to policies and procedures as conservation measures, without a full appreciation of the impact on safety.

Recommendations
- Establish clear directives to ensure that efforts to reduce wastage do not compromise safety. Stress that hoarding products or having staff prepare doses in advance in patient care areas is to be avoided. If a product is to be divided into multiple doses to avoid waste, this repackaging should ideally be performed in the pharmacy. If circumstances require that a product be divided in a patient care area, at a minimum ensure that independent double checks are used, that individual doses are appropriately labelled and used only within the care area where they are prepared, and that handling of doses remains consistent with safe practices. It is important to keep in mind that products intended for single use may not contain preservatives or stabilizers and should not be stored for extended periods after being opened or prepared for administration. Additional information about product preparation, stability, and handling may need to be provided with dispensed doses.
- Maximize the use of conservation strategies that may lower the potential for harmful errors, such as using oral medications rather than parenteral medications if appropriate.

Selected alternative medications, concentrations, and dosage forms may not be covered by the hospital's usual systems, services, and resources. For example, nonformulary agents may not be included in parenteral therapy manuals, in the clinical decision support tools of computerized prescriber order entry systems and pharmacy information systems, or in smart pump libraries.

Recommendation
- Establish a protocol to ensure that temporary changes to hospital formularies and drug inventories are supported by appropriate modifications to drug information resources, information systems, and other technologies.[7,8] This would include, for example, order sets and dose range checks in pharmacy and prescriber order entry systems, product selection options in automated dispensing cabinets, smart pump drug libraries, bar code verification systems, and drug

monographs in parenteral therapy manuals. Ensure that the accuracy of all adjustments is verified, keeping in mind that a single error in the set-up of technological tools has the potential to affect multiple patients.

Acquisition or preparation of alternative products may introduce new look-alike/sound-alike hazards. Labels prepared during in-house packaging and repackaging may not provide the same level of differentiation as the labels of commercially prepared products.

Recommendation

- Be on the alert for the introduction of new look-alike/sound-alike hazards. Be particularly aware of factors that may increase the likelihood of substitution errors when commercially manufactured products are replaced by products that have been packaged or repackaged in house. Consider differentiation and segregation strategies, such as use of TALLman lettering,[9-12] highlighting of dose designations, use of warning labels, or storing of unique products in individual bins.

There is a significant potential for errors if facilities attempt to compound preparations from raw materials without adequate expertise, facilities, equipment, staffing, and other resources.

Recommendation

- Avoid extemporaneous compounding of products unless the necessary expertise, facilities, equipment, staffing, and other resources are in place to ensure the quality and accuracy of the finished product. ISMP (US) has reported the occurrence of fatal errors when products in short supply have been compounded extemporaneously from raw materials.[13]

Management of drug shortages and use of alternative agents can generate additional workload for staff. This additional workload has the potential to increase stress levels, fatigue, and mental distraction.

Recommendation

- Ensure that adequate resources are in place to address workload increases associated with drug shortages. It may be necessary to increase casual staff hours, reallocate staff, or reprioritize the activities of existing staff.

Additional opportunities for error may arise once the shortage of a product is resolved and facilities revert to previously stocked agents.

Recommendation

- As previously stocked agents become available after a shortage, consider applying safety measures similar to those used when alternative agents were introduced.

Additional Recommendations

- Integrate consideration of the impact of drug shortages into existing medication safety initiatives such as medication reconciliation.
- If circumstances during drug shortages require that a patient's own medications be used during a hospital stay, ensure that appropriate safety processes are in place, such as confirming the identity and integrity of each product.
- Monitor and report medication incidents and other adverse events associated with drug shortages.[8]

Conclusions

This bulletin is not intended to provide a comprehensive summary of all strategies to mitigate the risks associated with drug shortages. The reader is reminded that maintaining the safety of the medication-use system remains at the core of safe practice at all times. Nonetheless, it is hoped that the information presented here will form a starting point for dialogue and collaboration within and among organizations and institutions affected by current drug shortages.

ISMP Canada encourages you to contribute to the development of recommendations to reduce the risk of harmful medication incidents. We welcome your reports of medication incidents associated with drug shortages (including reports of hazardous situations, near misses, safe practice compromises resulting from drug shortages, and any unintended consequences of efforts to mitigate shortages) at https://www.ismp-canada.org/err_ipr.htm or by telephone at 1-866-54-ISMPC (1-866-544-7672).

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Additional Resources

- American Society of Health-System Pharmacists. Drug Shortage Resource Center. Bethesda (MD): The Society; 2012 [cited 2012 Mar 12]. Available from: http://www.ashp.org/DrugShortages
- Canadian Pharmacists Association. Drug shortages: a guide for assessment and patient management. Ottawa (ON): The Association; 2010 [cited 2012 Mar 12]. Available from: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf
- Saskatchewan Drug Information Services. Drug shortages. Saskatoon (SK): University of Saskatchewan; 2008 [cited 2012 Mar 12]. Available from: http://druginfo.usask.ca/healthcare_professional/drug_shortages.php
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- US Food and Drug Administration. Drug shortages. Silver Spring (MD): The Administration; [updated 2012 Feb 21; cited 2012 Mar 18]. Available from http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:

(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System