MULTI-INCIDENT ANALYSIS ON INCIDENTS INVOLVING PATIENTS:

Lessons Learned from a Provincial Pilot Study

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Although this pilot study was situated in New Brunswick, lessons learned from this multi-incident analysis will be relevant and applicable to pharmacy practitioners in other provinces in Canada.

BACKGROUND

As of December 31, 2015, the New Brunswick College of Pharmacists requires all pharmacy managers in the province to implement a quality management program (QMP) to support safe practices and facilitate adherence to professional standards and requirements. The QMP must include monitoring staff performance, equipment, facilities, and adherence to the standards of practice.[1]

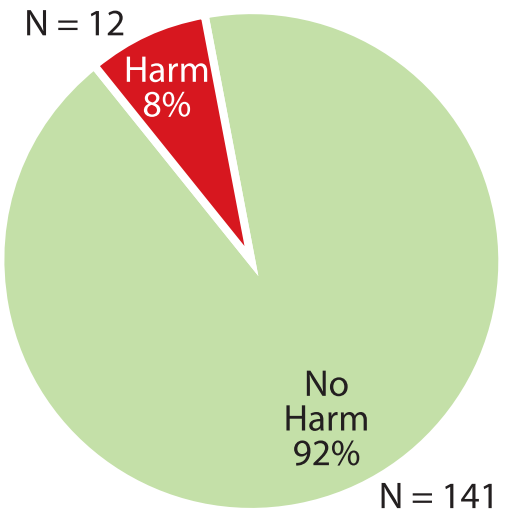
The Community Pharmacy Incident Reporting (CPhIR) Program is an anonymous program designed by the Institute for Safe Medication Practice Canada (ISMP Canada) to empower pharmacies for continuous quality improvement. The purpose of CPhIR is for community pharmacies to report and analyze near misses and medication incidents as learning opportunities to prevent similar incidents from occurring in the future. These anonymously reported medication incidents will also be analyzed by ISMP Canada for shared learning and incident prevention strategy formulation.[2]

MULTI-INCIDENT ANALYSIS (MIA) INVOLVING MEDICATIONS DISPENSED TO PATIENTS: A PILOT STUDY IN NEW BRUNSWICK

A Multi-Incident Analysis (MIA) was performed on incidents reported from New Brunswick pharmacies to CPhIR from July 2015 to February 2016. Of the 223 pharmacies in New Brunswick, 82 were enrolled in a complimentary pilot project for the use of CPhIR as a QMP. The objective of this multi-incident analysis is threefold; first, to understand how and why these medication incidents occur; second, to identify the potential contributing factors of these incidents; and third, to provide recommendations to prevent future medication incidents.

A total of 669 medication incidents were extracted from the CPhIR database. 511 incidents were near misses that were intercepted at the pharmacy and did not reach the patient. 158 incidents involved medications that were dispensed to patients. Of the 158 incidents, 5 were excluded from this analysis due to: 1) duplicate reports, or 2) test or dummy incident records. Figure 1 illustrates that despite reaching the patient, majority (92%) of these medication incidents did not lead to harm.

FIGURE 1: FREQUENCY OF INCIDENTS ACCORDING TO THE DEGREE OF HARM TO PATIENTS



When conducting a qualitative, multi-incident analysis of the 153 incidents that reached patients, five main themes were identified: 1) look-alike/sound-alike medications, 2) high-alert medications, 3) use of multi-medication compliance aids, 4) technical error, and 5) incorrect patient. Table 1 includes the definition and sample cases of each of these themes, as well as the corresponding potential contributing factors. (Note: The "Incident Examples" provided in Table 1 were limited by what was inputted by pharmacy practitioners to the "Incident Description" field of the CPhIR program. The "Potential Contributing Factors" apply to the corresponding "Themes" in general and may not necessarily pertain to the selected "Incident Examples" that were shown in Table 1.)

