

**COMPASS Harm Incidents Qualitative Analysis**  
**December 1<sup>st</sup>, 2017 to January 31<sup>st</sup>, 2019**

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## Objective

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Community Pharmacy Professionals Advancing Safety in Saskatchewan (COMPASS) is a standardized continuous quality improvement (CQI) program specific to Saskatchewan community pharmacies. The objective of this analysis is to provide a qualitative analysis of harm incidents submitted to the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program by COMPASS pharmacies. A multi-incident analysis was conducted to develop overarching themes and identify possible factors that may have contributed to these incidents. A list of system-based recommendations ([Table 6](#)) was developed to address these contributing factors and mitigate the risk of future harm incidents.

## Methods

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Incident data were extracted from the CPhIR Program. The date range of this analysis was from December 1st, 2017 to January 31st, 2019. A total of 267 harm incidents were reported, comprising of 247 mild harm incidents, 16 moderate harm incidents, 4 severe harm incidents, and no death incidents.

## Results

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Four major themes were identified from this qualitative, multi-incident analysis: (1) communication gaps; (2) non-traditional dispensing procedures; (3) order entry errors; and (4) product mix-up. [Table 1](#) shows the four main themes and their associated sub-themes accordingly.

Table 1. Overview of Main Themes and Sub-Themes

<b><u>Theme 1. Communication Gaps</u></b> 1. Patient Communication 2. Pharmacy Staff Communication 3. Interprofessional Communication	<b><u>Theme 2. Non-Traditional Dispensing Procedures</u></b> 1. Long-Term Care and Compliance Packaging 2. High-Risk Procedures (E.g. Methadone, Injections, Compounding)
<b><u>Theme 3. Order Entry Errors</u></b> 1. Technical Errors 2. Clinical Errors	<b><u>Theme 4. Product Mix-Up</u></b>

### Theme 1. Communication Gaps

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Effective communication is vital for safe medication use in patients. In the pharmacy, a breakdown in communication can result in pharmacists lacking the information needed to safely verify prescriptions, patients receiving medications not intended for their care, or patients using medications incorrectly.<sup>1</sup> In this data set, incidents were reported in which ineffective, incomplete, or a lack of communication between the pharmacy, the patient, and other caregivers might have contributed to patient harm.

### **Patient Communication**

Pharmacies are one of the last points of contact between the healthcare system and the patient. When verifying prescriptions, pharmacists are expected to provide the necessary counselling such that patients can use their medications safely. In this data set, we identified incidents, which might have resulted from inadequate confirmation of patient understanding despite counselling. In addition, patient requests for refills and other patient encounters might have resulted in harm incidents when information gathering was incomplete and/or assumptions were made.

As the one constant throughout their journey in the healthcare system, patients themselves can act as the last layer of protection against preventable harm from medications. The IDEA framework (which stands for **I**ndication, **D**uration, **E**ffect, and **A**dverse Effects) or the "show and tell" technique can both be implemented during counselling to enhance patient understanding and medication safety.<sup>2</sup> To improve completeness of information gathering, standardizing the process, such as the use of the Best Possible Medication History (BPMH) approach, can be used.<sup>3,4</sup> Similarly, information gathering during any patient encounters at community pharmacies can also be standardized to include key questions, such as confirming the indication and name of the medication to be dispensed, etc.

### **Pharmacy Staff Communication**

Any member of the pharmacy team may be involved in the initial patient encounter. To fulfil patients' needs regarding their medication therapy management, pertinent information obtained initially will need to be documented and communicated among pharmacy team members, especially during shift changes. Lacking documentation after patient encounters or neglecting pre-existing documentation within patient profiles have led to harm incidents.

Pharmacy practice management system (PPMS) or pharmacy dispensing software provides a platform where documentation can be stored in a patient's profile for future reference and an opportunity to improve communication among team members.<sup>5,6</sup> PPMS functions should be properly utilized in order to flag or alert pharmacy team members regarding pre-existing documentation in patient profiles, such as drug allergies, medical conditions, etc. A common issue is that documentation may not be completed consistently due to various reasons, for instance, a lack of time.<sup>5</sup> As such, a cultural change to recognize the importance of documentation is warranted.

