COMPASS Phase II Incident Analysis Report

Prepared by

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INTRODUCTION

Incidents as part of COMPASS (Community Pharmacists Advancing Safety in Saskatchewan) Phase II reported by 87 participating community pharmacies were abstracted from the Community Pharmacy Incident Reporting (CPhIR) database. The data spanned from January 1st, 2015 to December 31st, 2015, totaling 3933 incidents.

ANALYSIS RESULTS

QUANTITATIVE ANALYSIS

The quantitative analysis was conducted by one ISMP Canada analyst, and independently reviewed by two ISMP Canada analysts. The vast majority of CPhIR incidents were near misses (83%), and of those reported as incidents (17%), most caused no harm (94%) [Figure A]. About half the incidents occurred at the order entry stage (51%), with prescription preparation/dispensing (25%) and prescribing (13%) rounding out the top three error-prone stages of the medication use process [Figure B]. The most common types of incidents were incorrect dose/frequency (25%), incorrect quantity (19%), and incorrect drug (16%) [Figure C], with the most problematic drug classifications being part of the cardiovascular system (21%), systemic anti-infectives (18%), and the nervous system (15%) [Figure D].

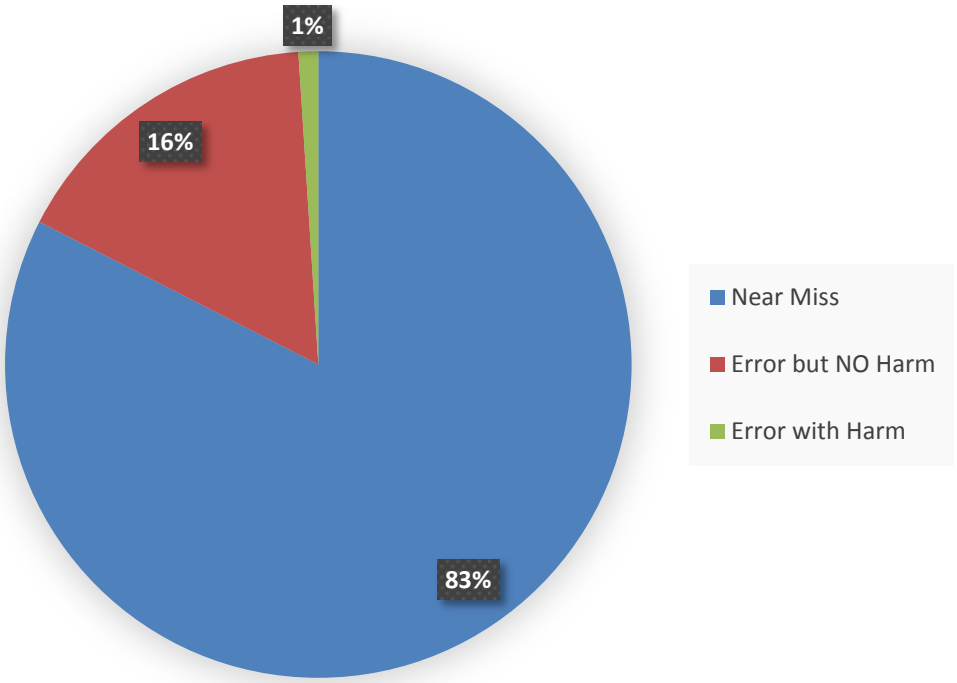

Figure A: The severity of reported incidents, defined as: near miss, which are incidents that did not reach the patient; error but no harm, which are incidents that reached the patient but did not cause harm; and error with harm, which are incidents that reached the patient and caused some degree of harm.