Although the majority of the medication incidents in this analysis did not result in patient harm, they provided good learning opportunities to identify potential contributing factors and develop recommendations to prevent similar incidents from occurring in the future. Two common potential contributing factors are present in all five themes – (1) look-alike / sound-alike (LASA) medications; and (2) lack of independent double checks. LASA medications can easily be confused for one another by pharmacy staff, leading to a medication incident. The lack of independent double checks among pharmacy staff also greatly increases the risk of errors.

TABLE 1: DEFINITION, INCIDENT EXAMPLES AND POTENTIAL CONTRIBUTING FACTORS

THEMES	DEFINITION OF THEMES	INCIDENT EXAMPLES	POTENTIAL CONTRIBUTING FACTORS
Look-alike / Sound-alike (LASA) Medications	LASA medications have either similar names or similar packaging.	[The patient] went to outpatient department on weekend for treatment for shoulder pain, [and] was **prescribed Diclofenac** which was **interpreted as Diflucan**™. [The pharmacist] had [to] follow up with family doctor who thought it was a "weird choice" for shoulder pain. Prescription written for **nitro patch 0.4 mg** and was entered as is - product **dispensed** to patient was **nitro patch 0.6 mg** - mistake was discovered by patient herself when she got home she realized she did not get dose prescribed . . .	• Lack of variety in pharmaceutical manufacturer • Proximity of storage of LASA medication pairs • LASA medications in the same therapeutic class
High-alert Medications	High-alert medications carry a higher risk of more serious harm to patients if an error occurs.	Patient called (about 2 weeks after receiving her prescription) saying she was not feeling as much relief with her pain medication (**MS-IR® 10 mg**) as usual - she then brought in her bottle with some pills left in it - the pharmacist on duty **identified the tablets in the bottle as MS-IR® 5** mg (but bottle said MS-IR® 10 mg) - **wrong strength dispensed initially** . . . Patient was **given wrong take home doses of methadone.** Patient was contacted to verify bottles and asked to return wrong doses. Patient returned 2 doses and received correct doses. Patient consumed half of another take home dose that was for another patient even though patient was asked to check them. **Patient consumed approximately 70 mg methadone instead of 9 mg. Patient vomited dose.** Contacted doctor and doctor is monitoring patient.	• Confirmation bias* • Inconsistent verification of patient identity

CONTINUED

THEMES	DEFINITION OF THEMES	INCIDENT EXAMPLES	POTENTIAL CONTRIBUTING FACTORS
Use of Multi-medication Compliance Aids	Preparing medications by placing different medications in the same compartment organized by dosing intervals.	Pillpak was returned from special care home after errors were noticed by the staff on [the] 4th card of 4-week supply of pillpaks. Clozapine 100 mg **tablet was missing from AM slot** (one whole card), irbesartan 75 mg was missing from one evening slot and **there were two tablets in the next day's evening slot** . . . Evening nurse noticed **patient to receive 5 medications, however [only] 4 medications are in bubble.**	• No standardized process for preparing compliance packs • Compliance packs prepared well in advance of patient pick-up or delivery • Lack of verification with patient's current prescription orders
Technical Errors	In this analysis, technical errors refer to any errors that occurred during the order entry and dispensing stages of the medication-use process. The therapeutic or cognitive aspects of the medication-use process were not included.	Patient dropped off new prescription for an increase in strength; prescription was logged to profile but old strength was not discontinued; patient ordered refill and the **old strength was filled.** Patient realized his **30-day prescription** (60 caps) ran out in 15 days; he brought the vial in to me and it was **evident that 60 caps would not have fit** into the vial used to dispense the prescription . . .	• Multi-tasking • Insufficient staff orientation, education, or training
Incorrect Patients	Prescriptions or medications were dispensed to a patient for whom the medication was not prescribed or ordered.	Patient noticed after giving herself injection that the **name on the label was not hers**. She brought the box to the pharmacy and we looked into what had happened. We realized that 2 patients had the same injection in the fridge waiting to be picked up . . . Pharmacy Assistant noticed bag still on counter when patient had picked up medications. Had to figure which bag I had given to patient, looked through our filing and realised patients had same first name and both bags were placed on [the] counter next to each other.	• Confirmation bias* • Inconsistent verification of patient identity • Failure to follow up on patient's medication therapy management

* Confirmation bias leads us to "see" information that confirms our expectation rather than to see information that contradicts our expectation. (For further information, refer to ISMP. Inattentional blindness: What captures your attention? ISMP Medication Safety Alert!® Acute Care. 2009; Feb 26. Available from https://www.ismp.org/newsletters/acutecare/articles/20090226.asp.)