### **Interprofessional Communication**

Optimal medication use requires effective collaboration among different healthcare providers. Communication within the healthcare system is often challenging, in particular, in situations where patients have multiple care providers.<sup>7</sup> Harm incidents occurred when ambiguous prescriptions were not clarified with prescribers; this occurs most frequently when medication formulation was unspecified or hand-writing was unclear.<sup>8</sup> In long-term care (LTC) settings where there are multiple healthcare professionals practicing, confusion over interprofessional roles has resulted in medication-related harm as well.

To help reduce communication gaps between healthcare providers, patients can be encouraged to keep an up-to-date medication and vaccination history and be empowered to become an active participant in

managing their own health.<sup>9</sup> To healthcare practitioners, e-prescribing should be encouraged.<sup>10</sup> If a prescription is ambiguous or illegible, it should always be clarified with the prescriber.<sup>10</sup>

[Table 2](#) illustrates examples of harm incidents that were associated with communication gaps.

Table 2. Communication Gaps Sub-Themes and Incident Examples

<b>Communication Gaps</b>	
Harm incidents were most attributable to miscommunication or a lack of disclosing information within a timely manner.	
<b>Sub-Themes</b>	<b>Incident Example(s)</b>
<u>Patient Communication</u>  Miscommunication during patient encounters or patient counselling	Patient was taking Gabapentin 100 mg 3 capsules twice daily. A new prescription was filled with 300 mg capsules instead. The pharmacist documented the change and left a note for the cashier to inform the patient. The patient did not recall being informed. The patient took three 300 mg capsules twice daily and noticed adverse effects. The error was discovered when an early refill was requested.
	Patient dropped off a new prescription of an anti-depressant with a dose increase. When requesting for a refill, the patient asked the staff to refill "the two medications". The staff saw the two strengths of the anti-depressant and refilled both. The patient received both strengths of the anti-depressant while the anti-hypertensive medication was omitted.
<u>Pharmacy Staff Communication</u>  Miscommunication between pharmacy team members, including technicians and students	Patient requested for a refill for one prescription. A relief pharmacist on duty at the time was not aware that the patient preferred brand name. The generic was dispensed. The patient returned the next day after experiencing adverse effects.
<u>Interprofessional Communication</u>  Miscommunication between pharmacies and other healthcare providers, such as physicians or nurses, and misinterpretation of physician orders	The patient is seen by several physicians. A new prescription was received by the pharmacy for an increased dose of the patient's medication. At the patient's telehealth meeting, a home care nurse noted a discrepancy where an order was received from a different physician indicating that the dose should not be increased. The nurse was giving the lower dose to the patient during this period.

## Theme 2. Non-Traditional Dispensing Procedures

Community pharmacies sometimes offer non-traditional dispensing services that may not involve the usual linear medication-use process. Some of these procedures involve dispensing medications to LTC homes, preparing compliance packs, dispensing methadone, administering injections, and compounding mixtures, etc. These alternative dispensing procedures may have a greater potential of causing significant patient harm if errors occur.<sup>11</sup>

### **Long-Term Care (LTC) and Compliance Packaging**

Many community pharmacies prepare compliance packs to assist individual patients in managing their medications or dispense medications in "rolls" or packs to LTC homes. These forms of dispensing may have additional requirements and accountabilities compared to traditional dispensing process.<sup>12</sup> Errors often

occur when there are changes to a patient’s medication therapy management, for example, failure to verify the most up-to-date prescription(s) to the compliance packs, omission of independent double checks, and missing corresponding changes to prescription labels and medication administration records (MARs), etc. In addition, as compliance packs are often prepared for patients with complex medication regimen, this element of complexity increases the likelihood of errors.<sup>13</sup>

There are several important considerations when preparing compliance packs or LTC medication “rolls”. Any compliance pack guides, or templates, used to prepare the packs should be updated as soon as there are changes to a patient’s medication therapy and a copy of the new prescription should be attached for checking purposes. In addition, the patient’s profile should be compared to the medication administration records (MARs), the prescription, and compliance pack labels each time the packs or rolls are prepared. Lastly, independent double checks should be applied throughout the process to reduce the risk of errors.<sup>14</sup> We would like to refer readers to a [multi-incident analysis on compliance pack preparation](#) that was previously conducted by ISMP Canada for further information.<sup>15</sup>

### High-Risk Procedures

High-risk procedures that were prevalent amongst reported harm incidents involved daily methadone dispensing, administering injections, and compounding. Methadone and compounding incidents were often related to calculation errors, leading to over-dosing of methadone or preparation of an inappropriate mixture. Other incidents involving injections and methadone were associated with a lack of pharmacy staff training in these high-risk procedures.

