Ontario College of Pharmacists
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PHARMACY CONNECTION

FALL 2020 • VOLUME 27 NUMBER 3
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THE OFFICIAL PUBLICATION OF
THE ONTARIO COLLEGE OF PHARMACISTS

ASK, LISTEN, LEARN:

Understanding Opportunities to Enhance Care for Indigenous Patients

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ALSO IN THIS ISSUE:

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BOARD OF DIRECTORS (as of December 7, 2020)

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.

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- Drug Preparation Premises
- Finance & Audit
- Governance
- Screening

Ontario College of Pharmacists
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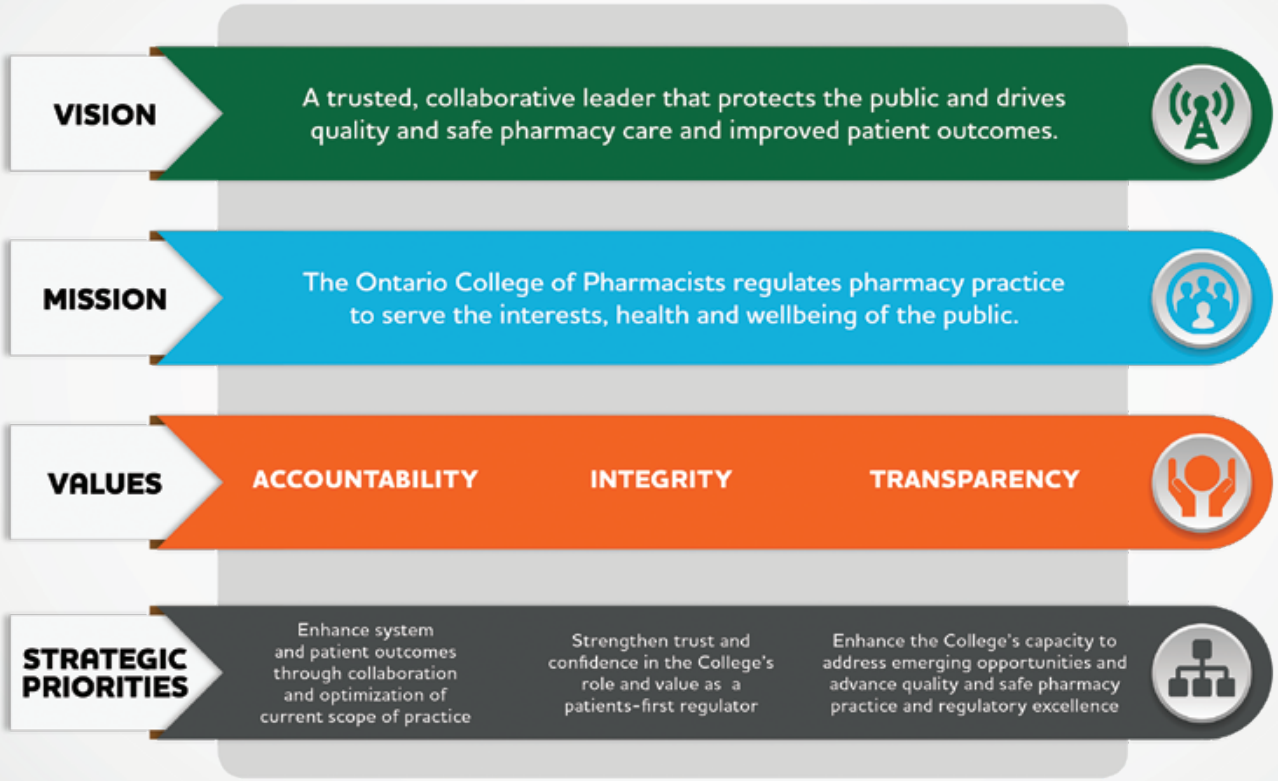
*(2019-2022/2023)**

OCP STRATEGIC FRAMEWORK



*In September 2020, the Board reaffirmed the priorities expressed within the existing multi-year strategic framework and deferred strategic planning activities through to 2022 or 2023.

