

THE ONTARIO COLLEGE OF PHARMACISTS

NON-STERILE COMPOUNDING STANDARDS

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COUNCIL MEMBERS

Elected Council Members are listed below according to District. PM indicates a public member appointed by the Lieutenant-Governor-in-Council. U of T indicates the Dean of the Leslie Dan Faculty of Pharmacy, University of Toronto. U of W indicates the Hallman Director, School of Pharmacy, University of Waterloo.

- H Régis Vaillancourt
- H Nadia Facca
- K Esmail Merani
- K Tracey Phillips
- L Billy Cheung
- L James Morrison
- L Sony Poulose
- M Mike Hannalah
- M Kvro Maseh
- M Laura Weyland
- (President)
- N Tom Kontio
- N Karen Riley
- N Leigh Smith
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- T Ruth-Ann Plaxton
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- U of T Christine Allen U of W David Edwards

- **Statutory Committees**
- Accreditation
- Discipline
- Executive Fitness to Practise
- Inquiries Complaints & Reports
- Patient Relations
- Quality Assurance
- Registration

Standing Committees

- Drug Preparation Premises
- Elections
- Finance & Audit
- Professional Practice



(2019-2021) OCP STRATEGIC FRAMEWORK

VISION

A trusted, collaborative leader that protects the public and drives quality and safe pharmacy care and improved patient outcomes.



MISSION

The Ontario College of Pharmacists regulates pharmacy practice to serve the interests, health and wellbeing of the public.



VALUES

ACCOUNTABILITY

INTEGRITY

TRANSPARENCY



STRATEGIC PRIORITIES

Enhance system and patient outcomes through collaboration and optimization of current scope of practice

Strengthen trust and confidence in the College's role and value as a patients-first regulator

Enhance the College's capacity to address emerging opportunities and advance quality and safe pharmacy practice and regulatory excellence



The objectives of *Pharmacy Connection* are to communicate information about College activities and policies as well as provincial and federal initiatives affecting the profession; to encourage dialogue and discuss issues of interest to pharmacists, pharmacy technicians and applicants; to promote interprofessional collaboration of members with other allied health care professionals; and to communicate our role to members and stakeholders as regulator of the profession in the public interest.

We publish four times a year, in the Fall, Winter, Spring and Summer.

We also invite you to share your comments, suggestions or criticisms by letter to the Editor. Letters considered for reprinting must include the author's name, address and telephone number. The opinions expressed in this publication do not necessarily represent the views or official position of the Ontario College of Pharmacists.

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Nancy Lum-Wilson, R.Ph., B.Sc.Phm., MBA **CEO and Registrar**

Dear Colleagues,

I recently attended an event to hear Harry Cayton, a renowned expert and authority in regulatory reform, talk about his views on the transformation of how professions are regulated and the role of oversight authorities around the globe. Among the many powerful messages he shared with audience members, one

in particular resonated with me: "Regulation provides a framework in which professionalism can flourish."

Such a powerful message, but also a simple one. Oftentimes, pharmacy professionals view their regulator as "the stick" and ultimately, the regulator does have a critical role to play in serving and protecting the public by creating and enabling the right systems, structures, programs and guidance to promote quality, safe and ethical pharmacy care. But there is also a role that pharmacy professionals must play to protect the profession in which they have chosen to practice. This means not only ensuring patients are first in every professional decision that's made, but also in upholding the high ethical principles and standards that made pharmacists one of the most trusted healthcare professionals in the first place.

Regulation provides a framework in which professionalism can flourish.

Earlier in March I was privileged to help launch Pharmacist Awareness Month at the Leslie Dan Faculty of Pharmacy to celebrate the invaluable role that pharmacists — and pharmacy technicians — play in our health system and in the lives of patients. It was my pleasure to do so as both as the CEO and Registrar of the College and as a fellow pharmacist.

As I reflected on why I chose a career to serve the public and patients, I was reminded that those in our chosen profession had similar if not the same thinking – that the calling to help those in need, to gain the knowledge that's necessary to practice in a specialized field, to become a *Professional* – was at the core of that decision. But what does it mean to be a *Professional?* With the title comes responsibility.

Professionalism isn't something that we do, but something that guides our actions. It is something that we feel and believe in. It is the foundation of our oath to serve and protect our patients and uphold our fiduciary duty as a regulated health professional.

Indeed, patients rely on the skill and expertise of pharmacy professionals every day in this province, and we expect that the role of pharmacists and pharmacy technicians as health professionals in Ontario will evolve over time just as the needs and expectations of patients evolve. Yet while we need to take these opportunities to recognize and celebrate our individual and collective *professionalism*, we must also work together to nurture it.

We all need to support one another and get the message out there that each one of us has a role to play when it comes to representing what the profession of pharmacy stands for. We must lead by example and hold ourselves and each other accountable for our actions, just as we celebrate the many accomplishments and contributions that pharmacists and pharmacy technicians make to the health and quality of life of patients every day.

Sincerely,

Nancy Lum-Wilson

CEO and Registrar

Ontario College of Pharmacists

DECEMBER 2018 COUNCII MEETING

As recorded following Council's regularly scheduled meeting held on December 10th, 2018.

IMPLEMENTATION PLAN FOR MODEL STANDARDS **OF PHARMACY** COMPOUNDING **OF NON-STERILE** PREPARATIONS ADOPTED

In 2017 Council approved the adoption of the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Pharmacy Compounding of Non-Sterile Preparations. These Standards will come into effect in each province/territory once they have been adopted or adapted by the respective provincial/territorial pharmacy regulatory authorities (PRAs).

At its December 2018 meeting, Council discussed, and subsequently approved, moving forward with a national multiphase implementation plan for these Standards that would allow for an opportunity to leverage resources and apply a consistent approach across the country. Timelines for implementation of the Standards are as follows:

- Phase 1 Assessing Risks and Gaps Date: January 1, 2020
- Phase 2 Personnel Training and Quality Assurance Date: July 1, 2020
- Phase 3 Facilities and Equipment Date: January 1, 2021

The College will develop and implement an education and communication plan to support the implementation in Ontario. In the meantime, the College has already directed pharmacy professionals to begin to identify their knowledge needs and assess gaps between the Standards and their current practice and compounding environment. Please visit the Kev Initiatives section of the website for further details.

COUNCIL APPROVES BYLAW AMENDMENTS **AND 2019 FEES**

In September 2018, Council approved for circulation bylaw amendments that align the public register bylaws with requirements following the proclamation of the Protecting Patients Act 2017, enable fee changes proposed in the 2019 Operational Budget and prepare for the future approval of new Quality Assurance and Registration regulations that will remove the student class for pharmacists and introduce an intern class for pharmacy technicians.

The fee changes proposed will enable the College to deliver on operational imperatives that advance the vision, mission and strategic priorities in the newly created Strategic Plan.

These are outlined in the operational plan and budget approved by Council in September, and are publicly available online in the September Council Meeting materials. Among other things, these priorities include the roll-out of the Medication Safety Program, our response to the increasing complexity and volume of complaints, reports and investigations, and the development of a comprehensive and formal data strategy that will improve our ability to report on and demonstrate regulatory performance and make evidenceinformed decisions.

At its December 2018 meeting, Council considered the feedback received through the consultation and discussed the need to move forward with the fee increases to adequately fund the College's activities to fulfill its public-protection mandate and fiduciary responsibilities. Council subsequently approved the bylaw amendments, including the fee changes for 2019, which are effective January 1, 2019.

Following Council's approval of the bylaw amendments and fees, and in consideration of the feedback received during the consultation, the College will continue to rigorously examine work processes to find efficiencies while strengthening its ability to act on

its mandate. It will also examine cost recovery options in cases of misconduct findings, consider alternative ways of communicating information about the College's finances and fiscal stewardship, and better inform registrants about the College's regulatory role versus that of professional bodies or associations.

Please refer to the <u>news item on our website</u> regarding Council's approval of bylaw amendments and fee changes for more information.

COLLEGE TO DEVELOP DISCIPLINE COST RECOVERY POLICY

While the College does, in most cases, seek costs from members found guilty of professional or proprietary misconduct, the actual costs incurred by the College related to such proceedings are significantly higher than what is ordered by the Discipline Committee to be recovered. The College's current approach to cost awards is based on precedents and can vary depending on the details of the case.

To increase the proportion of discipline costs that are recovered from subjects of disciplinary processes and to decrease the financial burden on the rest of the profession, College staff proposed developing a policy that would formalize the criteria and manner in which cost awards are sought when allegations of professional or propriety misconduct are proven. Council accepted the recommendation and directed staff to draft such an operational policy and report final recommendations to Council at its next meeting.

GOVERNANCE RENEWAL PARTNERSHIP TO MOVE FORWARD

At its December 2018 meeting, Council considered a recommendation to join other Advisory Group for Regulatory Excellence (AGRE) colleges in developing options for legislative changes to support the government in modernizing governance that considers provincial, national and international trends and best practices in health regulation. This includes the adoption of a governance renewal framework aimed at reducing the size and adjusting the composition of Council, separation of Council and statutory committees, and supporting competency-based Council appointments.

Council agreed to support the collaboration with AGRE and approved the governance reform framework and principles. Please see the <u>Council materials for December 2018</u> for more information.

An update on the progress of governance reform is expected at the next Council meeting.

COUNCIL APPROVES AN OPIOID POLICY FOR PHARMACY

Last year, the College developed an Opioid Strategy to address relevant areas of practice while considering the health and social factors that are related to opioid use disorder. One of the initiatives identified within the Strategy was the development of an <u>Opioid Policy</u> to outline the College's expectations for pharmacy professionals regarding opioid therapy.

In September 2018, a draft Opioid Policy was circulated for open consultation before being brought to Council for final review and approval. Based on the analysis of the feedback received through the consultation, revisions to the policy were made and presented to Council, which approved the amended policy at its December 2018 meeting.

The revised policy has now been posted to the <u>Practice Policies and Guidelines section</u> of our website. Further information about the policy will be broadly communicated over the coming weeks and months.

COUNCIL SUPPORTS EXPLORING A PROVINCIAL PHARMACY SAFETY INITIATIVE WITH THE ONTARIO ASSOCIATION OF CHIEFS OF POLICE

Council welcomed a presentation by Mr. Barry Horrobin of the Ontario Association of Chiefs of Police (OACP) who outlined the opportunity to engage with the College and explore options for a pharmacy safety initiative aimed at helping to curb the incidence and impact of robberies and thefts in pharmacies. Such crimes are often committed by individuals in search of opioids, which are then frequently used for trafficking. Efforts to reduce diversion of these drugs through theft from pharmacies would be aligned with the harm reduction component of the College's Opioid Strategy.

Following the presentation and after considering staff recommendations, Council agreed that the College should engage with the OACP for the purpose of exploring the most appropriate options to collaborate in a provincial pharmacy safety initiative. College staff will now identify next steps including reviewing and analyzing the potential benefits of a province-wide initiative and consider options for implementation. A progress update is expected to be shared at an upcoming Council meeting.

COUNCIL CONSIDERS POTENTIAL CONCERNS RELATED TO PREFERRED PROVIDER NETWORKS

Council discussed the matter of Preferred Provider Networks (PPNs) as it relates to the College's regulatory mandate. Please see the briefing note available in the Council meeting materials online for details.

Although the College does not have legislative or regulatory jurisdiction to restrict the use of PPNs and has not been presented with any evidence that would cause it to conclude that PPNs are in violation of any regulations or the Code of Ethics, the College would have concerns should any established or emerging business model restrict, prevent or create new barriers to pharmacies or pharmacy professionals from being able to act on their professional obligations.

Council subsequently directed the Registrar to formally communicate its concerns about the impact of closed preferred provider networks (PPNs) on patient well-being and suggest government encourage employers and unions to support open PPN models. Communication to government about the impact on patients, and the potential to enhance access to care through an open PPN model, would be aligned with the College's mandate to serve the public interest and improve patients' well-being.

In the meantime, the College continues to remind registrants that they are expected to practice in accordance with the <u>Standards of Practice</u> and to ensure that continuity of care, access to care and patient safety is not compromised, regardless of whether there are multiple providers involved in the care of a patient.