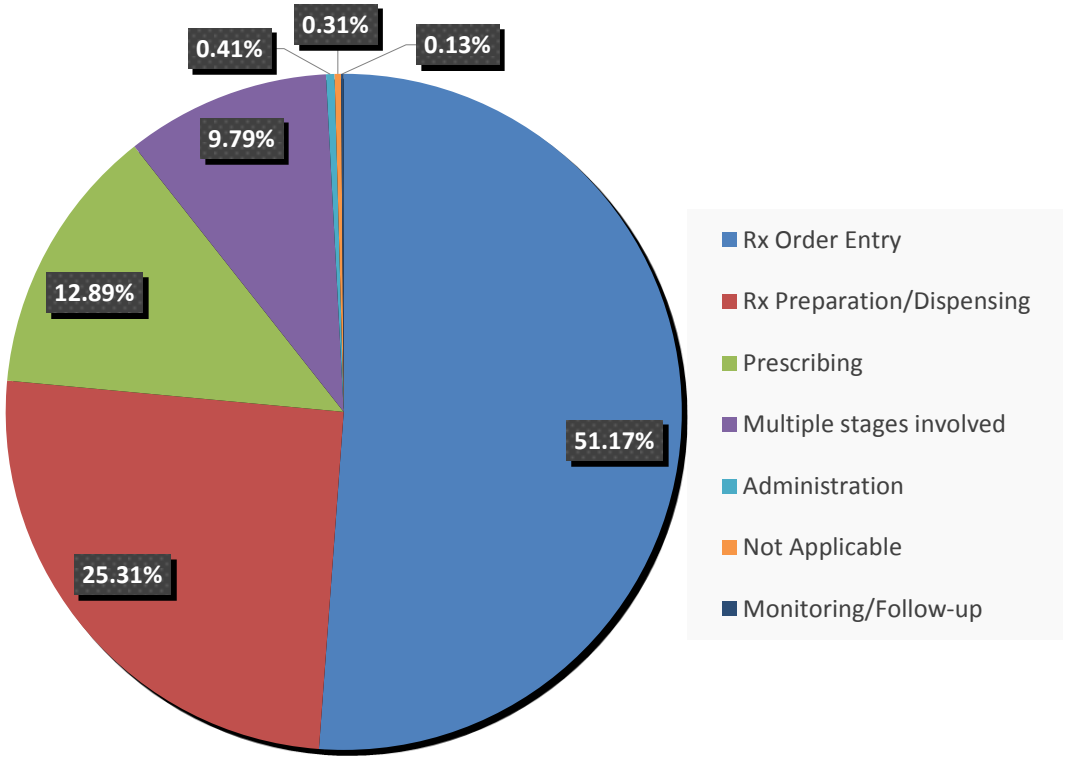

Figure B: The proportion of incidents that occurred at each stage of the medication use process, which involves prescribing, prescripton order entry, prescription preparation/dispensing, administration, and monitoring/follow-up.

