PROFESSIONAL RESPONSIBILITY #5

"Members must be diligent in identifying and responding to red flag situations that present in practice."

Drug tapering is a great example of a red flag situation!

Medication Incidents Involving Drug Tapering in Community Pharmacy:

A MULTI-INCIDENT ANALYSIS BY ISMP CANADA

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INTRODUCTION

Prescriptions involving a drug tapering process are often complex in nature, involving multiple, sequential doses of medication(s), extensive directions of use, and complex mathematical calculations.¹⁻³ In addition, the lack of standard-

ized tapering guidelines may explain the fact that in practice, a wide variety of unique tapering regimens are prescribed that do not follow a homogenous, consensus-based pattern. As a result, pharmacists may find it challenging to assess the appropriateness of the prescription, with respect to its efficacy, safety and tolerability for the particular patient. 1-3 All of these considerations illustrate the inherent vulnerability of drug tapering to errors that may occur at any stage of the medication-use process, including prescribing, order entry, dispensing, administration, and/or patient monitoring. As such, further investigation of incident reports may be beneficial to help elucidate a better understanding and appreciation of potential contributing factors that are associated with drug-tapering incidents.

TABLE 1 – THEMES AND SUBTHEMES				
THEME	SUBTHEME			
Lack of standardized tapering guidelines	Prescribing error Miscommunication			
Inadequate patient counseling	Cross-taper Multi-medication compliance aids			
Operational limitations	Labeling restrictions Billing restrictions			
Complexity of prescription	 Calculation error Transcribing error Wrong selection of prescription to be filled Prescription preparation error 			

Drug tapering is defined as the gradual discontinuation or reduction of a therapeutic dose of a particular drug over a period of time. Conversely, drug titration refers to the incremental increase in drug dosage to a level that provides a desired therapeutic effect. In practice, these terms are sometimes used interchangeably to signify gradual dosage change - up or down - to achieve the targeted goal of either discontinuation of therapy, lowered maintenance dose, or optimal therapeutic effect. For this analysis, incidents involving drug tapering as well as drug titration are included, as both are associated with similar challenges and risks for medication errors.

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.⁴ CPhIR has allowed collection of invaluable information to help identify system-based vulnerable areas in order to prevent medication incidents.⁴ This article provides an overview of a multi-incident analysis of drug tapering-related incidents reported to the CPhIR program.

MULTI-INCIDENT ANALYSIS OF DRUG-TAPERING INCIDENTS IN COMMUNITY PHARMACY PRACTICE

Reports of medication incidents involving "taper," "titrate," "wean," "escalate, "de-escalate," "increasing dose," or "decreasing dose" were extracted from the CPhIR Program from 2010 to 2014. In total, 122 incidents met the criteria and were included in this qualitative, multi-incident analysis. The majority of the incidents involved corticosteroid therapy (e.g., prednisone, dexamethasone, budesonide), but antidepressants (e.g., SSRIs, SNRIs, TCAs), pain medications (e.g., opioids, methadone), and anti-epileptics (e.g.,

gabapentin, pregabalin) were also commonly reported.

The 122 medication incidents were independently reviewed by two ISMP Canada Analysts. The incidents were analyzed and categorized into four major themes, all of which are potential contributing factors for drugtapering incidents in community pharmacy practice: (1) lack of standardized tapering guidelines, (2) inadequate patient counseling, (3) operational limitations, and (4) complexity of prescription. The four major themes were further divided into subthemes, as shown in Table 1. Tables 2 to 5 provide further details and incident examples for each subtheme. (Note: The "Incident Examples" provided in Tables 2 to 5 were limited by what was inputted by pharmacy practitioners to the "Incident Description" field of the CPhIR program.)