COUNCIL SUPPORTS RENAMING THE COLLEGE TO BETTER REFLECT ITS OVERSIGHT ROLE

Council passed a motion to formally express to government Council's desire to change the name of the College to the Ontario College of Pharmacy to more accurately reflect its mandate of regulating pharmacists, pharmacy technicians and pharmacies in the public interest. It is recognized that for a new name to take effect, the provincial government must approve the name and amendments would need to be made to various pieces of provincial legislation. As this process can take some time and subject to government approval, no timeline has been established.

COUNCIL MEETINGS IN 2019:

- March 25, 2019
- June 17, 2019
- Sept. 16 Sept. 17, 2019
- Dec. 09. 2019

Council meetings are open to the public, and are held at the College: 483 Huron Street, Toronto, ON M5R 2R4. Highlights are tweeted throughout the meeting. If you plan to attend, or for more information, please contact Sarah MacDougall at smacdougall@ocpinfo.com.





This feature in *Pharmacy Connection* is a place to find information about news stories we're following. Here, you'll read summaries of recent stories relating to pharmacy in Ontario and Canada. For the latest updates, stay tuned to <u>e-Connect</u> and <u>www.ocpinfo.com</u>

REGULATION OF MEDICAL DEVICES TO BE STRENGTHENED

Canada's Health Minister Ginette Petitpas
Taylor "directed Health Canada to bring forward
a comprehensive action plan to better police
problematic devices, more transparently report
their risks to the public and improve how the
regulator approves devices." The <u>Action Plan</u> is now
available. A number of stories reported in the media
previously highlighted examples of where a patient's
health was impacted following implantation of highrisk products banned from other countries.

PROVINCE ANNOUNCES CHANGES TO OHIP+ COVERAGES

As announced by the provincial government, effective April 1, 2019, <u>private insurance plans</u> will now become the "first payer" for prescription medications. Children and young adults who are not covered by private health insurance will continue to get their prescriptions covered free of charge.

STUDY FINDS UP TO ONE-FIFTH OF OPIOID PATIENTS ON LOWER DOSES INCREASED THEIR DOSE ABOVE RECOMMENDED LEVELS

A national study of more than six million prescription claims found that as many as <u>one-fifth of patients</u> taking opioids had their dose increased above recommended levels. The study urges healthcare professionals to refrain from continually increasing opioid doses if patients are not reaching their goals within the recommended limits.

PHARMACY IN THE 21ST CENTURY

A group of pharmacist-researchers from the Ontario Pharmacy Evidence Network is calling for the pharmacy profession to make fundamental changes to effectively and safely meet society's health care needs. An overview of these recommendations is captured in a peer-reviewed paper published in February 2019 in the Canadian Pharmacists Journal (CPJ/RPC). The research was supported by the Ontario College of Pharmacists and Ontario Pharmacy Evidence Network.

NEW OPIOID MEDICATION WILL REPLACE DAILY DOSES WITH MONTHLY INJECTION

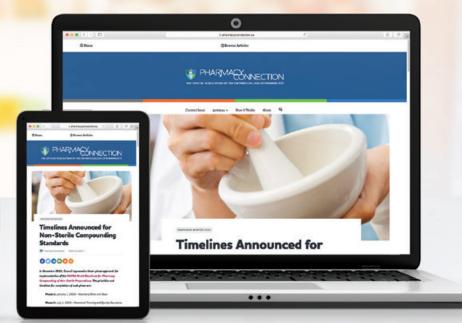
Patients with an opioid use disorder who have difficulty taking medication every day may be able to benefit from a monthly injectable form of Suboxone® called SublocadeTM. The drug is expected to be available to Canadians by the second half of 2019.

HEALTH CANADA RELEASES DATA ON CANNABIS USE IN CANADA

Health Canada released its <u>2018 Canadian</u> <u>Cannabis Survey</u> in November 2018 which provides a snapshot of the views and habits of 13,000 Canadians between May and July 2018 related to cannabis, including how much and how often they use cannabis, what forms of cannabis they consume, what they think about its potential to be habit forming, and more.

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Approach is Effective IN FOSTERING PATIENT DIALOGUE AND EDUCATION

In this four-part series, the College focuses on each domain of the community pharmacist practice assessment while incorporating trends seen in practice by the College's community practice advisors (CPAs). This final instalment focuses on the Communication and Education domain. The previous domains examined in the past three issues can be viewed by visiting Practice Assessments Practice Tool on the website as well as in our archived Pharmacy Connection stories available on our website library or at pharmacyconnection.ca.

STANDARDS OF PRACTICE

Communication and Education are critical aspects to delivering optimal patient care and comprise one of the four domains evaluated during a pharmacist practice assessment Good communication skills, both verbal and written, are essential for providing appropriate and comprehensive patient care.

Pharmacists must also be able to provide information and educate their patients to help them make informed decisions and receive the intended benefits of their medications or therapies. Engaging sound communication strategies enables pharmacists to gauge patient comprehension which is paramount to ensuring medication regimens are successfully implemented.

The use of open-ended questions during assessments with patients and/or their advocates is a useful technique shared by CPAs as it encourages dialogue and avoids the yes/no answers that hinder free-flowing conversation that can be crucial to the delivery

of safe and quality patient care. Imparting information in a conversational tone, making eye contact and asking patients questions (such as what they know about the medication and what their doctor has told them about the medication) helps to foster effective care-focused dialogue between both the patient and the professional. Closing a consultation by inviting questions or asking the patient to repeat the information they found important are other communication tools commonly suggested by CPAs.

MUTUALLY BENEFICIAL

In the course of a consultation, it is the pharmacist's role to instruct patients to take medication appropriately and also to confirm the medication is therapeutically appropriate. Taking time from a busy environment to communicate with patients is a mutually beneficial activity as engaging with patients at each encounter can create an opportunity for collaboration in the course of their care and ensure each medication is indicated and still effective — such as in the case of refills.

Active listening by pharmacists is important as it ensures patient questions, needs and concerns are both understood and being addressed. A first step is being aware of a patient's health conditions that require appropriate verbal and non-verbal adjustments such as situations in which a patient is hearing impaired. It is important that pharmacists recognize that patients may have various communication or comprehension barriers that may or may not be readily apparent and that these need to be accommodated.

CPAs encourage pharmacists to give their full attention to patients during counselling. Some suggestions include avoiding documenting as you speak in order to focus on non-verbal patient cues such as surprise and distress, taking the time to acknowledge and respond to the patient's reaction with empathy. Professionals can also use relevant information to identify drug therapy problems and/or issues that have the potential to affect the optimization of health outcomes (patient issues, patient-specific needs) and to create, adjust or review the patient profile.

PATIENT FOLLOW-UP

CPAs have emphasized the need for pharmacy staff to ensure patients receive counselling for prescriptions flagged specifically for patient follow-up. Counselling is not an option left to the discretion of the patient because pharmacists must acquire all required therapeutic information about the patient and the prescription in order to make a proper assessment. This is a part of the Standards of Practice.

Interaction within a pharmacy extends beyond the patient to encompass the pharmacy team and other healthcare professionals to ensure continuity of care. Communication can take the form of a phone call, written note, face-to-face conversation, sometimes through an agent or third party. Several options exist to ensure information is shared in an appropriate manner to each audience within scope. Each situation may necessitate a unique combination of communication tools to support effective and safe patient care.

PATIENT SCENARIO

The past three issues of the practice assessment series in Pharmacy Connection has featured the following patient scenario to reinforce learning:

The patient is a 59-year-old male who has filled his prescriptions at the pharmacy for about one year. His

patient profile shows that his medical conditions are type 2 diabetes, dyslipidemia and osteoarthritis and he is also a smoker. He fills his medications mostly on time, doesn't say much when picking up his medications and you haven't noticed any changes on his prescriptions profile. He is currently on:

- Atorvastatin 10mg once daily
- Metformin 1000mg twice daily
- Gliclazide MR 30mg daily
- Venlafaxine 150mg once daily

The prescriptions were written six months ago, with a one year supply. There is nothing on file that indicates whether he is on any over-the-counter medications or natural health products. It is not likely that he will have any kind of follow-up until his refills run out.

In looking at this patient case, what decisions may be made during the course of the interaction?

Consider the following:

- What type of conversation would you engage in with this patient?
- What tools could you use to help guide this conversation?
- What special considerations would you be mindful of?
- What needs to be communicated to the patient and is any additional education needed?

Begin the conversation by asking him open-ended questions such as: How well are your medications working for you? Are you experiencing any sideeffects? Have you recently had bloodwork? Did you get the results? Have you tried to quit smoking?

Use the IESU (Indicated, Effective, Safe, Use) tool to guide the conversation and engage in active listening. Watch for non-verbal cues to learn if the patient has misgivings about his course of treatment and if he has specific concerns. If the pharmacy is busy and you sense the patient is self-conscious about the conversation being overheard by others, continue the dialogue in a more private area.



INTERACTIVE APPROACH

Pharmacy professionals may also adopt a more interactive approach in this type of scenario. An example is to provide education to the patient but ensure it's a conversation, not a monologue. Guide the dialogue to cover appropriate questions pertaining to reassessing, asking for changes, new information, etc. Ask about his use of over-the-counter medications and natural health products.

You may also consider providing a written communication to follow-up with the physician

regarding a monitoring parameter for diabetes and perhaps the need for patient follow-up or communicating something new that was discovered in the course of conversation. When doing so, it's important to ensure that the written communication is clear and concise, free of spelling/grammar issues and is generally relevant, professional and organized.

Wrap up the conversation to confirm the patient's level of understanding through questioning that encourages further feedback to make sure the patient hasn't misunderstood something previously or during this interaction. Before he leaves, ask the patient if he has any questions.

Finally, consider how you will document or communicate within the healthcare team (including within the pharmacy team) to make sure that new information is noted to others to help ensure continuity within the pharmacy and the patient's broader healthcare team.

RESOURCES RELATED TO PHARMACY COMMUNICATION AND EDUCATION

- Code of Ethics
- <u>Code of Ethics Module: Principle of Respect for</u> Persons/Justice
- <u>Practice assessment criteria for pharmacists Communication & Education</u>
- Article Close Up on Complaints: The Importance of Sensitivity and Communication (Fall 2015)
- <u>Video Optimizing Patient Care: Motivating Patients</u> to Promote Adherence
- Chat, Check, Chart (Alberta College of Pharmacy)

How a pharmacist's open-ended approach to patient counselling can help overcome assumptions related to the indication of a medication (in this case, metformin).

Using a one-sided monologue, the pharmacist:

- Begins counselling by telling a patient that he/ she must have diabetes as metformin has been prescribed.
- Does not confirm this indication and continues with regular counselling for metformin without encouraging patient feedback.
- Does not make eye contact with the patient to confirm that he/she is listening or is confused/ upset by the indication being discussed.

Using open-ended questions, the pharmacist:

- Begins by asking such questions as "what did you see the doctor for today?" and "what has your doctor prescribed this medications for?"
- Could have learned the medication is for an off-label use – PCOS (polycystic ovarian syndrome) for young women on metformin.
- Could have learned the indication is for arthritic pain and the prescriber meant to give meloxicam.
 The electronic software used by the prescriber auto-populated the drug and directions on the prescription. The prescriber did not have an opportunity to check the prescription for accuracy before sending it to the pharmacy via fax.



The College will be hosting a series of Regional Meetings this spring at various locations across the province. Space is limited so be sure to promptly register for this free event at a location below:

- Thunder Bay: April 29, 2019
- Peterborough: May 2, 2019
- Ottawa: May 6, 2019
- Greater Toronto Area:
 - o Markham: May 14, 2019
 - o West Toronto: May 29, 2019
- Sudbury: May 16, 2019
- London: May 27, 2019
- Windsor: June 10, 2019

OUTCOMES MATTER: PROMOTING A DATA AND QUALITY CULTURE IN PHARMACY

During the Regional Meeting sessions, registrants will get the latest updates about the College's transformative approach to using data to inform regulatory programs and sector performance in order to achieve better patient outcomes.

Following an update from College representatives on several key initiatives and regulatory programs,

participants will engage in a facilitated session designed to identify best approaches to using data and evidence in promoting quality in their everyday practice. Participants will also discuss solutions to potential barriers that challenge professionals from adopting a quality culture in their pharmacies.