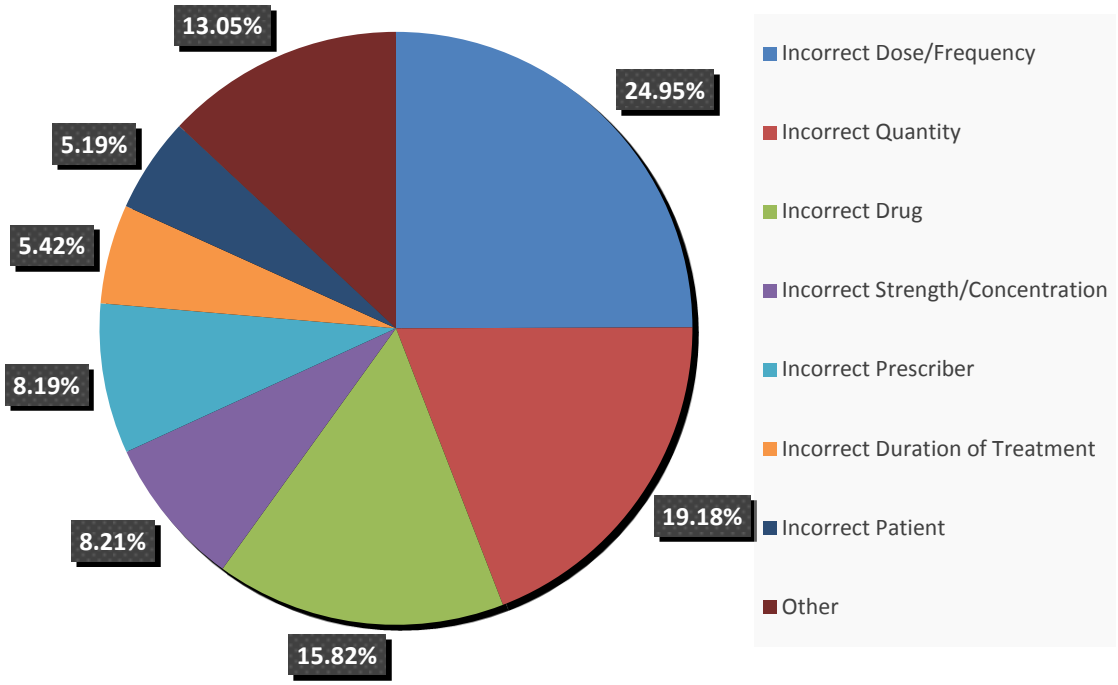

Figure C: The types of reported incidents, including incidents in dosing information and prescriber details. The types of incidents that occurred less than 5% have been subverted into 'Other' on this graph due to their relative infrequency. These types include: omitted medication/dose, incorrect dosage form/formulation, incorrect third party billing, incorrect route of administration, contraindication, documented allergy, drug-drug/OTC/NHP interaction, incorrect storage, expired medication, drug-disease interaction, and adverse drug reaction.

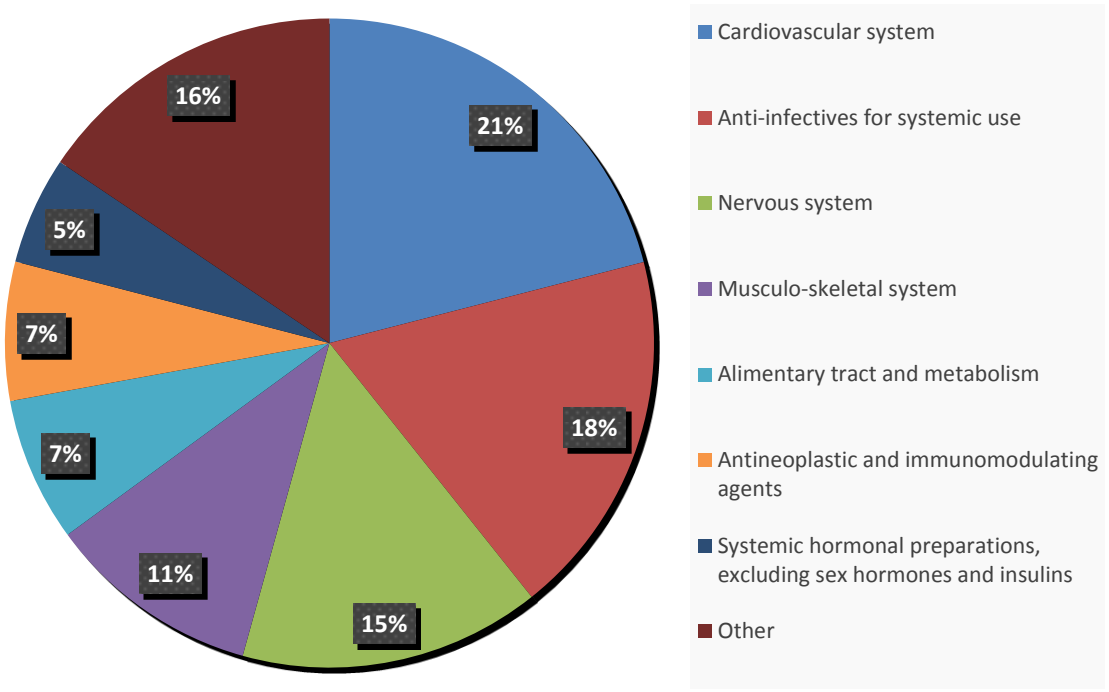

Figure D: The anatomical classification of medications involved in the reported incidents. The anatomical classifications that occurred less than 5% have been subverted into 'Other' on this graph due to their relative infrequency. These include: genitourinary system and sex hormones, respiratory system, blood and blood forming organs, dermatologicals, sensory organs, antiparasitic products, and insecticides and repellents.