** Independent double checks take place when the first practitioner does not communicate what he or she expects the second practitioner to see while the second practitioner is conducting verification. (For further information, refer to ISMP Canada. Definitions of Terms. Available from https://www.ismp-canada.org/definitions.htm.)

DISCUSSION

Recommendations were developed based on the medication workflow process, which includes inventory management, receiving/shelving, prescription order entry, dispensing, compliance packaging, and counselling/pick-up (Figure 2).

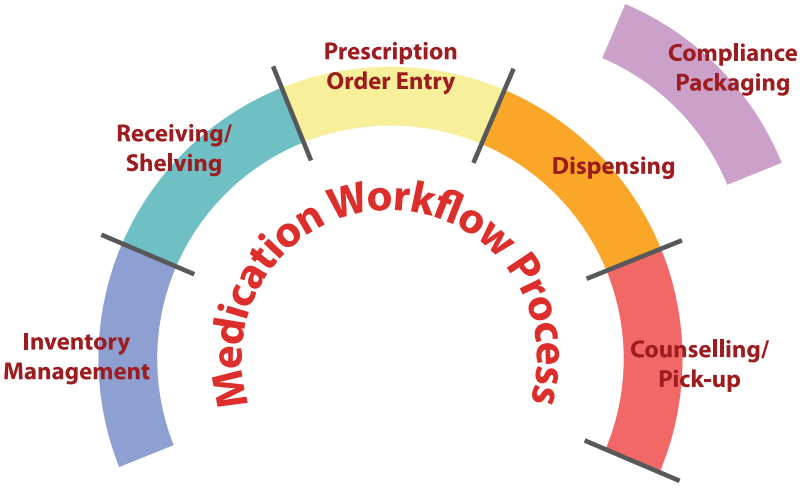
INVENTORY MANAGEMENT

Within each pharmacy, there are many LASA medications in the inventory due to the lack of manufacturer variety when ordering medications. The same manufacturer will often have the same size bottle, label colours and fonts for medication packaging.[3] At the inventory management stage, ordering from different manufacturers can help decrease the chances of confusing LASA medications.[4]

RECEIVING / SHELVING

While receiving and shelving the medications at the pharmacy, storing LASA medications in different areas or differentiating them with shelf labels, stickers, or dividers can accentuate their visual identification and prevent pharmacy staff from selecting the incorrect medication.[5]

FIGURE 2: MEDICATION WORKFLOW PROCESS



PRESCRIPTION ORDER ENTRY

At prescription order entry, staff should ask each patient for at least two patient identifiers, such as name and date of birth.[6] It may also be beneficial to contact software vendors to incorporate warning flags into the dispensing software program to alert staff of potential duplicate therapy and to consider incorporating TALL-man lettering into the computer system.[7]

DISPENSING

At the dispensing stage, incorporating barcoding into the dispensing software program can serve as an independent double check by the computer.[8] Staff would scan a software generated barcode on the prescription hardcopy (or label), followed by the medication stock bottle (or package) to ensure that the medications that are entered during order entry are selected from the inventory for preparation and dispensing.[9, 10] In fact, it is also a good practice to take this opportunity (that is, prior to the actual filling of the prescription) to visually review and confirm that the order entry was done correctly as per the original prescription. This will prevent subsequent re-processing of the prescription should an error was caught within the workflow.