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 registrants with other allied health care professionals; and to communicate our role to registrants 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 feedback 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,

The past several months have certainly been challenging, and particularly so for pharmacy professionals dealing with the uncertainties of providing safe, quality pharmacy care during a global pandemic. The rapidly evolving situation has tested the profession, and I want to thank you for your commitment to being there for patients when it matters most.

And despite the challenges, pharmacy professionals have adapted and innovated to ensure patients continued to receive the best possible pharmacy care. While physicians' offices were moving to virtual appointments across the province, pharmacies remained open. For many patients, pharmacists were the most accessible option for non-emergent care throughout most of 2020.

Here at the College, we have also had to find innovative solutions to meeting our obligations as a regulator while also protecting registrants and our own staff. We embraced virtual modes of interaction that made effective use of video—now the majority of practice and operational assessments, investigations and hearings are conducted virtually. Our Board continues to meet using video conferencing technology. And most of our College staff have been working remotely, while continuing to move our important work forward.

While COVID-19 remains a challenge for us all, the College remains focused on several important initiatives.

In the last edition of *Pharmacy Connection*, Laura Weyland, Chair of the OCP Board of Directors, co-wrote a letter with me about the College's responsibility to listen, reflect and act to eliminate social injustice in the pharmacy profession. Our Board has committed to work collaboratively with our academic partners to better understand how pharmacy students represent our diverse population, and we continue to look for ways to create dialogue and action that can make a difference to the communities we serve.

Part of that work involves understanding how the College and pharmacy professionals can better serve Indigenous communities, and in this edition of *Pharmacy Connection* I am pleased to share an interview with Dr. Jaris Swidrovich, Canada's first self-identified First Nations Doctor of Pharmacy. Jaris shares his insights about how the profession can work towards improving health outcomes for Indigenous patients, always with the understanding that the term "Indigenous" does not refer to a homogenous group.

Also in this edition is an article about Pharmacy Awareness of Indigenous Health (PAIH), a student-run group at the University of Toronto's Leslie Dan Faculty of Pharmacy that is seeking to bring awareness of healthcare barriers faced by Indigenous patients. Their work is helping to educate pharmacy professionals and improve cultural competency within the profession.

And you will read about the College's commitment to using data to inform quality improvement. The College has recently released data from its Assurance and Improvement in Medication Safety (AIMS) Program and its Quality Indicators initiative, using an interactive online tool that gives pharmacy professionals access to relevant data that may help focus their efforts when developing continuous quality improvement plans. As I mention in my Registrar's Reflection, I am passionate about using data to drive quality improvement and to inform our own work as a regulator, and I encourage you to consider how you can use data to achieve better health outcomes for your patients.

I know many pharmacy professionals are already in the midst of a busier-than-normal flu vaccination season, made even more challenging by the ongoing pandemic. The College is committed to continuing to support your important work, and I know that together we will help each other—and patients across Ontario—stay well and stay safe.

Sincerely,

Nancy Lum-Wilson

CEO and Registrar
Ontario College of Pharmacists

SEPTEMBER 2020 BOARD MEETING

As recorded following the Board of Directors' regularly scheduled meeting held on September 22nd, 2020.

This meeting was held via video and teleconference in consideration of provincial directives and social distancing measures recommended by Public Health due to the COVID-19 pandemic.

NEW PUBLIC MEMBER APPOINTED TO THE BOARD

The Board welcomed the newest public member, Rick Webster, to the College. Mr. Webster has been appointed to the Registration, Discipline and Inquiries, Complaints and Reports Committees.

RECOGNITION OF DEPARTING BOARD MEMBERS

This being the last regular meeting of the Board prior to the election, the Board Chair took the opportunity to extend the College's gratitude to the departing Board members including non-returning Elected Directors and Public Directors whose Order-in-Council appointments had expired since the last meeting.

BOARD DEFERS STRATEGIC PLANNING

The Board was presented with a briefing note outlining a proposal to defer planning of the next strategic plan. The Board considered and reaffirmed the priorities expressed within the existing multi-year strategic framework and decided to defer strategic planning activities through to 2022 or 2023. Current strategic priorities remain relevant and will continue to guide operational activities at the College as the Board also acknowledged the significant disruption caused by the COVID-19 pandemic and carefully considered the timing of governance reform .initiatives underway in making its decision.