QUALITATIVE ANALYSIS

The qualitative analysis was collaboratively conducted by three ISMP Canada analysts, and independently reviewed by a fourth expert ISMP Canada analyst. The summary of the qualitative analysis is outlined below.

INCLUSION

Incidents included in this analysis are those with the potential to harm patients, that is, they were actual incidents (resulted in mild, severe, temporary, or long-term symptoms) or near misses that were caught or intercepted before reaching the patient.

EXCLUSION

Incidents were manually and independently screened by three ISMP Canada analysts. A total of 1520 incidents were excluded from the qualitative analysis with the following exclusion criteria:

1. Incident description without sufficient information on how the error occurred.
2. Billing error with no potential to harm the patient.
3. Incident type "Wrong Prescriber", with no potential to harm the patient.

Table 1: Main theme 1, subthemes, and incident examples

PHARMACY'S ROLE IN CLINICAL DECISIONS Of the reported incidents, 477 were found to be therapeutic interventions by the pharmacy team and caregivers. Appropriateness of the drug, dose, and directions for use were ensured based on individual patient characteristics and indication. Several interventions incorporated the lab values made available during the expanded scope of practice in the fall of 2015.	
Identifying Unintentional Changes • A prescription will often be presented that is different from what the patient currently takes. The pharmacist plays an important role in ensuring that a patient's medication does not change in dose or frequency unless clinically indicated.	"Doctor wrote a [prescription] for Sotalol 80 mg daily. Patient had been taking 40 mg in the morning and 80mg in the evening. Faxed doctor and came back to continue with the 40 mg in the morning and 80 mg in the evening. "
Ensuring Therapeutic Appropriateness • Reviewing patient characteristics prior to prescription dispensing is an essential aspect of the pharmacy field. Identifying contraindications, drug interactions, and the most appropriate therapeutic choices are highlighted in this subtheme.	"[A] patient brought in a prescription for Flagyl® 500 mg bid and had an allergy to it in the past (i.e. swelling). Contacted doctor and got the order changed to clindamycin."
Patient-Specific Dosing Concerns • With the expanding scope of practice, providing pharmacists are provided with access to lab values, and many are taking this opportunity to ensure the patient receives the most appropriate individualized dose. This process has involved calculating doses considering patient weight, serum creatinine, electrolytes, etc.	"Patient has chronic renal disease and order written for Actonel® 150 mg monthly. Based on calculated creatinine clearance the dose needed to be reduced to 70 mg monthly. Faxed the Doctor on two separate occasions to get this order discontinued and if not then the dose reduced. Finally on the second fax the Doctor reduced to 70 mg monthly."