To reduce errors, pharmacy managers must ensure that all members of the pharmacy team are informed, educated, and trained on the standardized procedures. In addition, independent double checks should be included in all high-risk procedures (e.g. verifying calculations and methadone volume, etc.).<sup>14</sup>

[Table 3](#) illustrates examples of harm incidents that were associated with non-traditional dispensing procedures.

Table 3. Non-Traditional Dispensing Procedures Sub-Themes and Incident Examples

<b>Non-Traditional Dispensing Procedures</b>	
Harm incidents occur during non-linear or non-traditional dispensing procedures where individual pharmacies may have their own unique processes in place.	
<b>Sub-Themes</b>	<b>Incident Example(s)</b>
<u>Long-Term Care (LTC) and Compliance Packaging</u> Incidents that involve the unique aspects of dispensing to LTC homes or preparing compliance packs	The pharmacy received a new prescription for a Warfarin dose change. The change was reflected on the pharmacy dispensing system but not on the nursing home dispensing instructions. As a result, the Warfarin was packed with alternating 0.5 mg and 1 mg tablets instead of the correct 0.5 mg tablets daily. The incident was discovered several weeks later when a technician was checking and noticed a mismatch between the directions and the pack. Patient was scheduled for an INR that day by the physician.
<u>High-Risk Procedures</u>	Pharmacist was preparing the patient’s daily Methadone dose. During the dispensing process, the pharmacist went to assist another staff member before returning to finish the Methadone preparation. Patient

<b>Non-Traditional Dispensing Procedures</b>	
Harm incidents occur during non-linear or non-traditional dispensing procedures where individual pharmacies may have their own unique processes in place.	
Incidents that involve other community pharmacy services (e.g. methadone, injections, compounding) that have a greater risk of causing significant patient harm when errors occur	received 10 times his regular dose. Patient felt unwell and had to be hospitalized.
	An intramuscular vaccine was administered subcutaneously, and the patient developed hives, welts, and redness at the injection site.

### Theme 3: Order Entry Errors

Order entry is part of the medication-use process where prescriptions are transcribed onto the pharmacy practice management system (PPMS) or pharmacy dispensing software. Transcribing errors generally result in patients receiving the wrong drug, incorrect dose, incorrect formulation, or incorrect instructions. Transcribing errors commonly arise from technical errors where the information was transcribed incorrectly, but there are also clinical errors where dispensing should have been stopped due to an identifiable drug therapy problem.

#### Technical Errors

As part of the dispensing process, all members of the pharmacy team can be expected to transcribe prescriptions. Look-alike/sound-alike drug names is a well-known contributing factor of transcribing errors resulting in potential patient harm.<sup>16</sup> Similarly, transcribing errors have occurred when prescriptions are copied over from old prescriptions. There are system-based solutions that can minimize the risk of transcribing errors. Tall-man lettering can minimize the risk of medication errors attributable to look-alike/sound-alike drug names and should be considered in all pharmacy softwares.<sup>17,18,19</sup> Although copying prescriptions is a convenient method to speed up the transcribing process for similar prescription orders, it also offers a new avenue for errors to occur. As such, it should be used judiciously, ideally only when the medication, strength, and instructions are all identical.

#### Clinical Errors

Pharmacists are expected to perform therapeutic checks on prescriptions. Harm incidents have occurred when allergy or drug interaction alerts were bypassed. At times, therapeutically inappropriate medications were dispensed when pharmacists were not aware of new medications or formulations. Professional judgement made by pharmacists (e.g. bypassing a drug-drug interaction alert) should be well documented such that the rationale for a clinical decision can be traceable. An evidence-based point-of-care clinical decision support system and drug information resources should be easily accessible in order to support pharmacists' expanded scope of practice.

[Table 4](#) illustrates examples of harm incidents that were associated with order entry errors.