STATUTORY AND STANDING COMMITTEE REPORTS

Each year, the Board receives a written report from each of the Committees as per section 11.1 of the *Regulated Health Professions Act*, 1991. Under the new governance framework there is a need to bolster the reporting process to ensure adequate communication between the Committees and the Board and to allow the Board's mission, vision, and philosophy to be incorporated into the Committee work. Each Committee Chair was asked to provide a brief summary of the activities over the past year while providing feedback and learnings for consideration by future Committees.

UPDATE ON THE EXPANDED SCOPE OF PRACTICE FOR PHARMACISTS

The Board was informed that the Ministry has concluded the public consultation on regulatory changes to permit expanded scope for administering certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration, renewing prescriptions in quantities of up to a year's supply, and administering the influenza vaccine to children as young as two years old. The timelines for the provincial government's approval of these elements of expanded scope of practice for pharmacists are not known at this time.

College staff provided a brief summary of the work to support the implementation of expanded scope of practice for pharmacists once approved by the government. The College is currently developing:

- A mandatory e-Learning module to help pharmacists understand the ethical, legal and professional obligations

of prescribing while meeting the established standards of the profession

- A variety of resources to support a consistent approach to prescribing for minor ailments. These include a decision-making algorithm that outlines the Standards of Practice and a Practice Resource Page on the College's website to direct registrants to recommended clinical resources that will support therapeutic decision-making

- A communications plan to provide information to the public, registrants and other partners and stakeholders on the scope changes

As well, courses and resources to assist registrants administering influenza vaccinations to young children (ages two and up) have been developed by education providers and will be made available once the authority to do so takes effect, pending government approval.

NEXT BOARD MEETING

The next scheduled meeting will be held Monday, December 7, 2020. Board meetings are open to the public and are held in the Board Chambers of the College at 483 Huron Street, Toronto, ON, M5R 2R4 or electronically if necessary. If you plan to attend, or for more information, please contact Ms. Sarah MacDougall, Board and Committee Liaison at boardofdirectors@ocpinfo.com. You can also follow highlights from the Board meetings via the College's Twitter account.

BOARD APPROVES AMENDMENTS TO ALLOW EMERGENCY ASSIGNMENT REGISTRATION CERTIFICATES

At a special meeting held on November 19th, the OCP Board unanimously approved submitting to the Minister of Health regulatory amendments that enable the creation of an emergency registration certificate class of pharmacy professionals. These regulations require government approval and would only be implemented once the government determines, in collaboration with the College, that there is a shortage of qualified pharmacy professionals that puts at risk the ability of Ontarians to access timely and safe pharmacy services during an emergency situation—including the current pandemic. The Board also approved making a formal request to the Ministry of Health to waive the consultation period for the proposed regulatory changes.

The full rationale for the development of this regulatory-focused proposal, which is grounded in our mandate to serve and protect the public interest and our fiduciary duty expressed in legislation, can be found in the briefing note posted to our website. The College is now working on the next steps that include making the formal submission to the government for their consideration and approval, which is required before this regulation comes into effect.

2020-2021 OCP BOARD OF DIRECTORS

Terms come into effect December 7, 2020.

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Pharmacist

GORAN PETROVIC
Pharmacy Technician

TRACEY PHILLIPS
Pharmacist

BILLY CHEUNG
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MARK SCANLON
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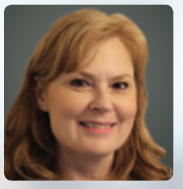

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DEVINDER WALIA

RICK WEBSTER

FACULTY OF PHARMACY

LISA DOLOVICH
Dean
University of Toronto

DAVID EDWARDS
Hallman Director
University of Waterloo

Planning for Safe Implementation of

EXPANDED SCOPE OF PRACTICE

Pharmacy professionals have an important role to play in helping meet the needs of patients while contributing to healthier communities and a high performing, collaborative health system. It is expected that their role will become even more significant with anticipated legislative changes that will expand their scope of practice – some of which could soon be approved by the provincial government.

