

Stepping into the Shoes of Community Pharmacists – Drug Shortage and Patient Safety

A MULTI-INCIDENT ANALYSIS BY ISMP CANADA

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INTRODUCTION

Since Avalide® (irbesartan and hydrochlorothiazide) 150/12.5 mg was backordered; the patient was given the 300/25 mg strength and was told to take $\frac{1}{2}$ of a tablet. However, the Avalide® 300/25 mg strength was on backorder as well and the regimen was changed to irbesartan 150 mg and hydrochlorothiazide 12.5 mg daily. The Avalide® 150/12.5 mg tablets became available again, and so the prescription was reversed, and the prescription was filled off or copied from the previous Avalide® 300/25 mg prescription. However, the directions were not changed from the $\frac{1}{2}$ tablet to a full tablet. During counseling, the patient was counseled properly on the directions for use by the pharmacist. When the patient went home, she discovered that the directions on the bottle did not match with what the pharmacist had said.

The above scenario is a classic example of a medication incident that is related to drug shortages. Drug shortages have been increasingly affecting pharmacy practice, often leading to adverse effects on patient care.¹ As such, the problem of ongoing drug shortages has been a source of frustration for pharmacists, patients, and prescribers.

The causes of drug shortages are multifactorial. For instance, the drug may not be available due to supply or manufacturing problems, safety concerns, and discontinuation of products, etc. It may also be attributed to an increase in demand, such as during disease outbreaks, or a shift in clinical or prescribing practice,

etc. Drug shortage is rarely owed to any one of the above listed contributing factors, but rather a combination of several causes.^{2,3}

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.⁴⁻⁶ However, the same may not apply to community pharmacy setting; and hence, the impetus for this multi-incident analysis.

The Community Pharmacy Incident Reporting (CPhIR) Program (available at <http://www.cphir.ca>) is designed for community pharmacies to report near misses or medication incidents to ISMP Canada for further analysis and dissemination of shared learning from incidents.⁷ CPhIR has allowed the collection of invaluable information to help identify system-based vulnerable areas in order to prevent medication incidents. This article provides an overview of a multi-incident analysis of drug-shortage-related incidents reported to the CPhIR program.

MULTI-INCIDENT ANALYSIS OF NEAR MISSES AND MEDICATION INCIDENTS RELATED TO DRUG SHORTAGES IN COMMUNITY PHARMACY PRACTICE

Reports of medication incidents involving “Drug Shortage” were extracted from the CPhIR Program from November 2010 to June 2012. In total, 75 incidents

were retrieved and 62 of them met inclusion criteria and were included in this qualitative, multi-incident analysis. 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 independently reviewed by two ISMP Canada Analysts. They were

analyzed and categorized into two major themes: (1) deviation from the intent of the original prescription and (2) near misses. The two major themes were further divided into subthemes, as shown in Table 1 and Table 2, respectively. (Note: The “Incident Examples” provided in Tables 1 and 2 were limited by what was inputted by pharmacy practitioners to the “Incident Description” field of the CPhIR program.) 

TABLE 1. THEME 1 – DEVIATION FROM THE INTENT OF THE ORIGINAL PRESCRIPTION

SUBTHEME	INCIDENT EXAMPLES	COMMENTARY
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.	In such cases where a certain brand of a medication is on backorder, it is best to dispense one brand of a medication (and create a balance owing, if necessary), rather than multiple brands at the same time, whenever possible. This would avoid confusion among pharmacy staff and to the patient. If this is not possible (e.g. the patient lives far away and/or pharmacy accessibility would be difficult), providing clear instructions for use and ensuring patient’s understanding is necessary before they leave the pharmacy.
	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.	When adapting or making alternative arrangements for a prescription during drug shortages, independent double checks should be performed for each prescription during the order entry and dispensing process. ⁸
	[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.	

continued

SUBTHEME	INCIDENT EXAMPLES	COMMENTARY
Patient Confusion & Misunderstanding	<p>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.</p>	<p>There are two opportunities where this incident should have been intercepted or caught during the checking process:</p> <ol style="list-style-type: none"> 1. When prescription was logged; and 2. When prescription was dispensed and checked against the original prescription. <p>Best practices would be for the pharmacist to ensure the accuracy and appropriateness of a prescription at the time it is logged and “sign off” accordingly.</p> <p>Independent double checks should be performed for each prescription during the order entry and dispensing process.⁸</p>
	<p>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.</p>	<p>Counseling patients on the identity of the altered medication (where applicable), the different or appropriate directions for use, etc. will help avoid misunderstanding and inappropriate use of the medication.</p> <p>Follow-up with patients or monitoring is important, especially in cases where an alternative brand or product was dispensed due to drug shortages.</p>

TABLE 2. THEME 2 – NEAR MISSES

SUBTHEME	INCIDENT EXAMPLES	COMMENTARY
Patient Confusion & Misunderstanding	<p>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.</p> <p>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.</p>	<p>Counseling patients on the identity of the altered medication (where applicable), the different or appropriate directions for use, etc. will help avoid misunderstanding and inappropriate use of the medication.</p> <p>Follow-up with patients or monitoring is important, especially in cases where an alternative brand or product was dispensed due to drug shortages.</p>
Association Error	<p>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.</p> <p>There was a shortage of Citalopram 10mg and we had to switch to the 20mg strength. We copied the prescription but forgot to change the directions to reflect the new dose.</p> <p>Betahistine 16 mg was backordered, and a patient at the</p>	<p>When adapting or making alternative arrangements for a prescription during drug shortages, independent double checks should be performed for each prescription during the order entry and dispensing process.⁸</p> <p>The process of copying from previous prescriptions should be restricted or eliminated to prevent confirmation bias.</p>

SUBTHEME	INCIDENT EXAMPLES	COMMENTARY
	<p>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.</p> <p>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.</p>	
Incorrect Brand Selected	<p>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.</p>	<p>When adapting or making alternative arrangements for a prescription during drug shortages, independent double checks should be performed for each prescription during the order entry and dispensing process.⁸</p>
Incorrect Strength	<p>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.</p> <p>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.</p>	

PATIENT SAFETY KEY LEARNING POINTS

Although many of the incident reports related to drug shortages were near misses and did not lead to patient harm, a substantial number of cases did cause patient confusion and misunderstanding. If left unresolved, these could potentially lead to negative outcomes such as non-compliance and/or incorrect use of the medication.

Pharmacies should be encouraged to adopt a workflow that allows independent double checks to verify stages of order entry, dispensing, and monitoring in the medication-use process. 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 dispensed to the right patient.

It is important to recognize the need to communicate with patients when a drug shortage has affected their

medication regimen, especially when it involves altering the medication or prescription in some way. Counseling patients on the identity of the altered medication, the different or appropriate directions for use, etc. will help avoid misunderstanding and inappropriate use of the medication.

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

CONCLUSION

The incidents gathered from this multi-incident analysis have reinforced the negative impact that drug shortages can have on patient safety. 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.² The following is a list of Canadian resources that may be helpful for pharmacies with respect to handling drug shortages.

CANADIAN RESOURCES FOR HANDLING DRUG SHORTAGES

National drug shortages online reporting system

- <http://www.drugshortages.ca>

Drug Shortages: A Guide for Assessment and Patient Management (Canadian Pharmacists Association (CPhA))

- <http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf>

Drug Shortages (University of Saskatchewan medSask)

- <http://medsask.usask.ca/professional/drug-shortages/index.php>

FridayPM

- <http://www.fridaypm.ca>

Drug Shortages and Medication Safety Concerns (ISMP Canada)

- http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf

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