Table 4. Order Entry Errors Sub-Themes and Incident Examples

<b>Order Entry Errors</b>	
Harm incidents result from inappropriate prescription transcribing, technical errors, or clinical errors.	
<b>Sub-Themes</b>	<b>Incident Example(s)</b>
<u>Technical Errors</u> Order entry errors resulting from choosing the wrong product or incorrectly transcribing the prescription directions or instructions	Patient was to be dispensed Citalopram 10 mg, but it was transcribed and dispensed as Escitalopram 10 mg instead. The patient returned to the physician due to nausea and lack of response to the medication.
	Patient was taking Bupropion XL 150 mg 2 tablets once daily. With a backorder, the physician issued a new prescription for Bupropion SR 150 mg 1 tablet twice daily. When entering the prescription, the Bupropion XL prescription was copied over; the medication was changed correctly but the prescription directions were not. As a result, the patient felt unwell for several weeks and had to see the physician.
<u>Clinical Errors</u> Order entry errors due to improper clinical verifications	Patient was prescribed Tylenol No. 3. There was an allergy notification for Codeine on the patient's profile, but the alert was bypassed by the pharmacy assistant when entering the prescription. The pharmacist did not review the patient's allergies when checking nor inquire about patient allergies upon counselling. Several days later, the patient reported allergy-related adverse effects.

#### Theme 4: Product Mix-Up

Two types of product mix-ups were most commonly observed: (1) An incorrect drug was selected during prescription filling; and (2) a patient received another patient's medication at pick-up. Many of these incidents occurred when the pharmacy was very busy. Workarounds (in order to save time or fill multiple prescriptions at the same time) may increase the likelihood of errors. In addition, many products have look-alike/sound-alike labelling and packaging. When coupled with confirmation bias, this may lead to an incorrect product being selected and given to the patient.<sup>16</sup> Errors occurred at pick-up are mostly associated with patients having similar identifiers (e.g. similar names or address) and when patient identifiers were not obtained to confirm the patient's identity.

There are system-based solutions that may help reduce these types of errors. Independent double checks are helpful in preventing medication incidents.<sup>14</sup> Patients are often familiar with the appearance of their regular medications and can act as the second check of their prescriptions at pick-up.<sup>20</sup> If pharmacies do not have a barcode scanning system, the addition of this feature and enforcement of its use would help ensure that the correct product is selected for filling. Alternatively, enforcing a policy that involves verifying the drug identification number (DIN) during filling would help minimize selection errors. Lastly, confirming at least two unique patient identifiers at pick-up would reduce the chances that a patient receives someone else's medication.

[Table 5](#) illustrates examples of harm incidents that were associated with product mix-up.

Table 5. Product Mix-Up Incident Example

## Product Mix-Up

Harm incidents occur when an incorrect product was selected, filled, and/or given to the patient.

### Incident Example

A prescription was brought in by a patient for 3 different medications. One of them was a narcotic. As the pharmacy was busy, the pharmacist counted the medications, while the student was entering the prescription into the dispensing software. The pharmacist noticed that a different brand of the narcotic was entered and billed to the third-party insurance and hence a return-to-stock process is needed. However, one of the 3 medications was incorrectly returned to the narcotic stock bottle. As a result, the patient received two different brands of the narcotic medication and did not receive one of his other medications. The error was discovered when the pharmacy was filling the same narcotic for a different patient.

## Conclusion

COMPASS is a standardized continuous quality improvement (CQI) program specific to Saskatchewan community pharmacies and it has been mandatory for all Saskatchewan community pharmacies since December 1, 2017. We conducted a qualitative analysis of harm incidents submitted to the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program by COMPASS pharmacies and identified four main themes. [Table 6](#) presents a summary of our findings with contributing factors and possible solutions/interventions to prevent patient harm from medications.