In May 2019, the Minister of Health asked the College to submit draft regulations that would enable pharmacists to administer the flu vaccine to children as young as two years old, renew prescriptions in quantities of up to one year's supply, and administer certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration.

These draft regulations were submitted to the Minister and Ministry of Health in November 2019 following a collaborative, system-wide engagement process that involved patients, registrants, physicians and other healthcare providers, professional associations, regulators and others. Their insights shaped the development of regulatory amendments, and are informing the work required to support expanded scope of practice for registrants.

Over the summer, the government posted the draft regulations on the Ontario Regulatory Registry for a 45-day public consultation. No changes will come into effect until the government has approved the regulatory amendments.

MINOR AILMENTS

In June 2020, the College also submitted draft regulations to the Minister of Health that would allow pharmacists to prescribe for certain minor ailments, including:

- Urinary tract infections
- Dermatitis
- Insect bites, including tick bites, as well as hives
- Conjunctivitis
- Allergic rhinitis
- Candidal stomatitis
- Herpes labialis
- Hemorrhoids
- Gastroesophageal Reflux Disease
- Dysmenorrhea
- Musculoskeletal sprains and strains
- Impetigo

The minor ailments draft regulations were developed after several months of consultation with the Minor Ailments Advisory Group as well as feedback from registrants, the public, patient advisors, professional associations, health regulators and other stakeholders.

PROVIDING SUPPORT FOR PHARMACY PROFESSIONALS

While the government must approve the relevant regulations before pharmacists can practice these expanded scope activities, the College has been developing resources to support the profession in implementing the changes safely and with confidence.

For example, to ensure pharmacists fully understand their ethical, legal and professional obligations of prescribing for minor ailments, the College's Board of Directors has approved the requirement for all Part A pharmacists to complete mandatory orientation on the regulatory requirements and practice expectations that is free to registrants and not to exceed two hours in length. It is important to note that the mandatory orientation requirement does not relate to clinical training; the College will continue to expect that pharmacists who engage in this new authority, once approved by government, will have the required knowledge, skills and judgement to do so safely and ethically and in accordance with the standards of practice, Code of Ethics, and current clinical resources.

Once the government approves regulation changes, the College will share relevant tools and resources to support expanded scope activities. Further details about the ways the College will be supporting pharmacy professionals will be shared in future editions of e-Connect and on the College website.

THE CODE OF ETHICS:

Principle of Beneficence

The primary role of healthcare professionals is to benefit their patients and to actively and positively serve patients and society. Patients seek the trust and care of pharmacy professionals because they believe and trust that pharmacists and pharmacy technicians will apply their knowledge, skills and abilities to help make them better.

Key ethical standards, among others, require pharmacy professionals to:

- *Ensure that their primary focus at all times is the well-being and best interest of the patient.*
- *Utilize their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize health outcomes for patients.*
- *Apply therapeutic judgment in order to assess the appropriateness of current or proposed medication therapy given individual patient circumstances.*
- *Provide patients with the relevant and sufficient information they need in order to make more informed decisions about their healthcare.*
- *Ensure that information provided to patients is current and consistent with the standards of practice of the profession and best available evidence.*
- *Make every reasonable effort to provide quality cost-effective pharmacy care and services to patients and society.*

LEARN MORE ABOUT BENEFICENCE

- Read the Code of Ethics
- Watch the e-Learning Module on Beneficence
- Review the Framework for Ethical Decision Making

The Code of Ethics articulates the ethical principles and standards that must guide the practice of pharmacists and pharmacy technicians. As a way to draw attention to the Code since its introduction almost five years ago, we will be featuring one ethical principle in each upcoming edition of *Pharmacy Connection*.

COMMUNITY PRACTICE ENVIRONMENT INITIATIVE:

Engaging patients and professionals in the journey towards guiding principles

Earlier this year, the College initiated a Community Practice Environment Initiative aimed at understanding confirmed and potential barriers to the provision of consistently safe and high quality care in community pharmacy through thoughtful, respectful and meaningful collaboration and engagement with pharmacy stakeholders. An important milestone in this work is the development of principles of shared accountability intended to guide the development of specific strategies to further strengthen the quality and safety of pharmacy care, while helping position the profession for ongoing success as pharmacy plays an increasingly important role in the health and wellbeing of Ontarians.

