Medication Incidents Associated with Patient Harm in Community Pharmacy: A Multi-Incident Analysis

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BACKGROUND

Although pharmacy professionals and pharmacy organizations aim to provide error-free patient care, medication incidents are inevitable. Medication incidents are defined as any preventable events that may cause inappropriate medication use or patient harm while the medication is in the control of the healthcare professional or patient; these events occur when vulnerable medication-use systems and/or human factors affect prescribing, transcribing, dispensing, administration, and monitoring practices. [1,2]

Community pharmacies in Canada dispense over 600 million prescriptions annually, [3] but only a fraction of medication incidents will reach the patient and an even smaller proportion will result in harm. However, these incidents are associated with significant costs to patients and the healthcare system. In particular, they may lead to negative business implications for community pharmacies as a result of direct legal and financial costs, tarnished reputations, and decreased customer loyalty. On the other hand, these incidents often reveal broader system flaws, and thus, represent excellent opportunities for incident analysis and shared learning.

In an effort to identify and address factors that lead to harmful medication incidents, pharmacy organizations have developed and implemented incident reporting systems. At the local level, reporting systems are frequently an integral part of continuous quality improvement (CQI) programs, and as such,

are associated with long-term improvements in organizational learning and patient safety culture. [4] At the national level, reporting systems provide representative data for large-scale aggregate analysis, enabling healthcare stakeholders to better understand contributing factors that may have led to medication incidents, and aiding practitioners, pharmacies, and regulatory authorities in developing and sharing strategies to prevent recurrence. A multi-incident analysis is one form of aggregate analysis that is used to qualitatively analyze reported incident data to extract contributing factors and develop safety measures to prevent the incidents from re-occurring. By organizing and reviewing narrative incident data with common themes based on composition or origin, a multi-incident analysis can offer system-based learning that cannot be obtained through other analysis methodology.

The Institute for Safe Medication Practices Canada (ISMP Canada) established a national incident data repository for community pharmacies through its community pharmacy incident reporting (CPhIR) program. This article explores a multi-incident analysis conducted on harm-related medication incidents reported to CPhIR. The following sections contain an overview of the reported medication incidents and results from the analysis. Specific examples of reported incidents are also provided for reflection and to aid in developing strategies that can be customized to any practice setting. By systematically examining such incidents, root causes can be identified and process changes can be made to reduce the likelihood of similar errors from occurring again.

METHODS

A total of 971 medication incidents associated with patient harm were extracted from the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program (http://www.cphir.ca) from 2009 to 2017. Sixty-two incidents were excluded due to insufficient narrative incident description for analysis. A total of 909 incidents were included for the multi-incident analysis, which was conducted by two independent ISMP Canada analysts. Themes, sub-themes, contributing factors, and recommendations to address patient safety gaps corresponding to harm-related incidents were then derived from this analysis.

RESULTS

Three main themes were identified: (1) High Risk Processes in the Pharmacy; (2) Communication Gaps; and (3) Preventable Adverse Drug Reactions (Table 1). Subsequent sub-themes were then derived from these three main themes accordingly (Table 1). Incident examples, contributing factors and recommendations based on the hierarchy of effectiveness for CQI solution development (Figure 1) are also provided below (Tables 2, 3, and 4).

Table 1: Main Themes and Subthemes Derived from the Multi-Incident Analysis of Medication Incidents Associated with Patient Harm

Main Themes	Subthemes
High Risk Processes in the Pharmacy	Methadone Maintenance Therapy (MMT) Compliance Packs Compounding
Communication Gaps	Patient-Provider Engagement Interprofessional Collaboration
Preventable Adverse Drug Reactions	Drug-Drug Interaction Documented Drug Allergy

Figure 1: Designing Effective Recommendations Using the Hierarchy of Effectiveness