SUBTHEME	INCIDENT EXAMPLE	COMMENTARY	
Prescribing error	The physician wrote a high dose prednisone prescription that lasted over 14 days, but did not prescribe a tapering regimen thereafter. The prednisone prescription had a quantity of 30 days, but the tapering schedule only lasted for 17 days. The pharmacy technician filled the prescription assuming it was for the full 30 days, but later discovered that the prescription was intended to last only 17 days – 13 extra tablets were then given to the patient.	Standardized, pre-printed order forms for drug tapering prescriptions should be considered in order to encourage complete and accurate communication of information between physician, pharmacist, and patient.	
Miscommunication (i.e. amongst health- care professionals)	The patient brought in a computer generated prescription for prednisone, with the first line of directions stating 'take 6 tabs by mouth for 5 days.' The next line stated 'will wean after seven days' with no additional directions or total quantity given. The patient was not sure about the directions of use either.		

TABLE 3 - THEME #2 INADEQUATE PATIENT COUNSELING

SUBTHEME	INCIDENT EXAMPLE	COMMENTARY
Cross-taper	Patient brought in a new prescription for venlafaxine 150 mg daily, which was to be switched with his old prescription, sertraline 75 mg daily. However, cross-tapering directions were not specified on the prescription, and the patient was unclear on the directions of use as well. The physician was called to obtain these instructions.	Providing patients with a tapering schedule tool (i.e. personalized calendar or booklet) for their reference, may be beneficial to clarify confusing and extensive directions of use. This should be done in conjunction with adequate face-to-face counseling and appropriate follow-up.
Multi-medication compliance aids	The patient's prescriptions were being blister packed for the first time. Because her prednisone prescription was being tapered, it was not included in the blister pack, but in a separate vial instead. Several days later, the patient called the pharmacy to say that she just noticed the additional prednisone vial in the prescription bag and that she missed her doses for the past couple of days. She thought that all of her medications would have been included in the blister pack.	

TABLE 4 - THEME #3 OPERATIONAL LIMITATIONS

SUBTHEME	INCIDENT EXAMPLE	COMMENTARY
Labeling restrictions	The wrong sig (directions of use) was entered during order entry because the original instructions were too long for the space provided. The technician tried to shorten it, but important parts of the instruction were being left out. The prescription label was corrected before reaching the patient.	A helpful feature of the order entry queue would be an "extended labeling" function, where directions longer than the standard spacing restrictions would automatically populate into this new interface. The full directions would then be entered, printed, and affixed to the prescription vial.
Billing restrictions	The prescription was for budesonide 9 mg daily x 6 weeks, followed by 3 mg taper every 2 weeks, for a total duration of 10 weeks. Unfortunately, the patient's drug plan only allowed a month's supply (i.e., 35 days) per prescription fill, so the full supply was not able to be dispensed in one transaction, which added much confusion during prescription order entry. This resulted in a transcribing error on the second part of the prescription, which was logged.	A helpful feature of the order entry queue would be an interface for "chained" or "linked" prescriptions, where the total drug tapering schedule is entered sequentially with start and stop dates automatically populating as directions, durations, and quantities are entered. Another benefit of this feature is that it only allows prescriptions to be filled in sequential order (i.e., prescription in the middle of the chain cannot be selected to be filled), which is also helpful in addressing the following Theme #4 (Complexity of Prescription) – Subtheme #3 (Wrong Selection of Prescription to be Filled) – see Table 5.

TABLE 5 – THEME #4 COMPLEXITY OF PRESCRIPTION

SUBTHEME	INCIDENT EXAMPLE	COMMENTARY	
Calculation error	Prescription for lamotrigine involved a gradual dose titration up before reaching steady maintenance dose. The wrong total quantity was calculated – 448 tablets were given, but should have been 280 tablets.	Independent double checks should be performed for each prescription during the order entry and dispensing process. ⁶ More specifically, rules and policies in the dispensary should be implemented to increase awareness and conscientiousness during the prescription	
Transcribing error (e.g., typo, wrong dose, wrong formulation, wrong frequency, wrong addition/exclusion of refills)	The patient was prescribed a tapering dose of prednisone and given the correct number of tablets to complete it. He noticed 2 refills on the vial, so he called the pharmacy for the repeat prescription. As he was leaving with the medication, he asked if he should start with taking 8 tablets again and wean down. The pharmacist looked up the original prescription and noted that there were no refills prescribed. The pharmacist took back the medication and explained that he had completed his therapy.		
Wrong selection of prescription to be filled	The prescription was written for an increasing dose titration for galantamine. On June 28th, the 8 mg strength was filled, while the 16 mg was logged for July, and the 24 mg was logged for August. When the patient came in for a refill in July, the 24 mg prescription was filled in error, skipping the 16 mg dose. The patient felt unwell after taking 1 dose, and returned to pharmacy.	preparation process. For example, calculations should be documented by both the order entry staff as well as the independent double-checker to enhance accuracy.	
Prescription preparation error	Prescription was written for 'prednisone 50 mg daily x 5 days, then taper by 5 mg every 3rd day until discontinued.' Prescription was filled as prednisone 50 mg — take 10 tablets once daily for 5 days, then taper by 1 tablet (5 mg) every 3rd day until discontinued. Prescription should have been filled with Prednisone 5 mg tablets, not 50 mg tablets. The error was picked up when the pharmacist was checking the prescription.		