Table 2: Main theme 2, subthemes, and incident examples

PHARMACY'S ROLE IN COMPLIANCE PACKAGING Compliance packaging incidents were associated with 319 incidents. ISMP Canada has previously released a comprehensive multi-incident analysis regarding compliance packaging incidents and should be reviewed (https://www.ismp-canada.org/download/PharmacyConnection/PC2014Winter_PackPreparation.pdf). For this reason, this theme's analysis has identified three concerning subthemes in relation to COMPASS II:	
Dose Omission, Extra, or "Jumper" • During the compliance packaging process, minor physical and mental slips/bumps can result in missing a dose, providing an extra dose, or pushing a dose from one slot to another – i.e. "jumpers".	"Patient has both [Aspirin®] and Coversyl® Plus HD in the morning slot. Pharmacist was checking blister package and because of their slight appearance difference, noticed that 2 tablets of [Aspirin®] were in one slot and 2 tablets of Coversyl® Plus HD was in the slot below."
Wrong Drug, Wrong Dose • Compliance packaging patients are often complex with multiple medications. This complexity can leave patients more prone to dispensing errors such as receiving the wrong drug or wrong dose. Split tablets errors are more difficult to catch in these cases as the instructions are not directly on the medication.	"Nursing home patient with an order to take 1.5 tablets of Vitamin D 1000 IU daily. Medication was packaged as 1 tablet daily."
Regimen Modifications • Compliance packaging requires a large amount of coordination with respect to order entry, refill dates, and the actual packing. This multi-step process can make a simple medication change to the regimen much more complex – an error in one step can result in the patient receiving the wrong drug, wrong dose, wrong strength, wrong frequency, etc.	"Furosemide was stopped in hospital but did not get removed from old blister packs on 1 card that was dispensed, so patient took 1 tablet this morning along with [morning] meds. It was discovered when pharmacist was fixing and checking other cards. Care home owner was notified ..."

Table 3: Main theme 3, subthemes, and incident examples

PHARMACY'S ROLE IN DISPENSING The medication dispensing process involved 1420 incidents. These incidents provide insights into potential system shortcomings, which are further categorized by the type of error. These types of incidents carry different levels of inherent potential harm.	
Wrong Formulation • Various medication formulations, release timing, and coatings, will impact therapeutic efficacy. Medications with multiple formulations – e.g. immediate versus extended release, enteric coating, cream versus ointment, etc. – require additional vigilance during product selection.	"Upon checking refill, [patient]'s wife had mentioned picking up a slow release medication. It was then identified that we had erroneously filled for [immediate release] formulation ..."
Wrong Patient • Dispensing medication to the wrong patient commonly occurs due to look alike/sound alike patient names, or even caregivers, family, or friends presenting a prescription on behalf of the patient. Incorrect labeling or packing can result in a patient receiving someone else's medications.	"The prescription was entered on the wrong patients file. Patients had the same name and error was found on prescription checking by checking the birth date and health number."
Wrong Drug • Medications that look alike/sound alike, or have similar packaging can result in pharmacy staff selecting an incorrect medication, and patients subsequently receiving the wrong medication.	"Refill of prescription for Verapamil 80 mg, [...] filled with Valsartan 80 mg. Client got home and noticed the tablets were brown and not the usual yellow and called store to verify."
Wrong Directions • Dangerous abbreviations, instruction typos, or illegible hand-writing can result in the patient administering the medication incorrectly.	"Incorrectly labelled as QID when it should have been QD"
Wrong Dose • Incidents regarding the wrong dose often involved selecting the incorrect product during the dispensing process, or miscalculating the dose during order entry (see example).	"[Prescription] was for Cipro® XL 1000 mg daily. Entered as PMS-Cipro XL 500 mg daily. Should have been 2 tabs daily."

Table 4: Main theme 4, and incident example

PHARMACY'S ROLE IN OUTPATIENT COMMUNICATION
There were a total of 197 medication incidents identified by patients or caregivers (including nurses at long term care facilities). These incidents highlight the importance of pharmacy's communication with a patient and their health care team regarding administering medications at home.
"Patient's caregiver noticed that bottle labelled for Tamsulosin contained [Synthroid®]. None given to patient"

ACKNOWLEDGEMENTS

ISMP Canada would like to acknowledge the Saskatchewan College of Pharmacy Professionals for its support and facilitation of COMPASS Phase II. The incidents anonymously reported by COMPASS Phase II community pharmacy practitioners to CPhIR were extremely helpful in the preparation of this report.

ISMP Canada would like to acknowledge support from the Ontario Ministry of Health and Long-Term Care for the development of the Community Pharmacy Incident Reporting (CPhIR) Program (http://www.cphir.ca). The CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (https://www.ismp-canada.org/cmirps/index.htm). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings.