Drug shortage and patient safety

By Marvin, Ng, Jim Kong, and Certina Ho

Drug shortage has been an ongoing issue and has been described in various literature as a challenge common to both hospital and retail pharmacy settings today. For the purpose of this article, “drug shortage” is defined as any shortage of a prescription medication in a pharmacy’s inventory. The causes of drug shortages are rarely due to any one singular outstanding factor, but rather a combination of several causes.

Drug shortage issues can be broadly interpreted from a supply and demand perspective. Drug supply issues can include: the drug not being available due to manufacturing problems, availability of raw ingredients, safety concerns, and discontinuation of products, etc. Conversely, the demand for drugs may shift drastically due to poor pharmacy inventory management, disease outbreaks, or a shift in prescribing practice, etc.

The consequences of drug shortages often lead to negative effects in the patient care continuum across various settings. The most common consequences include:

- Delay in treatment
- Discontinuation of treatment
- Receiving a less effective drug or formulation
- Extra time required to locate alternative drug by pharmacy staff
- Increased cost of alternative drug to the pharmacy department
- Patient safety-related issues in the acute care setting have been described in several reports. However, these issues may not apply to the community pharmacy setting and hence, the impetus for this multi-institutional analysis.

Medication incidents associated with drug shortages were collected from the Community Pharmacy Incident Reporting (CPhIR) Program and analyzed by medication safety analysts from ISMP Canada. Two major themes were identified from this analysis, which are further subdivided into subthemes as seen in Table 1.

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<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
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<tr>
<td>Deviation from the Intent of the Original Prescription</td>
<td>Risk of overdose</td>
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<td></td>
<td>Risk of under-dose</td>
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<td></td>
<td>Incorrect drug</td>
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<td>Patient confusion and misunderstanding</td>
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<td>Near Misses</td>
<td>Association error</td>
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<td>Incorrect brand selected</td>
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<td>Incorrect strength</td>
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<td>Patient confusion and misunderstanding</td>
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Deviation from the Intent of the Original Prescription - Modifying a prescription due to drug shortages is a common practice, but is often a multi-step process utilizing relatively complex calculations to attain an equivalent efficacious dose. All staff members should apply independent double checks to the order entry and dispensing processes in order to ensure patient safety.

Near Misses - These are medication incidents that could have caused harm to the patient, but were prevented or intercepted in time by the pharmacist, the pharmacy staff, or the patient. Most of these reported incidents stated that the patient often misunderstood the changes to their medication due to drug shortage. If left unresolved, these incidents could potentially lead to negative outcomes such as non-compliance and/or incorrect use of the medication.

ISMP Canada recommends the following to mitigate drug-shortage associated medication incidents:

1. Independent double checks should be implemented in the pharmacy workflow. Having a dialogue with the patient when the medication is being picked up may also serve as an independent double check to ensure that the right medication is being dispensed to the right patient.

2. Thoroughly counsel the patient on the identity of the altered medication, the appropriate directions for use, etc. will help to avoid any misunderstandings and inappropriate use of the medication.

3. Follow-up or monitoring is important in dealing with issues of drug shortages, especially in cases where an alternate brand of the medication has been dispensed. Some patients may be sensitive to brand changes and respond differently (better or worse) compared to the previous brand they were taking for their condition.

The incidents gathered from this multi-institutional analysis have reinforced the negative impacts that drug shortages can have on patient safety. Drug shortages continue to be an inevitable issue that many pharmacists, patients, and health care providers must face on a regular basis, but actions can be taken to prevent the likelihood of negative outcomes.

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Examples of Canadian Resources for Handling Drug Shortages
The following is a list of Canadian resources that may be helpful for pharmacies with respect to handling drug shortages.

Canadian Drug Shortage Database
- http://www.drugshortages.ca

Drug Shortages: A Guide for Assessment and Patient Management (Canadian Pharmacists Association [CPhA], 2013)
- http://www.pharmacists.ca

Drug Shortages (Canadian Society of Hospital Pharmacists [CShP])
- http://www.cshp.ca

Drug Shortages (University of Saskatchewan medSask)
- http://medsask.usask.ca

Drug Shortages and Medication Safety Concerns (ISMP Canada)
- http://www.ismp-canada.org