A particular focus of the discussion will be the Assurance and Improvement in Medication Safety (AIMS) Program rolling out to all community pharmacies in Ontario as well as the introduction of Quality Indicators for Pharmacy. To support the discussion, participants will review the selected outcome indicators as well as preliminary aggregate medication incident data collected through the AIMS Program.

Register now to attend a Regional Meeting. For those who can't attend in person, we will be <u>live webcasting</u> the meeting in Markham on May 14, 2019.

All meetings will be hosted from approximately 6:00 p.m. to 8:30 p.m. Refreshments will be provided.



related deaths, a significant rise from 20161.

The College has instituted an Opioid Strategy to address opioid related issues relevant to pharmacy practice in alignment with its mandate to serve and protect the public. The College's Opioid Strategy focuses on advancing opioid-related education, harm reduction initiatives, strategies to prevent opioid use disorder, and promoting quality assurance specific to opioid security and dispensing.

One of the key commitments of the Opioid Strategy was

the development of an Opioid Policy. The College engaged an external working group comprised of representatives from key stakeholder groups, pharmacy professionals from various geographic areas and practice settings, and persons with lived experience to assist in the development of the Policy. The College considered feedback from registrants and the public received through an open consultation and formally presented a Policy to Council

in December 2018. The Policy was subsequently approved and posted on the College website.

OPIOID POLICY RECOGNIZES THE IMPORTANT ROLE OF PHARMACISTS AND **PHARMACY TECHNICIANS**

The Opioid Policy was developed to support the College's mandate to serve and protect the public interest and is grounded in the following principles:

- Pharmacy professionals should employ the same respectful, patient-centered, professional approaches and attitudes towards all patients receiving opioid therapy, regardless of indication
- Pharmacy practice should be in alignment with the federal and provincial strategies and <u>HQO Quality</u> <u>Standards</u> with regards to opioids
- Pharmacists should abide by the most recent clinical practice guidelines and the appropriate standards

- of practice to ensure best patient outcomes for individuals on opioid therapy
- Pharmacists play an important role in ensuring appropriate access to controlled substances
- Pharmacists must abide by specific requirements when providing Opioid Agonist Treatment

The Policy consists of seven components aimed at supporting quality pharmacy care involving opioids. These are:







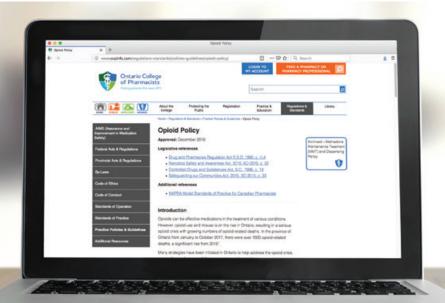








The Opioid Policy sets expectations regarding safe and appropriate opioid use through education and training, sharing of evidence-based best practice and outlining expectations. The policy also provides further direction to pharmacy professionals regarding the <u>NAPRA Model Standards of Practice</u> and is applicable to any opioid therapy regardless of the indication or practice setting. This policy is not intended to be clinical in nature, or duplicate information contained in other guidelines, policies, or resource documents.



All pharmacy professionals are strongly encouraged to review the Policy on the College's website. In addition to thoroughly reviewing the Opioid Policy, pharmacists should supplement their knowledge with opioid-related educational material including the <u>Practice Tools</u> on the College website to ensure they provide optimal care to all patients on opioid therapy.

¹MOHLTC. Newsroom: https://news.ontario.ca/mohltc/en/2018/3/ontario-moving-quickly-to-expand-life-saving-overdose-prevention-programs.html. Accessed July 6, 2018.

DID YOU KNOW?

Health Quality Ontario (HQO) has established <u>Quality Standards</u> addressing opioid prescribing for acute and chronic pain management, and opioid use disorder treatment to provide guidance for prescribing practices.

THE ROLE OF PHARMACY IN SUPPORTING VULNERABLE COMMUNITIES

Last fall, representatives of the College joined several other health system stakeholders and regulators at a community consultation meeting in Kingston to discuss the impact of opioids on Northern Ontario communities. A state of emergency has been declared in the James Bay Coastal and the Mushkegowuk regions of the province in response to the impact that diversion has had on those communities.

Attendees were presented with information that demonstrated the importance of cultural awareness about the unique challenges experienced in indigenous communities and the relationship to diversion of opioids. Participants also heard that opioids distributed locally in one area of the province could even find its way to northern communities as dealers become more sophisticated with ways to distribute narcotics to populations disproportionately affected by the public health impact of opioid misuse.

The meeting brought critical awareness on two issues:

First, that prescribers of narcotics and pharmacy professionals play an incredibly important role in the appropriate management of narcotics and have a responsibility to do everything possible to prevent the misuse of narcotics under their control. This includes prevention of loss and theft of controlled substances, identifying forgeries and tampering and

collaborating with prescribers should there be any questions related to the legitimacy of a prescription. Please see the article on <u>Preventing Drug Diversion</u> in the Fall 2017 edition of *Pharmacy Connection*.

Second, that there should be greater acknowledgement and awareness of the unique health needs of the diverse communities and cultures we collectively serve. Other regulators, such as the British Columbia College of Pharmacists, have taken important steps to educate registrants regarding cultural safety and humility in their role as healthcare providers. In this province, the College of Physicians and Surgeons of Ontario and Royal College of Dental Surgeons of Ontario have developed programs to build awareness of the role their registrants play in supporting the healthcare needs of various populations and cultures, including indigenous peoples.

Recently, the College's Patient Relations Committee discussed how we as the province's pharmacy regulator can better support cultural competency within the profession, complementing the existing tools and resources that the College already makes available to registrants. This is an area of development for the College and we expect to share more with registrants over the coming months.

White Coat Ceremonies at

UNIVERSITY OF TORONTO and UNIVERSITY OF WATERLOO

The University of Toronto and University of Waterloo recently hosted ceremonies to formally mark the beginning of incoming pharmacy students' professional journey. During the ceremonies, students make their commitment to ethics and integrity and are welcomed into the professional community.

College CEO and Registrar Nancy Lum-Wilson participated in the ceremonies.



College CEO and Registrar Nancy Lum-Wilson addresses guests attending White Coat Ceremonies at the Leslie Dan Faculty of Pharmacy at the University of Toronto. (Photo courtesy of the Pharmakon Year Book Club.)



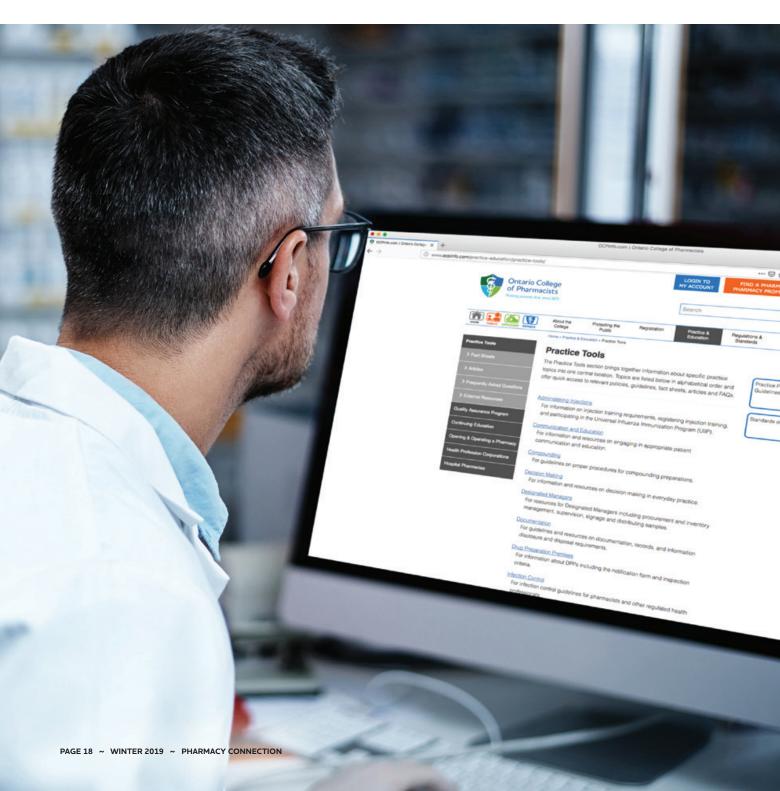


College CEO and Registrar Nancy Lum-Wilson with Christine Allen, Interim Dean, Leslie Dan Faculty of Pharmacy at the University of Toronto. (Photo courtesy of the Pharmakon Year Book Club.)



When Might **Connecting** To A College Practice Consultant Be

BENEFICIAL TO YOU?



One of the ways the College fulfills its mandate to serve and protect the public is by developing and enforcing pharmacy standards, policies and guidelines and the Code of Ethics, which outline the professional obligations of pharmacists and pharmacy technicians. Alongside legislation, these documents create a framework for pharmacy professionals to practice independently, using their knowledge, skills and judgment.

The College provides access to Practice Consultants who support registrants in navigating this framework and, ultimately, providing safe and ethical patient care. The following FAQs outline what to expect when contacting Pharmacy Practice.

CAN YOU EXPLAIN WHAT A PRACTICE CONSULTANT CAN DO FOR ME?

A Practice Consultant is familiar with the detailed content of the Code of Ethics, Standards of Practice and Practice Policy and Guidelines of the College and will refer you to the most appropriate resource(s) for your inquiry. Practice Consultants are also well-versed in, and can guide you to, the relevant Practice Tools, other resources, and overall content of the OCP website. Practice Tools bring together information about specific practice topics into one central location. Topics are listed in alphabetical order and offer quick access to relevant policies, guidelines, fact sheets, articles and FAQs.

While Practice Consultants are conversant in pharmacy-related legislation, it is important to be aware that they cannot interpret legislation or provide legal advice. They may assist in identifying and evaluating the options and risks involved in taking various courses of action with the intention to support an individual's decision-making process.

Practice Consultants cannot provide opinions, operational advice, or clinical information. It is also important to recognize and respect that each registrant is a self-regulated professional, responsible for his/ her own decisions and actions. Practice Consultants cannot direct a pharmacy professional on what to do, intervene in a situation, or evaluate or approve a proposed business concept. When applicable, they may refer you to external resources for guidance on issues that are not within the College's mandate.

WHAT IS THE BEST WAY TO REACH A PRACTICE CONSULTANT?

You can email pharmacypractice@ocpinfo.com at any time or call the College at 416-962-4861 ext. 2210 during regular business hours.

Phone calls and emails are answered in the order in which they are received; one method does not take priority over another. However, communicating by email makes it easier to receive a reply at your convenience and also facilitates sending links to recommended resources. Practice Consultants strive for a high level of service with the goal of providing timely responses to all inquiries. Please allow up to three (3) business days for a reply before following up. Multiple points of contact are discouraged as this creates inefficiencies and prolongs response times to inquiries.

WHAT IF I HAVE AN URGENT QUESTION AND NEED TO SPEAK TO A PRACTICE **CONSULTANT IMMEDIATELY?**

All College standards, policies, guidelines, fact sheet and frequently asked questions are publicly available on the College website to assist you when an immediate response is required. It is important to familiarize yourself with the content of the website before an urgent or difficult practice issues arises so you will know where to find the information you require quickly.

In addition, pharmacy professionals are encouraged to develop a network of peers to consult with for urgent difficult practice issues that arise and/or create uncertainty. The College's Practice Consultants are available to help you navigate the various College documents and links to relevant external resources; however, the pharmacy practice department is not intended to operate as an emergency resource.

DO PRACTICE CONSULTANTS HAVE **ACCESS TO COLLEGE INFORMATION** THAT THE PUBLIC DOES NOT?

No. In keeping with the College's core value of transparency, all resources available to the Practice Consultants are publicly available on the OCP website. To access information related to your question in the timeliest manner, please visit ocpinfo.com before contacting a Practice Consultant. Pharmacy professionals should be familiar with the <u>Practice Tools</u> and <u>Regulations & Standards</u> sections of the website. The search function can also be used to locate OCP resources and documents. It is also expected that registrants keep up-to-date on official College communications including <u>e-Connect</u> and <u>Pharmacy Connection</u>.