THE IMPORTANCE OF DRUG TAPERING

Drug tapering can be a very long and arduous process fraught with confusion, miscommunication and medication errors, as demonstrated in the incident examples from Tables 2-5. But there are specific scenarios that warrant its use. First, drug tapering is important to help prevent adverse drug withdrawal reactions that would otherwise be very difficult and challenging for patients to

withstand.⁵ Second, the gradual and sequential reduction in dose allows for early detection of return of condition/symptom(s) being treated.⁵ These symptoms can be mitigated immediately with a consequent increase in dose, followed by close monitoring. Both of these beneficial effects of drug tapering ultimately help to increase patient tolerability and overall comfort, which is one of the key goals to pharmaceutical care and patient-centred care.

CONCLUSION

Errors associated with drug tapering regimens occur on all levels of patient care that involve physicians, pharmacists, patients, and caregivers alike. Learning from medication incidents is an imperative step in improving medication-use systems. Future development of a general framework for drug tapering (e.g. aggressive or conservative regimens) may be helpful for prescribers in clarifying safe

and effective drug tapering methods. The objective of this multi-incident analysis was to identify potential systems-based contributing factors and areas of vulnerability towards medication incidents involving drug tapering. It is hoped that these insights can pave way for future developments in quality improvement initiatives at the local, provincial and national levels

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CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (http://www.ismpcanada.org/cmirps.htm). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings. The incidents anonymously reported by community pharmacy practitioners to CPhIR were extremely helpful in the preparation of this article.

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BULLETIN BOARD

RUBBING ALCOHOL COMPOUND ALERT

The Alberta College of Pharmacists has recently received a number of reports of individuals being admitted to emergency departments with alcohol toxicity, having consumed rubbing alcohol compound and isopropyl alcohol purchased from pharmacies.

Ontario pharmacists should watch for customers purchasing frequent or large amounts of rubbing alcohol compound and isopropyl alcohol. Pharmacies that notice a high number of customers in their community displaying these behaviours may wish to store these products behind the counter and avoid promoting these products in sale flyers and advertisements. All pharmacies should ensure that alcohol products are stored in an area where sales can be monitored.

NAPRA'S PHARMACISTS' GATEWAY CANADA

On August 20, 2014 the National Association of Pharmacy Regulatory Authorities (NAPRA) launched its Pharmacists' Gateway Canada — a new, national approach to facilitate the pharmacist licensure process for applicants who graduated with a pharmacy degree not accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).

The new registration portal is now the first point of contact for internationally educated pharmacist applicants, including graduates from an Americanaccredited pharmacy degree program. The Gateway is meant to eliminate duplication and create a fair, consistent approach to registration in all Canadian provinces.

All internationally educated pharmacist applicants who wish to be licensed to practise pharmacy in Ontario will follow the new procedure within the Gateway.

The Gateway provides a website with key information online and through telephone support, and features two self-assessment tools that assist internationally educated pharmacist applicants in making informed decisions before starting the process to become licensed as a pharmacist in Canada.

The Gateway is a simple, transparent and safe way to facilitate licensure for internationally educated pharmacist applicants wishing to live and work in Canada.