Drug Shortages and Patient Safety

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Objectives

- The issue of drug shortages is one that presents a significant challenge to pharmacists in both hospital and retail pharmacy settings today. Several reports have published the myriad of issues that drug shortages have posed to patient safety in acute care settings. However, the same may not apply to community pharmacy setting; and hence, the impetus for this study.
- This study shares information about medication incidents involving drug shortages voluntarily reported to the ISMP Canada's Community Pharmacy Incident Reporting (CPhIR) Program (www.cphir.ca) and highlights the common themes identified through a multi-incident analysis.
- Specific examples of reported incidents are provided to develop system-based improvements that can be customized to pharmacy practice setting.

Methods

- Reports of medication incidents involving "Drug Shortage" were extracted from the CPhIR Program from November 2010 to June 2012.
- 75 incidents were retrieved and 62 of them met inclusion criteria and were included in this qualitative, multi-incident analysis.
- The 62 medication incidents were independently reviewed by two ISMP Canada Analysts.

Results

- The outcome of the majority of the incidents were reported as "no error" (i.e. near misses), meaning that an error was made, but it was intercepted or corrected before the medication was dispensed to the patient.
- The 62 medication incidents were categorized into two main themes (Table 1):
  1. Deviation from the intent of the original prescription; and
  2. Near misses.
- The two main themes were further divided into subthemes (Table 2 and Table 3).

TABLE 1. Main Themes and Subthemes from the Multi-Incident Analysis

Deviation from the Intent of the Original Prescription	Near Misses
Risk of Overdose	Patient Confusion & Misunderstanding
Risk of Under-dose	Association Error
Incorrect Drug	Incorrect Brand Selected
Patient Confusion & Misunderstanding	Incorrect Strength

TABLE 2. Theme 1 – Deviation from the Intent of the Original Prescription

Subtheme	Incident Examples
Risk of Overdose	*A prescription called for acebutolol 200 mg tablets. At the time of dispensing, the pharmacy had insufficient quantities of acebutolol from one manufacturer so the prescription was filled using two different brands of acebutolol from two different manufacturers in separate vials to make up the final quantity. However, the patient began taking tablets from both vials at the same time and took double the dose of acebutolol, which continued for approximately a month.* *Since there was a shortage of Avalide® (irbesartan and hydrochlorothiazide) 150/12.5 mg tablets, the pharmacy team dispensed irbesartan and hydrochlorothiazide separately. However, hydrochlorothiazide was dispensed as 25 mg tablets instead of 12.5 mg. The pharmacist discovered this the next time the patient was in the pharmacy asking questions.*
Risk of Under-dose	*In looking for another brand of atorvastatin to cover for a shortage, a different brand of atorvastatin was chosen, but at a lower strength than the original. The patient had been taking 20 mg, but it was filled as 10 mg tablets.* *[Drug unknown] A physician called to refill a medication and was reviewing the doses with the pharmacist on duty. It was discovered that while switching between brands due to a shortage of one brand of the medication, that the strength of the capsule was inadvertently switched from 100 mg to 25 mg, resulting in a total decreased dose from 200 mg to 50 mg. The patient suffered decreased control of her mental state.*
Incorrect Drug	*Patient was prescribed Amiloride 5 mg, but Amiloride/Hydrochlorothiazide 5/50 mg was dispensed instead. The drug dispensed was a combination drug, which included the right drug he was used to get, but had an additional fluid pill in it.*
Patient Confusion & Misunderstanding	*A patient presented with a prescription for carbamazepine 200 mg and asked for it to be logged (i.e. put on hold). However, there was a shortage of the medication and the CR (controlled-release) formulation (i.e. not the regular strength) was selected. The logged prescription was subsequently filled as the CR formulation. The patient had inquired as to why the tablets looked different.* *A prescription vial was labeled as Endocet®, but the Apo brand of the therapeutic equivalent was dispensed. This was discovered by the patient, since the tablets appeared smaller than usual.*

TABLE 3. Theme 2 – Near Misses

Subtheme	Incident Examples
Patient Confusion & Misunderstanding	*A patient presented to the pharmacy after having a one-off fill of Tri-Cyclen® 21 at another pharmacy due to a shortage at that pharmacy of the 28-day pack. The patient was going to forego the last seven days of the 21-day pack thinking it was the same as the last seven days of the 28-day pack. She returned to taking the 28-day pack but was advised to finish the last seven days of the 21-day pack first.* *A pharmacy normally had Ventolin® in stock, but since it was backordered, Apo®-Salvent was ordered instead. The inhalers look different between the two brands, and the patient was not informed of the brand change. The patient went home and was worried that he/she received the wrong medication.*
Association Error	*Commercially available [oral] solution (Teva-Ranitidine) was backordered from the manufacturer. An alternative was compounded for the patient, but it was a different, lower-strength [product]. When changing the prescription over, the directions/quantity was not updated to reflect taking more of the new, lower-strength product, and the label was not updated.* *There was a shortage of Citalopram 10 mg and we had to switch to the 20 mg strength. We copied the prescription but forgot to change the directions to reflect the new dose.* *Betahistine 16 mg was backordered, and a patient at the pharmacy was taking 1 tablet BID (twice daily). We called the doctor and he changed the prescription to Betahistine 24 mg 1/2 tablet BID. When the 16 mg was available again, we notified the doctor, who changed the prescription back to one 16 mg tablet BID, but the unit dose on the patient's compliance label did not get changed; a pharmacy staff member left it as 1/2 tablet BID in the pill-packs.* *A drug shortage forced pharmacy staff to use a different brand of Apo®-Amilzide, and was therefore switched to Novamilor. When Apo®-Amilzide became available again, the plan was to switch back to the original Apo®-Amilzide, however a staff member chose [Midamor®] instead of Apo®-Amilzide. The patient noticed the yellow color of the tablets when picking up her prescription, saying that she had never been on yellow tabs – pharmacy staff checked file and noticed the error.*
Incorrect Brand Selected	*A prescription for warfarin was filled with the wrong generic brand since it was backordered, but the error was found upon checking the prescription and corrected before dispensing.* *The incorrect generic for methylprednisolone 40 mg/ml was chosen off shelf as the generic brand that is normally carried in the pharmacy for this medication was backordered.*
Incorrect Strength	*There was a manufacturer shortage of Levodopa-Carbidopa 100/10 mg. As a result, the brand of this medication was changed, and in doing so, the 100/25 mg strength was selected by mistake.* *While switching between manufacturers due to a shortage, brand name Gliclazide MR 30 mg was chosen instead of the regular Gliclazide 80 mg. The error was picked up while checking.*

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Conclusions

- Two major points in the management of drug shortages have been illustrated:
  1. It is important to perform independent double checks during the order entry and dispensing process when making alternative arrangements for a prescription;
  2. There is the need for patients to understand the identity and use of the altered medication through prescription counseling, monitoring, and follow-up.
- Although drug shortages continue to be an inevitable issue that many pharmacists, patients, and healthcare providers must face on a regular basis, actions can be taken to mitigate and prevent the likelihood of negative outcomes from occurring. Such actions include identifying which medications are likely to be unavailable or in limited supply (where possible), assessing the utilization of these medications in the pharmacy, preparing for a possible shortage of these medications, communication among staff members of drug shortages, as well as education on policies and procedures for potential problems that may be encountered when dealing with certain drug shortage situations.

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