Table 6. Summary of Recommendations

Summary of Main Themes / Sub-Themes / Contributing Factors / Recommendations	
<b>Theme 1. Communication Gaps</b>	
Sub-Themes / Contributing Factors	Recommendations
<u>Patient Communication</u> <ul style="list-style-type: none"><li>Inadequate confirmation of patient understanding</li><li>Non-standardized information gathering during patient encounters</li><li>Assumptions made by care team and/or patients</li></ul>	<ul style="list-style-type: none"><li>Double check patient understanding after counselling</li><li>Standardize patient encounters (e.g. always include medication name and indication verification)</li></ul>
<u>Pharmacy Staff Communication</u> <ul style="list-style-type: none"><li>Lack of documentation after patient encounter</li><li>Overlooked existing documentation</li><li>Inability to identify clinically significant issues and bring to pharmacist's attention</li></ul>	<ul style="list-style-type: none"><li>Adopt a standard for written and verbal communication among pharmacy team members</li><li>Flag or use alerts for patients with clinically significant documentation on profile</li></ul>
<u>Interprofessional Communication</u> <ul style="list-style-type: none"><li>Incomplete information sharing among care providers within the patient's circle of care</li><li>Ambiguous physician orders</li><li>Lack of understanding of the respective roles among different health care professionals</li><li>Confirmation bias</li></ul>	<ul style="list-style-type: none"><li>Encourage patients to carry an up-to-date medication and immunization records</li><li>Mandate clarification of ambiguously hand-written orders or unclear formulations with prescribers</li><li>Establish clear roles and responsibilities among healthcare professionals</li></ul>

Summary of Main Themes / Sub-Themes / Contributing Factors / Recommendations	
<b>Theme 2. Non-Traditional Dispensing Procedures</b>	
Sub-Themes / Contributing Factors	Recommendations
<u>Long-Term Care (LTC) and Compliance Packaging</u> <ul style="list-style-type: none"> <li>Compliance packs / LTC medication “roll” changes</li> <li>Medication administration record (MAR) errors</li> <li>Complex medication regimens</li> <li>Lack of independent double checks</li> <li>Lack of verification with the most up-to-date patient’s medication therapy</li> </ul>	<ul style="list-style-type: none"> <li>Update compliance pack guides or templates as soon as changes are made to the patient’s medication therapy and attach a copy of the new prescription to the guide or template for verification</li> <li>Compare patient profile with the MAR and prescription labels every time the medication is dispensed.</li> <li>Incorporate independent double checks throughout the medication-use process</li> </ul>
<u>High-Risk Procedures</u> <u>(E.g. Methadone, Injections, Compounding)</u> <ul style="list-style-type: none"> <li>Calculation errors</li> <li>Inadequate training on high-risk procedures</li> </ul>	<ul style="list-style-type: none"> <li>Incorporate independent double checks in all high-risk procedures</li> <li>Ensure all pharmacy team members are well trained on high-risk procedures</li> </ul>
<b>Theme 3. Order Entry Errors</b>	
Sub-Themes / Contributing Factors	Recommendations
<u>Technical Errors</u> <ul style="list-style-type: none"> <li>Look-alike/sound-alike drug names and medications with multiple strengths available</li> <li>Copying from old prescriptions</li> </ul>	<ul style="list-style-type: none"> <li>Incorporate tall-man lettering in pharmacy dispensing software to help differentiate look-alike/sound-alike drug names</li> <li>Implement policy to minimize copying from old prescriptions</li> </ul>
<u>Clinical Errors</u> <ul style="list-style-type: none"> <li>Bypassing or overlooking system alerts</li> <li>Inadequate knowledge of drug formulations, therapeutics, and patient information</li> </ul>	<ul style="list-style-type: none"> <li>Mandate documentation (with rationale) when bypassing or overriding system alerts</li> <li>Implement evidence-based, point-of-care clinical decision support system and easily accessible drug information resources</li> </ul>
<b>Theme 4: Product Mix-Up</b>	
Contributing Factors	Recommendations
<ul style="list-style-type: none"> <li>Workarounds (e.g. bypassing barcode scans, filling multiple prescriptions at the same time)</li> <li>Look-alike/sound-alike labelling and packaging</li> <li>Similar patient identifiers</li> <li>Lacking authentication process for patient identification at pick-up</li> </ul>	<ul style="list-style-type: none"> <li>Complete the filling process for one medication before moving on to another</li> <li>Verify the drug identification number (DIN) of the product when selecting the medication for filling</li> <li>Incorporate barcode scanning of medication stock bottles when filling</li> <li>Show patients the medications that they are expecting at pick-up (especially when it is a refill prescription); this can serve as an independent double check</li> <li>Require at least 2 different unique patient identifiers at prescription pick-up</li> </ul>

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