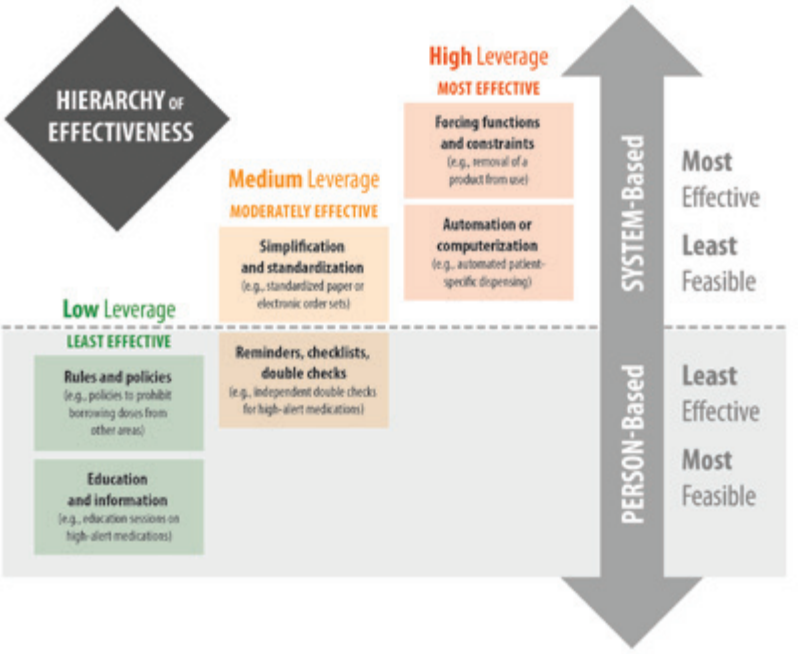

Table 2: Theme 1 – High Risk Processes in the Pharmacy

Methadone Maintenance Therapy		Recommendations	More Effective / Less Feasible
Incident Example	**Contributing Factors**	1. Implement barcode scanning to ensure correct selection of medication [5] [Automation and Computerization].	
A patient was mistakenly given another patient's dose of methadone. The dose given was significantly higher than the patient's normal dose. Both patients had similar names and the incident was discovered when the second patient arrived for his dose, but it could not be found.	• Pre-pouring of daily methadone doses. • Lack of a standardized process to verify patient identification.	2. Develop standardized procedures and documentation for high-risk processes [Simplification and Standardization].	
Compliance Packs		3. Perform independent double checks throughout all steps of a high-risk process [5,6,7] [Reminders, Checklists, Double Checks].	
Incident Example	**Contributing Factors**	4. Only designated staff members are allowed to perform high-risk processes [Rules and Policies].	
A patient was prescribed hydrochlorothiazide and her blister packs were repackaged to include the medication. When the following month's blister packs were made, hydrochlorothiazide was omitted. The patient experienced higher than normal blood pressure as a result.	• Change of drug regimens in the middle of a pack. • Lack of a standardized process for documentation of medication regimen changes. • Preparing of blister packs weeks in advance of pick-up.	5. Ensure designated staff members are adequately trained and equipped [7] [Education and Information].	
Compounding			
Incident Example	**Contributing Factors**		
A patient reported that the menthol and hydrocortisone cream compound she had received caused burning, which did not happen previously. The technician who prepared it did not get another staff member to double check the amount measured and initial for it. The compound was re-made and the patient reported no burning.	• Lack of standardized compounding process. • Inadequate training of personnel.		Less Effective / More Feasible

Table 3: Theme 2 – Communication Gaps

Patient-Provider Engagement		Recommendations	More Effective / Less Feasible
Incident Example	**Contributing Factors**	1. Implement Electronic Health Records and E-prescribing in pharmacy practice [Automation and Computerization].	
A patient experiencing cough was given a new prescription for valsartan to replace ramipril. The patient discontinued metoprolol instead of ramipril and brought the metoprolol back for destruction. The incident was discovered when the patient called for a refill of his ramipril.	• Complicated medication directions. • Inadequate verification of patient understanding.	2. Have standardized documentation for follow-up of problematic orders and hand off between health care professionals [8] [Simplification and Standardization].	
Interprofessional Collaboration		3. Use "show and tell" and "teach back" technique to ensure understanding during counselling [Reminders, Checklists, Double Checks].	
Incident Example	**Contributing Factors**	4. Require staff to offer medication reviews to eligible patients annually to identify drug therapy problems [9,10] [Rules and Policies].	
The nursing home contacted the pharmacy for a refill of a patient's prescription for Arthrotec® (diclofenac/ misoprostol). There was no record of Arthrotec® on the patient file, but there was a prescription for diclofenac. It was discovered that, in addition to receiving diclofenac, the patient was taking a sample of Arthrotec® that he received from the doctor.	• Limited sharing of medical information between providers. • Lack of an up-to-date medication list.	5. Encourage patients to carry an updated medication list when interacting with health care professionals [Education and information].	Less Effective / More Feasible

Table 4: Theme 3 – Preventable Adverse Drug Reactions

Drug-Drug Interaction		Recommendations	More Effective / Less Feasible
Incident Example	**Contributing Factors**	1. Clinical decision support systems (CDSS) for prescribers and pharmacists should have the functionality to detect drug-drug interactions/drug allergies and be updated regularly to prevent "alert fatigue". [11] [Automation and Computerization].	
A patient was started on lithium carbonate and was prescribed metronidazole 7 days later without cautioning about the interaction. The patient called the pharmacy reporting side effects consistent with lithium overdose.	• Knowledge deficit of the practitioner. • Too many insignificant alerts resulting in "alert fatigue".	2. Develop standardized procedures and documentation when a drug interaction or drug allergy is identified [Simplification and Standardization].	
Documented Drug Allergy		3. Double check allergy status at order entry and pick-up [Reminders, Checklists, and Double Checks].	
Incident Example	**Contributing Factors**	4. Require documentation when a drug interaction or allergy override occurs, and audit regularly (i.e. monthly) [11] [Rules and Policies].	
A patient complained of tight throat over several days. He/she went to emergency and was diagnosed with an allergic reaction to moxifloxacin. The pharmacist had missed the allergy caution when dispensing.	• Inadequate alert to indicate drug allergy. • Bypassing entry of allergy information. • Free-form entry of allergies.	5. Subscribe to a drug information service and post information on known dangerous drug interactions [Education and Information].	Less Effective / More Feasible

CONCLUSION

Medication incidents associated with patient harm present an opportunity for learning and improvement of the medication-use system in community pharmacy. This multi-incident analysis revealed that high risk processes, communication gaps, and preventable adverse drug reactions were the most common themes for reported medication incidents associated with patient harm.

When designing safety solutions using the hierarchy of effectiveness (Figure 1), we have provided different recommendations that can be implemented in your practice based on feasibility and effectiveness. In particular, implementing independent double checks is a feasible strategy for preventing incidents associated with high-risk processes. Furthermore, developing standardized communication and documentation is necessary to ensure safe and effective medication use within the circle of care. Finally, improving the effectiveness of clinical decision support systems utilized by health care practitioners will help mitigate the potential for preventable adverse drug reactions. We hope our findings from this multi-incident analysis help improve medication safety by providing a platform for reflection and shared learning.

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