COMPLIANCE PACKAGING

While compliance packaging is not typically part of the normal medication workflow process as illustrated above, many medication incidents analyzed in this report pertained to multi-medication compliance aids. Therefore, it is important to consider strategies to mitigate these incidents. When preparing compliance packaging, it is essential to develop a standardized process.[11] Prior to preparing the multi-medication compliance packages, staff should verify that the printed prescription hardcopy (or label) is accurate by referring to the most current prescription orders.[10]

It is also advisable to assign designated pharmacy personnel or allot time to allow pharmacy staff to work in a quiet and uninterrupted environment (i.e. away from the usual pharmacy workflow) for compliance packaging. Furthermore, preparing compliance packs well in advance of patient pick-up or delivery may lead to discrepancies of patient's most current prescription orders. Compliance packs should only be prepared for the frequency the patient receives or picks up his/her prescriptions at the pharmacy. For example, compliance packs should be prepared weekly for patients who come to the pharmacy on a weekly basis. If a change in therapy occurs during this period, it is easier to identify and reconcile the discrepancies accordingly.

COUNSELLING / PICK-UP

During prescription pick-up, it is always good practice to ask each patient, using open-ended questions, for at least two patient identifiers, such as name and date of birth. [12]

Counselling at pick-up is not only important for educating patients on their medication therapy, but also serves as a last check before patient leaves the pharmacy.[13] While having a dialogue with the patient, take the opportunity to review the prescription labels and contents of each prescription vial to check that the medications are correct.[12]

Finally, regular monitoring and following up with patients on their medication therapy can ensure that patients are using their medications in a safe and effective way.

Table 2 presents a checklist that summarizes the above recommendations for improving the medication workflow process.

TABLE 2: A CHECKLIST FOR QUALITY IMPROVEMENT OF THE MEDICATION WORKFLOW PROCESS

MEDICATION WORKFLOW PROCESS	SUGGESTED QUALITY IMPROVEMENT STRATEGIES
Inventory Management (ordering medications from suppliers or wholesalers)	• Consider ordering from different manufacturers for LASA medications[4]
Receiving/Shelving (scanning medications into dispensing system and placing them onto pharmacy shelves)	• Store LASA medications in different areas[5] • Differentiate LASA pairs through the use of shelf labels or dividers[5]
Prescription Order Entry (inputting prescriptions into computer system)	• Verify patient with at least two patient identifiers (e.g. name, date of birth, phone number, etc.)[6] • Assess opportunities for system-based alerts to inform staff of potential duplicate therapy [6] • Consider incorporating TALLman lettering into computer system[7]
Dispensing (preparation of medication, e.g. counting tablets, compounding medications, etc.)	• Incorporate barcoding into the dispensing software program[8] • Conduct independent double checks[9,10]
Compliance Packaging (preparing medications by placing different medications in the same compartment organized by dosing intervals)	• Outline standardized policies and procedures for preparing compliance packaging[11] • Verify printed prescription hardcopies (or labels) with patient's most current prescription orders[10] • Designate pharmacy staff to prepare compliance packaging • Allot time for pharmacy staff to prepare compliance packaging in a quiet and uninterrupted environment • Conduct independent double checks • Avoid preparing compliance packs well in advance of patient pick-up or delivery • Prepare compliance pack only for the frequency the patient receives or picks up his/her prescriptions at the pharmacy (e.g. For patients with weekly blister packs, only prepare one week's worth of blister pack at a time.)
Counselling/Pick-up (educating patients on proper medication use, side effects, etc.)	• Verify patient with at least two patient identifiers (i.e. name, date of birth, phone number, etc.) using open ended questions [12] • Consider technological enhancement at the point-of-sale where staff is required to input a patient identifier (i.e date of birth) before the transaction can be completed at the POS register [12] • Review pharmacy labels and contents of each prescription vial to check that the medications are correct[12] • Perform regular monitoring and follow-up on patients' medication therapy[13]

CONCLUSION

This analysis of medication incidents involving patients in New Brunswick identified vulnerabilities to patient safety that may occur after medications were dispensed to patients and potential factors that may have contributed to these incidents. The importance of system-based recommendations was recognized and quality improvement strategies were suggested to the medication workflow process for advancing safe medication use.

It is hoped that this multi-incident analysis demonstrated the importance of reporting and analysis of medication incidents as learning opportunities for pharmacy practitioners to prevent similar incidents from occurring in the future.

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