DO PRACTICE CONSULTANTS RESPOND TO INQUIRIES FROM THE PUBLIC?

Yes. Patients often contact the College with questions about a recent experience at a pharmacy, looking for guidance on what is acceptable practice – from both a professional obligation and a legislative perspective. In addition to guiding patients to the same resources as they would a registrant, Practice Consultants also encourage patients to speak with the pharmacy professional or pharmacy manager directly.

Members of the public are also referred to the information on the OCP website specifically intended for them, such as:

- About the College describes the mandate, vision, mission, values and authority of the College
- Protecting the Public summarizes the ways the College fulfills its mandate and includes a video entitled "Trust in the Care Your Pharmacist Provides"

- You & Your Pharmacy: What You Should Expect
 When You Visit Your Pharmacy & video –
 educates the public about five aspects of the care
 they are entitled to receive as a pharmacy patient
- <u>People in Your Pharmacy</u> provides an overview of the roles and responsibilities of pharmacy professionals

IS THE INFORMATION I GIVE TO OR RECEIVE FROM A PRACTICE CONSULTANT KEPT CONFIDENTIAL?

Information provided remains confidential and will not be shared or used by other programs or departments within the College unless it is required by law, or where it is necessary in the interest of public safety. The intent is to encourage open discussion by providing appropriate privacy, while still enabling the College to fulfill its mandate of regulating the profession to protect the public.

Importantly, the response provided by a Practice Consultant is specific to the inquiry and not intended for circulation or advice in any other circumstances. The guidance or resources provided may not be exhaustive and registrants who remain unsure about their particular circumstance should exercise due diligence and obtain independent legal advice to address their outstanding concerns.

TOP FIVE INQUIRIES (THEMES) RECEIVED BY THE PHARMACY PRACTICE TEAM IN 2018:

INQUIRIES FROM REGISTRANTS:

- 1. Dispensing of controlled substances (methadone or buprenorphine/naloxone)
- 2. Pharmacist scope of practice (particularly injections)
- 3. Compounding (NAPRA Standards)
- 4. Prescription authenticity prescriber authorization/transmission
- 5. Recordkeeping and retention of documentation

INQUIRES FROM MEMBERS OF THE PUBLIC:

- 1. Professional/dispensing fees and practices
- 2. Concerns about a specific prescription or situation
- 3. Seeking verification of information or of a practice
- 4. Requesting personal health information
- 5. Pharmacy personnel scope of practice

Look for more information in the 2018 annual report to be published in April.

AIMS PROGRAM On Track To Be Fully Rolled Out BY MID-2019



Since the College moved forward with plans to fully implement its Assurance and Improvement in Medication Safety (AIMS) Program last November, access to the AIMS platform administered by program partner Pharmapod has been granted to approximately half of Ontario's 4,400+ pharmacies.

The province-wide rollout followed a nine-month ambassasdor phase in which the College worked with approximately 100 pharmacies to test and provide feedback on the program. This feedback has been used to support the full implementation of the mandatory medication safety program that, once fully in place in Ontario by mid-2019, will be the largest of its kind in the country.

ONBOARDING NOTIFICATION

The AIMS Program supports continuous improvement and establishes a mandatory, consistent standard for medication safety for all community pharmacies across the province. To support an effective implementation and promote a smooth transition as pharmacies adopt the program and integrate it within their daily practice, the College and Pharmapod collaboratively notify pharmacies in advance of their onboarding date and provide details about what to expect during the onboarding process including mandatory e-training for all pharmacy staff.

As pharmacies are oriented to the program and onboarded onto the anonymous incident recording platform, a series of six e-training modules and other resources provided by Pharmapod are designed specifically to help facilitate the required training behind this medication safety program. Each of the modules focus on the following training topics:

- Describing the difference between a medication incident and a near miss and identifying specific information required to ensure good quality recording of medication incidents and near misses
- Understanding the importance of using standardized terminology as part of the AIMS Program and locating these definitions
- Submitting a medication incident and near miss using the Pharmapod system
- Describing what Continuous Quality Improvement is and how it can be implemented within your pharmacy
- Applying a root-cause analysis of medication incidents and near misses
- Generating reports and reviewing data from medication incidents and near misses

INCIDENT RECORDING PLATFORM

Once the e-training is completed, pharmacies are expected to anonymously record all incidents and near misses into the incident recording platform administered by Pharmapod.

WHAT IS A NEAR MISS?

Near misses are defined as events that could have led to inappropriate medication use or patient harm but did not reach the patient. Near misses provide valuable insight into areas of risk, and may indicate where systems can be improved to prevent harm. If a potential error is caught outside of the established processes and procedures at the pharmacy but before the prescription reaches the patient, then it should be recorded as a near miss. Established processes and procedures could include the technical and therapeutic signoffs and/or any other regular process in place to catch errors such as input or DIN errors.

Regardless of when a near miss or medication incident is caught, if you notice that similar incidents are reoccurring on a frequent basis, this may indicate that the processes and procedures you have implemented into the workflow are not effective and should be reviewed.

The extent to which near misses are recorded will be a professional judgment decision of the Designated Manager in consideration of the nature of the near miss, its implication for patient safety and the extent to which it is recurring.





The pharmacy team should take prompt and appropriate measures when a near miss or incident is discovered to document what happened and to analyze the incident in order to determine causal factors, and to implement improvements so that similar incidents can be prevented. The tools and resources available through the program, including the incident recording platform, are designed to support pharmacies to meet these expectations and to do so in a consistent and standardized manner across the province.

PHARMACY SAFETY SELF-ASSESSMENTS (PSSA)

This summer, a Pharmacy Safety Self-Assessment (PSSA), also available as part of the Pharmapod platform, will be introduced on a pilot basis to all community pharmacies.

Pharmacies should complete a PSSA within the first year of the implementation of the AIMS Program, then at least once every two to three years thereafter. The PSSA can be used as an informative quality-improvement tool, acting as a baseline of the pharmacy's efforts to enhance patient safety over time. Pharmacy leaders should also take the opportunity to analyze aggregate pharmacy data regularly to help inform the development of quality improvement initiatives.

Pharmacies will learn more about the PSSA through the onboarding process.

ANALYZE AND IDENTIFY TRENDS

As pharmacies are onboarded to the AIMS Program, the College will be able to use aggregate and de-identified data reported through the anonymous incident recording platform to work with other partners and experts to analyze and identify trends and provide appropriate guidance and recommendations for quality improvement that will be shared across the province. A Response Team of pharmacy professionals and patient safety experts will assist the College in analyzing the de-identified aggregate data and develop recommendations on strategies for continuous quality improvement to reduce the risk of patient harm associated with medication incidents

The members of the Response Team are:

- Dr. Corey Lester (Research Assistant Professor at College of Pharmacy, University of Michigan)
- Dr. Nancy Waite (Associate Director at the School of Pharmacy, University of Waterloo)
- Dr. Lisa Dolovich (Professor, Leslie Dan Faculty of Pharmacy, University of Toronto and Professorship in Pharmacy Practice, Ontario College of Pharmacists)
- Shelita Dattani (Director, Practice Development and Knowledge Translation, Canadian Pharmacists Association)

- Alison Bodnar (CEO of the Pharmacy Association of Nova Scotia)
- Dr. James Barker (Professor and the Herbert S. Lamb Chair in Business Education at the Rowe School of Business, Dalhousie University and Team Lead at SafetyNET-Rx)
- Deb Saltmarche (Senior Director, Professional Affairs, Shoppers Drug Mart)
- Mark Naunton (Head of Pharmacy, Faculty of Health, University of Canberra, Australia)

The analyzed aggregate data, along with the analysis and recommendations of the Response Team, will be made available directly to pharmacies and healthsystem stakeholders and will be shared publicly, along with improvement recommendations, on the College's website. The analysis and sharing of this information will be key in providing helpful, actionable insights to pharmacy professionals and other healthcare stakeholders to reduce medication errors and improve patient safety.

HOSPITAL PHARMACIES

To date, the AIMS Program has been focused on community pharmacies; however, the College plans to apply learnings acquired from the community pharmacy implementation and build upon current hospital experiences to facilitate systems-level learning across the sector through the AIMS Program. Engaging hospital professionals throughout 2019 to better understand the operating environment and explore opportunities will help the College determine how to best utilize the AIMS Program to augment and enhance patient safety in hospitals.

Resources are periodically updated on the AIMS section of the website. Visit: Standards and Expectations and Program Resources and Updates.

The College appreciates the support of pharmacies to date and their commitment to patient safety and thanks all of those who are already active on the anonymous incident reporting platform.





"Close-Up on Complaints" explores incidents reported to the College that have occurred in the provision of patient care and which present learning opportunities. Ideally, pharmacists and pharmacy technicians will be able to identify areas of potential concern within their own practice, and plan and implement measures to help avoid similar incidents from occurring in the future.

SUMMARY OF THE INCIDENT

A nine-year-old patient had to be taken to a hospital's emergency department after experiencing an overdose due to a prescription filled improperly at the patient's pharmacy.

The patient had a recent change in prescription. The patient's mother indicated to the pharmacy that this was not a change in total dosage but in administration such that the patient was to take 1 mg in the morning and 2 mg in the evening rather than 3 mg at once. Unfortunately, the pharmacy dispensed the medication as three 3 mg tablets daily.

WHY DID THIS HAPPEN?

When entering the new prescription into the pharmacy computer system, pharmacy staff used the computer system's "copy" function to copy the patient's previous prescription. The previous prescription was ordered and entered as 3 mg, take one tablet every evening.

In the process of entering the new prescription, the old prescription was copied and inactivated and the original drug, strength and directions were inserted into the new prescription record. A note was made that the dose had been changed; however, while the instructions were changed to read "take 1 tab in the morning and 2 tablets in the evening," the drug strength was not changed from 3 mg to 1 mg.

Copying prescriptions creates inherent risks including the potential for serious medication incidents. The pharmacist did not recognize this risk in the pharmacy process until an error occurred. Pharmacy professionals should be able to recognize the potential issues created by copying over old prescription information to a new prescription.

Moreover, the pharmacist reviewed the prescription and should have been able to catch the error by comparing the original prescription to the medication vial and the dispensing record when conducting both the technical and therapeutic checks. Since this prescription was dispensed for a child, a "red flag" patient, even greater care ought to have been exercised during all steps in the dispensing and verification process.

Ultimately, the pharmacist in this case was not fully cognizant of critical risks associated with the pharmacy's established processes and their potential impact on patient care and did not take adequate time to ensure the accuracy of the medication and instructions given to the patient.

COMPLAINT OUTCOME

The College's Inquiries, Complaints & Reports Committee oversees investigations of each complaint the College receives. A committee panel considers a pharmacy professional's conduct, competence and capacity by assessing the facts

of each case, reviewing submissions from both the complainant and the professional, and evaluating the available records and documents. related to the case.

The pharmacist, who was also the pharmacy's designated manager, accepted responsibility for the incident and addressed the situation appropriately once learning of the error. The pharmacist contacted the patient's doctors and implemented a number of changes to the pharmacy's processes, including ensuring prescriptions with changes are no longer copied and reinforcing step-by-step checks for data verification.

The pharmacist also changed the way directions are to be written to highlight the intended dose. One way to do this is to specify the total strength in brackets. For instance, 3 tablets (9 mg) in the morning and 2 tablets (6 mg) in the evening.

While it acknowledged that the pharmacist responded well to the error, the panel felt that the pharmacist did not recognize processes which created inherent risk prior to an incident occurring. The panel also felt that the pharmacist may not recognize other risks in pharmacy procedures and that, therefore, a further examination of the pharmacist's processes was warranted. Additionally, they observed that the pharmacist did not engage in proactive remediation in response

to a serious medication error involving a child.

In light of the above, the panel issued the pharmacist an Oral Caution and a requirement to complete specified remediation. The pharmacist in this case was directed to successfully complete the Root Cause Analysis workshop provided by the Institute for Safe Medication Practices (ISMP) which provides a "standardized approach to the retrospective analysis of critical incidents and near-miss events in healthcare."

ORAL CAUTIONS

An oral caution is issued as a remedial measure for serious matters where a referral to the Discipline Committee would not be appropriate. Oral cautions require the pharmacy professional to meet with the ICRC in person for a face-to-face discussion about their practice and the changes they will make that will help avoid a similar incident from occurring in the future.

REMEDIAL TRAINING (SCERPS)

A SCERP is ordered when a serious care or conduct concern requiring a pharmacist or pharmacy technician to upgrade his or her skills has been identified. The ICRC orders SCERPs when they believe that remediation is necessary.

For all complaints filed after April 1, 2015, the College posts a summary of the oral caution and/or SCERP and its date on the "Find a Pharmacy or Pharmacy Professional" tool.

LEARNINGS FOR PHARMACY PROFESSIONALS

The Standards of Practice and Code of Ethics require that the patient's best interests be at the centre of decision making and that pharmacists apply their medication and medication use expertise to ensure patients receive the appropriate therapy. Before dispensing a drug or counselling a patient, it is imperative to make sure that the right patient is receiving the correct medication at the correct dose with the correct instructions.

Pharmacists should take a systematic approach to screening prescriptions before dispensing, such as examining the dose, frequency, and the indications for drug use. In this case, an effective therapeutic assessment and technical check would have identified that the medication dosage was not appropriate for the patient.

Pharmacy professionals should also be aware of "confirmation bias" which refers to one's tendency to "see" information that confirms one's own expectations and the propensity for one's mind to perceive what it thinks should be there as opposed to what really exists.

Additionally, pharmacy professionals must remember that a child is a "red flag", or particularly vulnerable, patient and, as a result, more care and attention must be provided, given the potential seriousness of outcomes that could occur in this patient population. For any "red flag" patients, it is incumbent upon pharmacy professionals to take extra care when dispensing.

It's important to emphasize that Designated Managers are responsible for ensuring that

processes and procedures at the pharmacy are designed to minimize errors, protect the public, and enable staff to satisfy their professional and patient safety obligations. This includes implementing the Standards of Operation to warrant that the right medication, dosage, strength, and instructions are given to the patient, as intended by the prescriber.

The Standards of Practice also require Designated Managers to review errors and incidents to determine patterns and causal factors that contribute to patient risk and support staff in their obligation to report adverse events and close calls. This not only is a requirement, it is a core aspect behind the AIMS (Assurance and Improvement in Medication Safety) Program currently being rolled out to all community pharmacies across the province.

Lastly, pharmacy professionals are responsible for making sure that their knowledge and skills are up-to-date and must identify areas for improvement and engage in professional remediation as necessary, especially when specific incidents that could have been easily presented arise.



In December 2018, Council approved a three-phase approach for implementation of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations.

The priorities and timelines for completion of each phase are:

Phase 1: January 1, 2020 - Assessing Risks and Gaps

Phase 2: July 1, 2020 -Personnel Training and Quality Assurance

Phase 3: January 1, 2021 - Facilities and Equipment

ABOUT THE STANDARDS

The College expects that all pharmacists and pharmacy technicians engaged in non-sterile compounding have thoroughly reviewed the <u>Standards</u> and the accompanying <u>Guidance</u> <u>Document</u>. For ease of use, the numbered sections in the Guidance Document correspond to the sections of the Standards.

Adherence to these standards is an important way of protecting patients and staff and ultimately enhancing the quality and safety of pharmacy care in the province. This article focuses on preparing for the first of the three-phase roll out.

PHASE 1 – ASSESSING RISKS AND GAPS

RISK ASSESSMENT

To provide non-sterile compounding services that meet or exceed the minimum standards, a risk assessment must be completed for each preparation compounded by the pharmacy. The Designated Manager (DM) and/or the non-sterile compounding supervisor (the pharmacy professional assigned to oversee all compounding-related activities)

is responsible for ensuring risk assessments are performed.

Three levels of requirements are defined in Section 8 of the Standards (A, B and C) which correlate to the risks associated with the preparation and its complexity. Both risk of contamination to the preparation, which is essential for patient safety, and risk to personnel, which must be mitigated by adequate protection measures, are considered

The steps for conducting a risk assessment are described in Section 4 of the Standards. The complexity of the compounds are categorized as simple, moderate or complex. The level of requirements the pharmacy needs to have in place is dependent on the category of the products compounded. The Decision Algorithm (Section 4.2 of the Guidance) can be used

in conjunction with workplace guidelines provided in Section 4.3 to determine if a preparation needs Level A, B or C compliance requirements.

WORKPLACE GUIDELINES

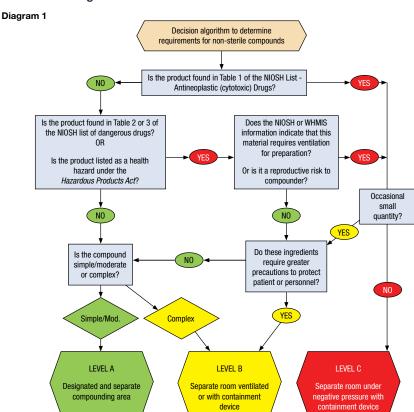
Workplace guidelines that play a role in pharmacy compounding include the Workplace Hazardous Materials Information System and the National Institute for Organizational Health and Safety.

The Workplace Hazardous

Materials Information System
(WHMIS) 2015 Safety Data
Sheets (SDS)

- Essential to occupational health and safety, the SDS provides a summary of a product's hazards
- Must be provided by the manufacturer or supplier per federal <u>Hazardous Products</u> <u>Regulations</u>

4.2 Decision algorithm for risk assessment



- Identify measures for risk mitigation, such as Personal Protective Equipment (PPE)
- For more information, the Canadian Centre for Occupational Health and Safety (<u>CCOHS</u>) offers several WHMIS 2015 Fact Sheets, including one outlining the content of the SDS
- Additional external resources include <u>Health Canada</u> and the province-specific information from <u>WHMIS</u>. org and the <u>Ontario Ministry of Labour</u>

The National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

- Drugs listed in Group 1 (Table 1) are antineoplastic and pose an occupational hazard due to their cytotoxicity and/or reproductive risks
- Preparations containing Group 1 drugs warrant Level C requirements and must be handled using the recommended engineering controls (e.g., specialized equipment and facility design)
- The PPE requirements at Level C are significantly more extensive than those encountered in Level A.
 These, along with other provisions specific to Level C, are explained in Section 9

GAP ANALYSIS

After completing risk assessments and determining the level of requirements for each preparation the pharmacy compounds (or intends to compound), a gap analysis can be performed. This involves evaluating the pharmacy's current practices in comparison to the minimum standards in each area.

The knowledge and skills of compounding personnel must be assessed for gaps. The potential need for training is not limited to the compounding processes or technique; personnel must also be educated on policies and procedures related to attire, personal protective equipment, cleaning, maintenance, conduct and behaviour.

The nature and extent of the gaps identified will be a good indicator of the magnitude of changes the pharmacy needs to make in order to fully achieve and maintain the standards. A significant factor to the success and sustainability of any program is collaboration between the people involved.

Where change is needed, it is important to

be cognizant that pharmacy personnel will require sufficient time and training to modify their usual routines and adapt to the Standards. The Designated Manager and/or compounding supervisor should develop a plan of action to address gaps with this in mind.

TEAM RESPONSIBLITIES

To proactively prepare for Phase 2 (Personnel Training and Quality Assurance) compliance by July 1, 2020, the College suggests compounding pharmacies consider holding a team meeting to determine how staff will divide the workload in Phase 1. Use the list below and corresponding guidance document references as resources to assist you.

- Identify the compounding supervisor who will develop, organize and oversee all activities. (5.1.2.)
- Confirm all personnel who will require skills and training assessment. (5.1.3-5.2.2)
- Complete the risk assessment for each non-sterile compound that you are preparing.
- Refer to the NIOSH list, SDS and WHMIS to determine level of risk to the compounding personnel (4.3)
- Identify the levels of requirements for the compounds you are preparing. Refer to algorithm in the NAPRA guidance document. (4.1-4.3)
- Ensure master formulations are comprehensive and evidence-based with safety data sheets for each chemical used. (6.2)
- Section 11 (page 58) of the <u>guidance document</u> provides a summary list of Diagrams, Tables, Checklist and Templates There are <u>Printable and</u> <u>Fillable Forms</u> available on the NAPRA website of some of these resources to facilitate their use.

The tools and resources provided above will help pharmacy professionals prepare to meet the deadlines approved by Council for non-sterile compounding compliance. Future articles will focus on Phases 2 and 3.

If you have any questions about these standards or the implementation dates, please contact pharmacypractice@ocpinfo.com.



ONTARIO MEDICATIONS RETURN PROGRAM

The Health Products Stewardship Association (HPSA) would like to remind all pharmacies to follow these simple steps for proper disposal of unused and expired medications returned from the public through the Ontario Medications Return Program:



- All pills should be removed from their original packaging (original and prescription vials) and be loosely disposed of into a medications return collection container. Liquids, creams, inhalers, etc. are the only exceptions to the "no original packaging" rule.
- If a person returns medication in its original packaging, be sure to remove all personal identification as well as extra packaging.
- All pharmacies should have a "Take It Back" rack card, which outlines the proper steps of

return and disposal. To ensure a member of the public is correctly preparing medications for return, please be sure to provide them with this easy to read information. If you wish to order rack cards, you can do so through HPSA's website: www.healthsteward.ca/ collection/Ontario.

SAFE DISPOSAL OF CONTROLLED SUBSTANCES RETURNED BY A MEMBER OF THE PUBLIC

Please review the College's

Destruction of Narcotics.

Controlled Drugs and Targeted

Substances fact sheet for information on destroying controlled substances.

HPSA would like to remind all Ontario pharmacy staff of their obligations in regards to the responsible management of postconsumer controlled substances:

- Pharmacy staff across Ontario should not denature drugs prior to putting them in the collection container. HPSA's programs are not licensed or authorized to handle denatured or altered controlled substances (narcotics, controlled drugs or benzodiazepines).
- The member of the public can combine all unwanted

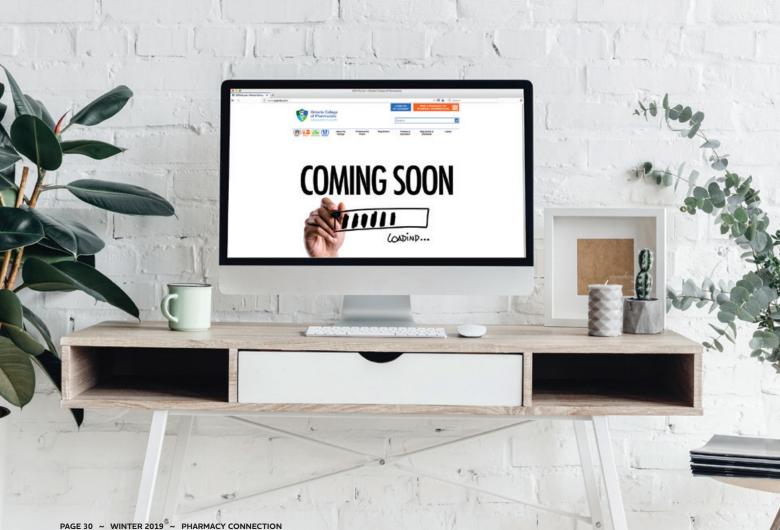
medications, including controlled substances, together for return to a pharmacy registered in HPSA's Medication Returns Program (take-it back programs).

- Controlled substances returned to a pharmacy by the public should be placed into the collection container immediately by pharmacy staff.
- Collection containers must be kept in a secure space in the dispensary during use.
- Once full, the collected container should be sealed and removed from the pharmacy by the HPSA contracted waste management service provider.
- The pharmacist must confirm the pickup service by signing a receipt indicating the number of HPSA containers received, the number of HPSA containers picked-up and the date of service. This information must be kept on file at the pharmacy for two years.

To learn more about the Ontario Medications Return Program, please visit http://www.healthsteward.ca/ collection/Ontario.

IMPROVING NAVIGATION, ACCESS TO KEY CONTENT FOR PUBLIC AND PROFESSIONALS

AFOCUS ON COLLEGE USEBSITE REFRESIA



The College's website is an information-rich resource with hundreds of pages of relevant content for registrants, applicants and the public. However, over the past few years we've heard from many website visitors that it is often challenging to find the content they're looking for online. And once they find the content, it may not be optimized to view on today's web browsers, technology platforms and accessibility standards.

Recognizing the incredibly valuable role our website plays in helping to communicate important information to pharmacy professionals and the opportunity to make more people, including the public and our health system stakeholders, aware of our collaborative efforts to promote quality pharmacy care, the College is planning to launch a refreshed website in late spring of this year.

WE LISTENED AND ACTED

In 2016, we conducted a communication survey among registrants who provided feedback on a number of the College's communications products including the website. Feedback we received showed that it was challenging to find website information and that content needed to be updated more

frequently. This past year, we conducted research which further reinforced the opportunity to improve navigation and access to timely and relevant content for professionals.

Accordingly, the changes to the website will include design enhancements to help align with the College's renewed strategic plan and improve accessibility across multiple platforms, focusing heavily on improving the navigation – helping you get to the content you're looking for quicker and easier.

The website is also being designed with the public and patients in mind so that they too have easier access to information relevant to them, from content about the role of the College and what they should expect from

their pharmacy experience, to timely updates about activities and projects aimed at enhancing quality and safe pharmacy care. Such content aligns with the Council-defined strategic priorities and our overall broader commitment to improving our communication with the public.

Stay tuned for more information as this work progresses. Don't worry, as we refresh the website, much of the content will remain in their existing sections and the current links won't break. We're just making it easier for you to get to the content you and the public are looking for. We're also developing some quick tips and other tools to help you as you explore the site once it's launched.

With a view to improving navigation and enhancing access to relevant content to pharmacy professionals and the general public, the College's website is being redesigned to help you:



Access the content you're looking for quickly and easily with fewer clicks



Print pages with simple formatting for easier offline reading



Benefit from an improved website search that makes it easier than ever before to find exactly what you're looking for



Customize your homepage experience and access relevant content by audience type



Quickly access content and timely updates from the College related to key programs, initiatives, consultations and more



Easily view content from anywhere using a mobile or tablet device as well as your PC or laptop

INCIDENTS ASSOCIATED WITH MISSED MEDICATION DOSES:

A Multi-Incident Analysis

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INTRODUCTION

An aging population and increasing medication use imply that pharmacies and patients may be at risk of experiencing errors that involve missed medication doses. Missed medication doses can attenuate or eliminate a drug's therapeutic effects resulting in suboptimal disease management, more frequent physician visits, and higher hospitalization rates.¹ For some medications, such as warfarin, even a few missed doses can reduce its beneficial effects and result in serious adverse events, such as a stroke.² Missed doses can also cause withdrawal symptoms with some medications, such as antidepressants, resulting in side effects such as flu-like symptoms, anxiety, and electric shock-like sensations.3,4

Factors, such as pharmacy environments, complex medication regimens, and training of pharmacy staff can contribute to incidents associated with missed medication doses. Identifying and addressing the root causes that may lead to these incidents in community pharmacy practice can have a significant positive impact on patient care and medication safety.

This multi-incident analysis aims to identify overarching themes encompassing underlying contributing factors that result in incidents associated with missed medication doses reported by community pharmacies. Additionally, this analysis targets vulnerable medication-use processes in community pharmacy settings in order to develop recommendations to mitigate the risk of future incidents associated with missed doses, and to optimize patient safety outcomes through safe medication practices.

METHODS

Incidents included in this analysis were voluntarily reported by pharmacy professionals to the Institute for Safe Medication Practices Canada (ISMP Canada) Community Pharmacy Incident Reporting (CPhIR https://www. cphir.ca) program. We extracted incidents with "Omitted Medication/Dose" reported as the primary type of incident from the CPhIR database between July 1, 2016 and June 30, 2017.

Using the specified inclusion criteria, an initial search yielded a total of 194 incidents. After removing duplicate entries and non-viable incidents (e.g. incidents with insufficient details, ambiguous description, etc.), a total of 156 incidents were included and subjected to a qualitative, multi-incident analysis, which was conducted by four independent medication safety analysts. Themes, sub-themes, contributing factors, and recommendations to address patient safety gaps corresponding to incidents associated with missed medication doses were then derived from this analysis.

RESULTS

We identified three main themes and corresponding sub-themes. Along with contributing factors and potential recommendations, they are listed in Tables 1 to 4 below.

We would also like to bring your attention to the following previous Multi-Incident Analyses that have been published in Pharmacy Connection, as most incidents reviewed in this analysis that were associated with missed medication doses were identified during some of the high-risk processes in community pharmacy workflow.

- Medication Incidents Associated with Hospital Discharge
- Medication Incidents Involving Drug Tapering in Community Pharmacy
- Complexity and Vulnerability of Compliance Pack Preparation
- Drug Shortage and Patient Safetv

CONCLUSION

Despite pharmacy professionals' best efforts to provide safe and effective pharmaceutical care. errors cannot be 100% eliminated. Whether errors are related to a lack of communication among healthcare practitioners, or from an inadequate medication management system, it is essential to recognize the importance of being proactive in addressing the root causes. In this analysis, we described some of the contributing factors that may lead to missed medication doses and offer

recommendations to prevent these incidents from occurring. Findings from this multi-incident analysis will help target areas of risk associated with missed medication. doses and support making changes to improve medication safety in your pharmacy.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Dr. Puja Modi for her assistance in conducting this multi-incident analysis. Dr. Modi completed a PharmD rotation at the Leslie Dan Faculty of Pharmacy, University of Toronto, and ISMP Canada in 2017. 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 (https:// www.cphir.ca).

The CPhIR Program contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (https://www.cmirpsscdpim.ca). 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.

Table 1. Summary of Themes

Main Themes	Subthemes
Main Theme 1: Compliance Packaging (Multi-Medication Compliance Aids)	Over-the-Counter (OTC) Medications Use of Samples Drug Shortages or Backorders Complex Medication Regimens
Main Theme 2: Transitions of Care	Pharmacy (Prescription) Transfer Hospital Discharge Long-Term Care (LTC) Admission or Discharge
Main Theme 3: Medication Distribution	Pick Up Delivery

Table 2. Main Theme 1 – Compliance Packaging (Multi-Medication Compliance Aids)

Subtheme 1 – Over-the-Counter (OTC) Medications			
Incident Examples:	Contributing Factors:	Recommendations:	
Nurse phoned to say that the horse chestnut capsule was not included in the blister pack. Physician called in renewals for patient's medications (including inhalers, blister-pack medications and OTC medications). However, during the transcribing of the verbal orders, the OTC medications were omitted and not updated on the patient profile. When the next blister pack was processed, the OTC medications (i.e. Vitamin D and ASA) were not included on the compliance pack labels and hence omitted from the blister packs.	OTC medications purchased separately by patient were not included in the blister pack. Incomplete medication review and/or medication list not up-to-date. Inadequate transcription and/or lack of verification of verbal orders.	Conduct regular medication reviews with patients: document and assess OTC medications in addition to prescription medications. Place a poster or reminder at prescription pick-up area to remind patients to carry an updated medication list (including OTC medications) with them and to consult their pharmacist if starting any new OTC medications. Develop or reinforce pharmacy policies and procedures when OTC medications are included in compliance packaging. 56	
Subtheme 2 – Use of Samples			
Incident Examples:	Contributing Factors:	Recommendations:	
 Patient usually gets Tridural® samples mailed directly from the pharmaceutical company to the nursing home; and the nursing home will administer the samples to patient. The order form for the samples was not filled out properly by the prescriber this time, so the samples did not arrive on time. Patient has been on samples. When prescription was called into the pharmacy, the prescription labels of the compliance packs for the next cycle were already printed. Hence, the sample medications were missed in the compliance pack preparation. Pharmacy staff expected that patient had enough samples to last until the next cycle. 	 Medication samples supplied directly to the patient. Lack of communication between pharmacy and prescriber. Lack of documentation of sample supply on patient profile 	 Develop or reinforce pharmacy policies and procedures to ensure appropriate documentation and communication when sample medications are included in compliance packaging.⁶ Ensure adequate training of pharmacy staff involved in compliance pack preparation.⁷ 	
Subtheme 3 - Drug Shortages or Backorders			
Incident Examples:	Contributing Factors:	Recommendations:	
Pharmacy ran out of Apixaban. We ran the medication roll via PACMED strip packaging (i.e. automated compliance packaging) without Apixaban. We then forgot to add Apixaban to the medication roll the next day and did not perform final check on PACMED pouch upon dispensing.	 Drug shortages and backorders. Inadequate maintenance of pharmacy inventory. Lack of communication among pharmacy staff members. Lack of independent double checks. 	Create end-of-day inventory maintenance checklist for pharmacy staff. Develop or reinforce existing pharmacy policies and procedures to manage drug shortages and/or backorders.8	
Subtheme 4 – Complex Medication Regimens			
Incident Examples:	Contributing Factors:	Recommendations:	
• A new blister-pack patient was supposed to receive Synthroid® 237 mcg daily alternating with 250 mcg daily (i.e. 100 mcg +137 mcg tablets daily). Somewhere down the line, the 150 mcg tablets were mistakenly discontinued from the patient's profile, therefore the patient's set of blister packs ended up containing 237 mcg daily alternating with 100 mcg daily. The directions on these prescriptions did not accurately reflect the patient's dosing requirements, so it was not obvious that something went wrong. • Patient brought back his blister packs asking if we had forgot to put in his medications. He is on a specific cycle, taking 1 tablet once daily and 2 tablets on Mondays and Thursdays. We forgot to add the second Rapamune®	id® 237 mcg daily alternating with 250 mcg 100 mcg +137 mcg tablets daily alternating 2 mcg +150 mcg tablets daily). Somewhere 3 le line, the 150 mcg tablets were mistakenly 3 mucd from the patient's profile, therefore the 4 set of blister packs ended up containing 237 4 y alternating with 100 mcg daily. The directions 5 prescriptions did not accurately reflect the 6 dosing requirements, so it was not obvious that 6 ng went wrong. 6 rought back his blister packs asking if we had 6 put in his medications. He is on a specific cycle, 6 tablet once daily and 2 tablets on Mondays and 6 or prescription directions. 6 Lack of independent double checks. 7 of prescription directions. 8 Lack of independent double checks. 9 Perform independent do patient when preparing a complex medication region regimens consideration of comment of the product formulations. 9 Perform independent double checks.		

Table 3. Main Theme 2 – Transitions of Care

Subtheme 1 – Pharmacy (Prescription)	Transfer	
Incident Examples:	Contributing Factors:	Recommendations:
• Patient's prescriptions were transferred [from another pharmacy. Patient then brought in a prescription vial from another pharmacy and said that we should already receive the transfers. However, we did not see Ativan® SL on her medication profile. We then referred back to the prescription transfer images and realized that the transfer was supposed to be two pages, but we only logged the first page. We missed the last two prescriptions on the second page.	Incomplete medication review and/or medication list not up-to-date. Lack of independent double checks.	 Perform independent double checks by conducting medication reviews with all new patients to the pharmacy.¹¹ Develop technology to allow Pharmacy Practice Management Systems (PPMS) to communicate prescription transfers seamlessly in order to avoid the need for human intervention or transcription.⁷
Subtheme 2 – Hospital Discharge		
Incident Examples:	Contributing Factors:	Recommendations:
Nurse at long-term care home phoned to ask about Metoprolol and why it was not in the patient's blister packs. It was discovered that at hospital discharge, Metoprolol had been accidently discontinued. There had been many medication changes and discontinuations upon patient discharge, but Metoprolol was not one of them. Pantoprazole was not in the patient's compliance packs. Prescription for Pantoprazole was on hospital discharge, but it was missed by the pharmacist when the orders were being inputted and prepared.	Lack of medication reconciliation at hospital discharge. Lack of medication reconciliation at community pharmacy post-discharge (e.g. MedsCheck Follow-Up). Lack of patient education on hospital discharge. Lack of independent double checks.	 Conduct medication reconciliation at hospital discharge and generate discharge prescriptions to minimize unintentional medication changes upor patient discharge. Provide copies of the medication list (ideally the up-to-date best possible medication history) to the patient, community pharmacy, and family doctor.^{9,10} Assign a hospital helpline for patients and other primary health care providers (HCPs) to improve communication among HCPs at the transitions of care.¹⁰ Educate patients on the "5 Questions to Ask About Your Medications" (https://www.ismp-canada.org/medrec/5questions.htm).¹³
Subtheme 3 – Long Term Care (LTC) Add	mission or Discharge	
Incident Examples:	Contributing Factors:	Recommendations:
Pharmacy was notified earlier in the week that the resident would be transferring out of the long-term care facility (but no specific date was given). When cycle fill was run on Friday, this resident's medications were suspended as it was thought that he was leaving the long-term care facility. Technician had asked nursing staff to notify pharmacy if the resident did not leave. However, pharmacy was not informed, and the resident went without medications for three days before nursing staff noticed. Medication was missed when entering an admission prescription order for the nursing home. Nurse at nursing home informed pharmacy of the omission.	 Lack of communication between pharmacy and LTC facility. Potential confirmation bias. 	Implement an electronic reminder to prevent discontinuation of patient's medication profile unless resident discharge has been fully completed and documented. Implement formal and standardized process for communicating LTC admissions and discharges between pharmacy and LTC facility (e.g. online communication). Recommend LTC homes to send daily or weekly patient census reports (electronically or manually prepared) to pharmacy. This can serve as a back-up or independent double check to verbal communication about admissions, transfers, and discharges.

Table 4. Main Theme 3 – Medication Distribution

Subtheme 1 – Pick Up				
Incident Examples:	Contributing Factors:	Recommendations:		
• Three prescriptions were filled for one patient – two at one time, and one at another time. Patient's daughter came in to pick up prescriptions and only received two; the third prescription was in a separate bag.	Medications for the same patient were prepared in separate prescription bags. Lack of communication between pharmacy staff and patient. Insufficient patient counseling at pick-up Lack of independent double check during pick-up and patient counselling.	 Perform independent double checks at pick up with patient to confirm the number of prescriptions to be picked up and for which medications.¹¹ Ask the patient to review the prescription labels and contents of each prescription container to make sure that the medication is correct. ¹² Develop reminders in the Pharmacy Practice Management Systems (PPMS) to flag all prescriptions for the same patient if additional prescriptions are filled and a previous prescription has not been picked up yet. Develop or reinforce existing pharmacy policies and procedures to ensure medications filled for the same patient are stored together. When a friend or caregiver picks up prescriptions on behalf of a patient, remind the patient to check the contents of the prescription package at home before taking any medications or questions.¹² 		
Subtheme 2 – Delivery				
Incident Examples:	Contributing Factors:	Recommendations:		
 Prescription was delivered to the wrong nursing home. Patient had transferred to a different LTC home and the delivery address on patient's profile was not updated. Patient called to have her prescriptions delivered. Prescriptions were not filled nor delivered until she called again two days later and informed the pharmacy about the outstanding delivery. 	Potential confirmation bias Lack of independent double checks. Ineffective communication among pharmacy staff members.	Implement automated refill reminder system to prevent missed medication doses if delivery systems are delayed. Remind pharmacy staff members of the importance of double-checking patient details (e.g. name, date of birth, delivery address) prior to sending prescriptions out for delivery.		

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Antimicrobial stewardship (AMS) remains an important topic in the role of pharmacy professionals in any practice environment and is becoming increasingly so for those in community practice settings. Pharmacy Connection welcomes contributors from the Antimicrobial Stewardship Program team at the Sinai Health System and University Health Network in Toronto to share their insights and perspectives.

This is the third in a series of articles about the role of community pharmacy professionals in AMS which reinforces important information for practitioners while providing practical tips and access to resources to support ongoing AMS efforts within our health system. In this issue, we'll be focusing on acute bronchitis.

In Ontario, respiratory pathogens (such as respiratory syncytial virus, rhinovirus, adenovirus and influenza) circulate at their highest levels annually between November and April. Many parts of the health system experience an increase in the demand for patient care during respiratory pathogen season. Community pharmacists can play an important role assessing patients with a sore throat/pharyngitis, sinus infection/acute sinusitis or simple cough/uncomplicated bronchitis in a stable patient and conditions that may require further medical care.

Respiratory viruses cause more than 90% cases of acute bronchitis. The course of bronchitis typically begins with a non-specific upper respiratory tract infection (sore throat, runny nose, nasal congestion) with a cough. Cough may be productive (i.e. involve sputum production) and can last anywhere from 3 to 6 weeks (mean duration = 17.8 days). This bothersome and potentially persistent symptom leads to discomfort, lost days of school or work and concern about the potential for a more severe infection, such as pneumonia.

ASSESSMENT OF ACUTE BRONCHITIS

Bronchitis is an infection of the major airways leading to the lungs while pneumonia is an infection of the lungs themselves. There is no definitive test to diagnosis bronchitis, however, due to symptom overlap, the need to exclude pneumonia is paramount. While the "gold standard" diagnosis of pneumonia is by chest x-ray, the absence of certain clinical parameters may help exclude a diagnosis of pneumonia in younger, healthy patients.

In some cases, it may be helpful for community pharmacists to discuss with patients the following clinical signs which their primary care provider will use to assess the difference:

If all of the following signs/symptoms are absent, pneumonia is unlikely and x-ray unnecessary (adult, uncomplicated bronchitis):

- 1) Tachycardia (Heart Rate > 100 bpm)
- 2) Tachypnea (Respiratory Rate > 24 breath/minute)
- 3) Temperature > 38°C
- 4) Chest auscultation findings suggestive of pneumonia (on physical exam)

In patients older than 65 or those with chronic cardiovascular disease, respiratory disease, immunocompromise or other comorbidities, a more thorough assessment is required. These patients should be referred to the appropriate care provider.

Appropriate referral based on the patient's presentation is vital. If you encounter a patient with moderate-severe respiratory symptoms (shortness of breath, tachypnea, accessory muscle use, difficulty speaking) or if you are uncertain of severity or comorbidity, refer them to the appropriate healthcare professional for diagnosis and further management. Persistent cough longer than 2-3 weeks, sputum tinged with blood, wheezing, chest pain or signs of systemic infection should also prompt referral to medical assessment. Sputum discolouration alone (white, yellow or green) does not indicate bacterial infection and is reflective of the body's immune system response.

MANAGEMENT OF ACUTE BRONCHITIS

Antibiotics do not benefit uncomplicated acute bronchitis and should not be prescribed.³⁻⁵

Community pharmacists can support a physician's decision not to prescribe an antibiotic in follow-up

discussions with the patient and can encourage selfmanagement of symptoms for viral infections when bronchitis is the likely cause.

Despite being the most common cause of acute healthcare contact, very little high quality evidence exists to guide symptomatic therapy.⁶ Setting expectations about the duration of symptoms and supportive care may be sufficient for many patients to reassure them that antibiotics provide no benefit and would only offer potential harms while treating uncomplicated bronchitis.⁹

Symptom Management of Acute Bronchitis

Symptom	Treatment	Comment
Fever/pain	Acetaminophen or Ibuprofen	Be aware of risk for inadvertent acetamino-phen co-ingestion with common cough and cold products and counsel patients accordingly
Cough	Dextro- methorphan	Modest (17%) reduction in cough frequency ^{6,7} Not to be used in children <12 years per Health Canada
	Codeine	No RCT* evidence to support use ⁷ Health Canada recommends that children and youth not use cough and cold products that contain opioids - http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69080a-eng.php
	Honey/Lemon	Limited data in adults, helpful in children 12 months to 18 years ^{7,8}

*Randomized, controlled trial. Although commonly used and considered by many the optimal choice, little evidence of benefit and risk of harm preclude routine recommendations for codeine in the management of cough in children and adults.

Prescribers may also employ a delayed antibiotic approach to reduce patient anxiety and antimicrobial use. ¹⁰ Pharmacists can support this by "logging" received medications with a "watch and wait" intention and following up with patients in 48-72 hours to reassess symptoms.

The pharmacist, in collaboration with the patient, should closely watch for worsening cough or other

symptoms as the indication the antibiotic should be started. Note that bronchitis will take many days to weeks to improve dramatically and the intention should be to assess for worsening disease.

STEWARDSHIP OPPORTUNITIES FOR COMMUNITY PHARMACISTS

Despite decades of research and stewardship interventions, antibiotic prescribing for acute bronchitis is common and unnecessary.¹¹ It may be difficult to confirm the diagnosis, but a few strategies can assist in reducing the use of antibiotics in bronchitis treatment.

71% of patients presenting to primary care receive antibiotics for bronchitis. >90% of acute bronchitis is viral¹¹

Proactive Strategies: Things to do before patients are ill with acute bronchitis

- 1) Educate:
 - a. Review the role of viruses as a common cause of respiratory illness
 - b. Ensure patients understand antibiotics do not kill viruses when discussing cold and flu treatment
 - c. Focus on infection prevention by encouraging good hand hygiene practices such as washing hands and/or using hand sanitizers

2) Immunize:

a. Influenza: although influenza causes only a small portion of acute bronchitis, it is an opportunity to discuss the topics above and reduce the chance of influenza by providing annual influenza vaccination

Reactive Strategies - Things to do when patients present with symptoms of acute bronchitis:

- 1) Assess severity and refer if necessary (see above)
- 2) Educate and set expectations: Consider the term "chest cold" instead of bronchitis to align with etiology and expectations of disease
- 3) Advise discuss warning signs that should prompt medical assessment (see above)
- 4) Support empathize and review available options to ensure safe symptom management
- 5) Follow up consider calling patients in 2-3 days to reassess symptoms
- 6) Antibiotic Prescriptions If presenting with an antimicrobial, ensure the indication and follow-up with prescribers as necessary

HELPFUL LINKS:

- SHS and UHN ASP Adult Acute Bronchitis
- SHS and UHN Antimicrobial Stewardship
- Do Bugs Need Drugs, Cough
- Public Health Ontario, Respiratory Pathogen Bulletin

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A Framework for Ethical Decision-Making

Ethical issues and dilemmas are a reality of everyday practice. The ability to make sound ethical decisions is a fundamental responsibility of pharmacists and pharmacy technicians as healthcare professionals.

Designed to enhance objectivity and consistency, the Framework for Ethical Decision-Making provides a systematic thought-provoking process to guide decision-making and document decisions made in practice that support our commitment to serve and protect our patients' best interests.

When confronted with an ethical issue or dilemma, pharmacists and pharmacy technicians should systematically work through the steps outlined in the Framework.

This article originally appeared in the Spring 2017 issue of Pharmacy Connection.

The Framework

- Is this a clear ethical issue of 'right and wrong'?
- What is the ethical issue or dilemma?
- Is the ethical dilemma complicated by a 'conflict of values'?
- What are the key facts?
- If related to a patient issue or dilemma, what are the patient's wishes? Does the patient have sufficient information to make an informed decision?
- Are there any unique situational factors that you need to consider?

Identify the Issue & Examine the Facts

- What does our Code of Ethics say about this situation?
- What does our Standards of Practice say about this situation?
- Are there any applicable legislation, policies or guidelines you need to consider?
- Is there any applicable research or literature available to inform and support you?
- Is there anyone you should consult such as a colleague and/or the College?

Apply Guidelines

and Standards

- Determine and critically reflect on at least 3 alternative courses of action. Consider the strengths and limitations of each.
- In considering potential resolutions, ask yourself: Would this course of action:
 - Put your patient first and respect his/her right as an autonomous person?
 - Bear public scrutiny, i.e., if your decision and conduct were made public, would it be considered ethical and appropriate?
 - Be considered acceptable as a precedent for future behaviour, i.e., would it be appropriate for all pharmacists or pharmacy technicians to now do this?
 - Support our commitment to serve and protect the best interests of our patients?

Evaluate Possible Resolutions

Implement & **Document Your** Decision-Making

- Choose the most appropriate course of action and implement your decision.
- Document the rationale for your decision, including an explanation of how it supports the best possible health outcome for the patient.

- Review and reflect on the outcome of your decision:
 - What did I learn from it?
 - What might I have done differently to produce a better outcome for my patient?
- Share learning with colleagues and other healthcare professionals if applicable.

Review and Reflect

Ethical Decision-Making

IN PRACTICE

AN EXAMPLE OF AN ETHICAL DILEMMA

After the narcotic order is received and reconciled at a community pharmacy, the pharmacist asks the pharmacy technician who is working that day to put away the order because the technician who usually manages the order is away sick. As the pharmacy technician is putting away the checked order, she looks at the previous orders for the month. She notices that quite a few of the previous orders include OxyNEO®, which she does not recall seeing in the pharmacy stock. On the previous order she notes that four bottles of OxyNEO® 20 mg were ordered. However, she recently had a patient with a prescription for that strength and the pharmacy didn't have any in stock and the patient ended up taking his prescription to another pharmacy. The only staff employed by the pharmacy are herself, the other technician and the owner. She suspects that the other pharmacy technician is diverting the OxyNEO®.

When presented with any ethical issue, pharmacy professionals should consider and apply the ethical principles of healthcare to determine the most appropriate ethical decision. If you are presented with a more complex situation, such as the one above involving a personal conflict of interest, it may be beneficial to take a more structured approach to decision-making to ensure that only the established ethical principles of healthcare, not your own personal values or beliefs, guide your decision-making.

The Ethical Decision-Making Framework can be used to assist pharmacy professionals in assessing a situation that poses a more complex ethical dilemma.

1. IDENTIFY THE ISSUE AND EXAMINE THE FACTS

The first step in assessing a complex ethical dilemma is to identify the key ethical issue(s) and then the facts of the situation. It is important to keep in mind that the facts surrounding the ethical issue include information that is known to exist or to have happened and are not influenced by the ethical issue itself.

In the above case, the pharmacy technician has noted that a quantity of narcotic drugs (OxyNEO®) is unaccounted for in the pharmacy. Of the three people on staff at the pharmacy, only one pharmacy technician routinely manages drug orders for the pharmacy. The pharmacy technician that has identified the discrepancy has strong evidence that the other pharmacy technician on staff has engaged in unethical behaviour.

If the pharmacy technician suspects that her colleague is diverting narcotic drugs, she has an ethical duty to report this to the Designated Manager for further investigation. There is also a professional duty of the pharmacy technician to report unethical behaviour by colleagues to the appropriate regulatory authority.

If an issue is identified in a pharmacy, simply reporting the employee within the organization or terminating employment is not enough. As a healthcare professional, you have a duty to act in society's best interest. If a Designated Manager releases an individual from employment and the individual is not reported (by

either yourself or the Designated Manager) to the appropriate regulatory body, you could be putting patients at other pharmacies and the public at risk if this former employee is simply hired at another pharmacy.

2. APPLY GUIDELINES AND STANDARDS

The Ethical Principles and Standards in the <u>Code of Ethics</u> provide guidance on expectations of conduct and behaviour. <u>Standards of Practice</u> set out minimal expectations of practice and provide guidance about the knowledge, skills, judgment and attitudes that members should apply to their practice to provide patients with safe and ethical care. College policies, guidelines and other supporting resources provide additional clarification on

Principle: Accountability

Related Standard: 4.10

Members report professional incompetence or unethical behaviour by colleagues or other healthcare professionals to the appropriate regulatory authority.

certain areas of practice. Legislation and regulations set out rules or requirements for the operation of a pharmacy and for individual practice. All of these can be applied when considering an ethical dilemma.

In this case example, pharmacy professionals are required to keep records of narcotic purchases and losses in accordance with relevant policies, guidelines and legislation. The Standards of Practice, legislation and College policies also outline requirements for narcotic inventory management. Review of the processes and narcotic records in the pharmacy against the requirements outlined in relevant resources would provide information indicating whether appropriate narcotic management is occurring in the pharmacy.

Examples of resources that should be considered with this case are:

- Code of Ethics Standards under Principle of Accountability
- Standards of Practice for Pharmacy Technicians -Standards under Standard 1: Expertise in drug distribution systems and Standard 4: Professionalism and Ethics
- Narcotic Control Regulations under the Controlled Drugs and Substances Act
- Medication Procurement and Inventory Management Policy
- Resources under the Narcotics Practice Tool that include Fact Sheets on Narcotic Purchases. Narcotic Purchase Records Narcotic Reconciliation and Security and Narcotic Reporting of Loss.
- The Code of Ethics section of the website provides an overview of the various resources related

to the core principles that dictate a healthcare professional's ethical duty to patients and society.

3. EVALUATE POSSIBLE **RESOLUTIONS**

The resources identified, including relevant ethical standards, should be used to determine possible resolutions to an ethical dilemma. Here are three options for this case, putting you in the role of the pharmacy technician:

Option A: Discuss the situation with the other pharmacy technician and determine if he has an explanation as to why the OxyNEO® is not in the pharmacy stock in the safe. Since you are good friends and you have been working with him for a long time and don't want to upset him, you tell him that if any additional issues arise you will have to bring it to the attention of the Designated Manager.

Option B: Inform the Designated Manager of the information that you have discovered and allow her to have a discussion with the other pharmacy technician. Since you feel you have done what you needed to and this is no longer your issue, you remove yourself from the situation after this point and leave any further decisions to the Designated Manager.

Option C: Although this is your friend and colleague you realize you have a professional responsibility to inform the Designated Manager of the information that you have discovered and allow her to have a discussion, with or without you, with the other pharmacy technician. You also ask that you be updated on the outcome and if unethical behaviour is identified fulfil your professional duty to ensure that the information is reported to the College and the

loss to Health Canada (either by yourself or the Designated Manager).

4. IMPLEMENT AND DOCUMENT YOUR DECISION-MAKING

Select an option from the possible resolutions you identified. Ensure that you document the specifics of the information you identified and why it concerned you, including dates and details regarding subsequent conversations on the particular issue. Information like this might be required if you make any kind of report.

In this specific case, Option C is the most appropriate option. The pharmacy technician has a professional duty to look past personal conflicts of interest to ensure that the unethical behaviour is reported to the appropriate authorities. Pharmacy professionals are reminded that dual relationships, such as a friendship with a professional colleague, often place the healthcare professional's needs - whether these are emotional. financial or social – in conflict with the needs, or best interests, of the patient and should be avoided.

5. REVIEW AND REFLECT

Consider the outcome of your decision and reflect on what the outcome may have been if you had chosen a different option. Review the outcome in relation to the standards in the Code of Ethics. Standards of Practice and other applicable resources and reflect on whether the outcome meets the requirements outlined in these resources. Use this opportunity to consider what you may do differently if presented with a similar situation in the future.

Thank you From Registration Programs PACE, SPT, SPE, Jurisprudence Exam

Many pharmacists and pharmacy technicians continue to demonstrate their commitment to the profession by ensuring that new registrants have met the entry-to-practice standards for the College's practice-based and jurisprudence registration requirements. These assessors, preceptors, evaluators, writers and standard setters also ensure that our registration programs reflect the current Standards of Practice. Thank you!

A list of preceptors and evaluators who served in 2018 is available at pharmacyconnection.ca





The College has moved Discipline Decisions online to pharmacyconnection.ca.

These easy-to-access decisions facilitate greater accessibility among pharmacy professionals, stakeholders and members of the public and allow us to share decisions more widely via e-connect, our website and social media. As always, pharmacy professionals are encouraged to view these decisions as opportunities to examine and enhance their own practice. Decisions also remain available to view on the <u>public register</u> and <u>CanLii</u>.



LIST OF WINTER 2019 DECISIONS:

Joy Abanzukwe (OCP #103497)

Violet Sargyos (OCP #210444)

Bhavesh Kothari (OCP #217389)

Abdelaziz Maharem (OCP #212352)

Amani Salama (OCP #216329)

The full text of these decisions is available at www.canlii.org.
CanLii is a non-profit organization managed by the Federation of Law Societies of Canada. CanLii's goal is to make Canadian law accessible for free on the Internet.



By Ian Stewart R.Ph, B.Sc.Phm.

Exercise caution when dispensing combination drug products - especially those available in multiple combination ratios.

There has been an increase in the development and utilization of multiple drug combinations over the last two decades. Benefits may include synergy and increased efficacy, the simplification of drug therapy and increased compliance.

Such drug combinations are regularly used in the treatment of a variety of medical conditions including HIV (e.g. Truvada®), diabetes (e.g. Janumet®), hypertension (e.g. Coversyl Plus®) and infection (e.g. Clavulin®).

However, many combination drug products are available in multiple dose combinations. The dispensing of the incorrect dose combination is often a factor in the dispensing of an incorrect drug product and/or dose.

CASE:

CLAMUN SUSPENSION
50 mg/12.5 mg/mL

Sig: take 35 ml to BID

MARE: / minth

* Note: we are using trich-bose equivalent to it of 675-tabs BID

The prescription was given to a 51-year-old patient upon discharge from hospital. The prescription was taken to a local community pharmacy and was entered into the pharmacy computer and processed for Clavulin® suspension containing 50mg amoxicillin and 12.5mg clavulanic acid/ml in a 4:1 ratio as prescribed. That is, Clavulin® 250 oral suspension containing 250mg amoxicillin and 62.5mg clavulanic acid per five milliliters. Thirty-five milliliters as prescribed would provide 1750mg amoxicillin and 437.5mg clavulanic acid.

However, the prescriber also indicated that the intent was to prescribe the equivalent of two Clavulin® 875 tablets. Each tablet contains 875mg amoxicillin and 125mg of clavulanic acid in a ratio of 7:1. Hence, two tablets would provide 1750mg amoxicillin and only 250mg clavulanic acid versus 437.5mg clavulanic acid as prescribed.

Fortunately, the pharmacist identified the calculation and substitution error during patient counselling and hence the incorrect drug product was not provided to the patient. The pharmacist was aware that Clavulin® 400 oral suspension contained amoxicillin and clavulanic acid in a 7:1 ratio similar to Clavulin® 875 tablets.

The prescription was, therefore, changed to Clavulin® 400 oral suspension which contains 400mg amoxicillin and 57mg clavulanic acid per five milliliters. The patient was instructed to take 21.9mls per dose equivalent to 1752mg amoxicillin and 250mg clavulanic acid.

POSSIBLE CONTRIBUTING FACTORS:

- Availability of amoxicillin:clavulanic acid in multiple combination ratios. See Table 1.
- Prescriber calculation/substitution error.

RECOMMENDATIONS:

- Educate all pharmacy staff about the potential for error when dispensing combination drug products, especially those products available in multiple combination ratios.
- Note that Clavulin®-125F and Clavulin®-250F oral suspensions are stable under refrigeration for ten days after reconstitution. However, Clavulin®-200 and Clavulin®-400 oral suspensions must be used within seven days after reconstitution.
- Double check all calculations including those completed by the prescriber. Do not assume all calculations performed by other healthcare practitioners are always correct.
- Wherever possible, a second individual should independently complete the calculation without prior knowledge of the results of the first calculation.

TABLE 11

Product	Content	Drug Ratio
Clavulin®-125F oral suspension	Each 5ml oral suspension contains 125 mg of amoxicillin as the trihydrate and 31.25 mg of clavulanic acid as the potassium salt	4:1
Clavulin®-250F oral suspension	Each 5ml oral suspension contains 250 mg of amoxicillin as the trihydrate and 62.5 mg of clavulanic acid as the potassium salt	4:1
Clavulin®-200 oral suspension	Each 5ml oral suspension contains 200 mg of amoxicillin as the trihydrate and 28.5 mg of clavulanic acid as the potassium salt	7:1
Clavulin®-400 oral suspension	Each 5ml oral suspension contains 400 mg of amoxicillin as the trihydrate and 57 mg of clavulanic acid as the potassium salt	7:1
Clavulin®-250 tablets	Each tablet contains 250 mg amoxicillin as the trihydrate and 125mg of clavulanic acid as the potassium salt	2:1
Clavulin®-500F tablets	Each tablet contains 500 mg amoxicillin as the trihydrate and 125 mg of clavulanic acid as the potassium salt	4:1
Clavulin®-875 tablets	Each tablet contains 875 mg amoxicillin as the trihydrate and 125 mg of clavulanic acid as the potassium salt	7:1

Please continue to send reports of medication errors in confidence to lan Stewart at: ian.stewart2@rogers.com. Please ensure that all identifying information (e.g. patient name, pharmacy name, healthcare provider name, etc.) are removed before submitting. Re

REFERENCES

1. Clavulin [product monograph]. GlaxoSmithKline Inc. Mississauga, Ontario; 2018