PRINCIPLES TAKING SHAPE THANKS TO IMPORTANT INSIGHTS

Over the past several months the College has implemented a series of engagement activities with patients and pharmacy professionals to hear from those who receive pharmacy services and those who directly deliver services to their communities about the realities of pharmacy practice in community pharmacies. From focus groups to surveys, the insights gleaned from participants have helped the College, with the support of a multi-disciplinary Advisory Group comprised of patients, pharmacists, pharmacy technicians, owners/operators and professional associations, get a better picture of the various perspectives of those most connected to the delivery of pharmacy services in our communities—insights which are leading directly to the development of accountability principles which will both complement and build on established Standards of Operation, standards of practice and the Code of Ethics.

ENGAGEMENT STRATEGIES IMPLEMENTED OVER THE SUMMER AND EARLY FALL:

Public/patient focus groups
The College engaged Leger Canada to host a total of 4 focus groups with members of the public, all of them patients of community pharmacies and from diverse backgrounds and representing different patient populations.

Registrant/Owner focus groups
The College also engaged Leger Canada to host a total of 4 focus groups, one each with pharmacists, pharmacy technicians, owners/operators who are also pharmacists and Designated Managers.

Registrant survey
The College deployed a practice environment survey to registrants asking for input on some of the insights received to date through the various engagement activities as well as the earlier jurisdictional scan conducted as part of this initiative.

Summary reports from each of those engagement activities can be found on the College's website under Key Initiatives > Community Practice Environment Initiative where you can also find summaries of each of the Advisory Group meetings held to date.

NEXT STEPS

The College and Advisory Group discussed how to transform the information and insights gained, along with the information from earlier jurisdictional scans, into principles that will provide a foundation for improving the practice environment and the experience of providing pharmacy services in community pharmacy settings. It was confirmed that the principles will need to be at a level that can be translated to pharmacy-level actions.

The principles are now being drafted and will be presented at an upcoming Board of Directors meeting. Pending endorsement by the Board, the College will move forward with finalizing the principles and then rolling them out across all community pharmacies in the province in the New Year.

REGISTRAR'S Reflection

Transparent data sharing informs pharmacy quality improvement

It's often been said that you can't fix what you don't measure, and that applies particularly well to making quality improvements in the way pharmacy care is delivered. Without robust data, we cannot clearly identify opportunities for enhancing patient outcomes at both the pharmacy and system levels, and we certainly can't define benchmarks.

Quality improvement helps achieve better health outcomes for patients, and it builds trust in the profession of pharmacy. And to be effective, quality improvement must be based on evidence.

That's why capturing, validating, analyzing and sharing data with pharmacy professionals is a top priority for the College. We know that successful quality improvement initiatives are data-driven, and we want registrants to have the tools and information they need to make informed decisions about the impact on patients of the care they are providing. This is an important part of the College's commitment to accountability and transparency, and to fulfilling our mandate of serving and protecting the public.

The key to improving patient outcomes—the crucial reason for driving quality improvement—is to ensure the data we are sharing are accurate, meaningful, and have the necessary context for registrants to make quality improvements in their own practice.

Continuous quality improvement is a core component of outcomes-focused regulation, which focuses on achieving broad objectives rather than on prescriptive rules. By consistently using data as a way to raise the bar for patient safety and better health outcomes, both the College and pharmacy professionals are enabled to make informed, evidence-based decisions that ultimately enhance trust in the quality of pharmacy care Ontarians receive.

Here at the College, we have started to shift our regulatory approach by applying a greater focus on using and analyzing data to help make evidence-informed decisions to impact more broadly on the profession and health system. I am passionate about using data to inform our work, shape quality pharmacy practice, and better inform sound regulatory decision making.

To support pharmacy professionals, the College's approach to data sharing is to make as much relevant information as possible available to help registrants and teams focus their efforts when developing continuous quality improvement initiatives in their own practice, and to give the public confidence in their pharmacy care.

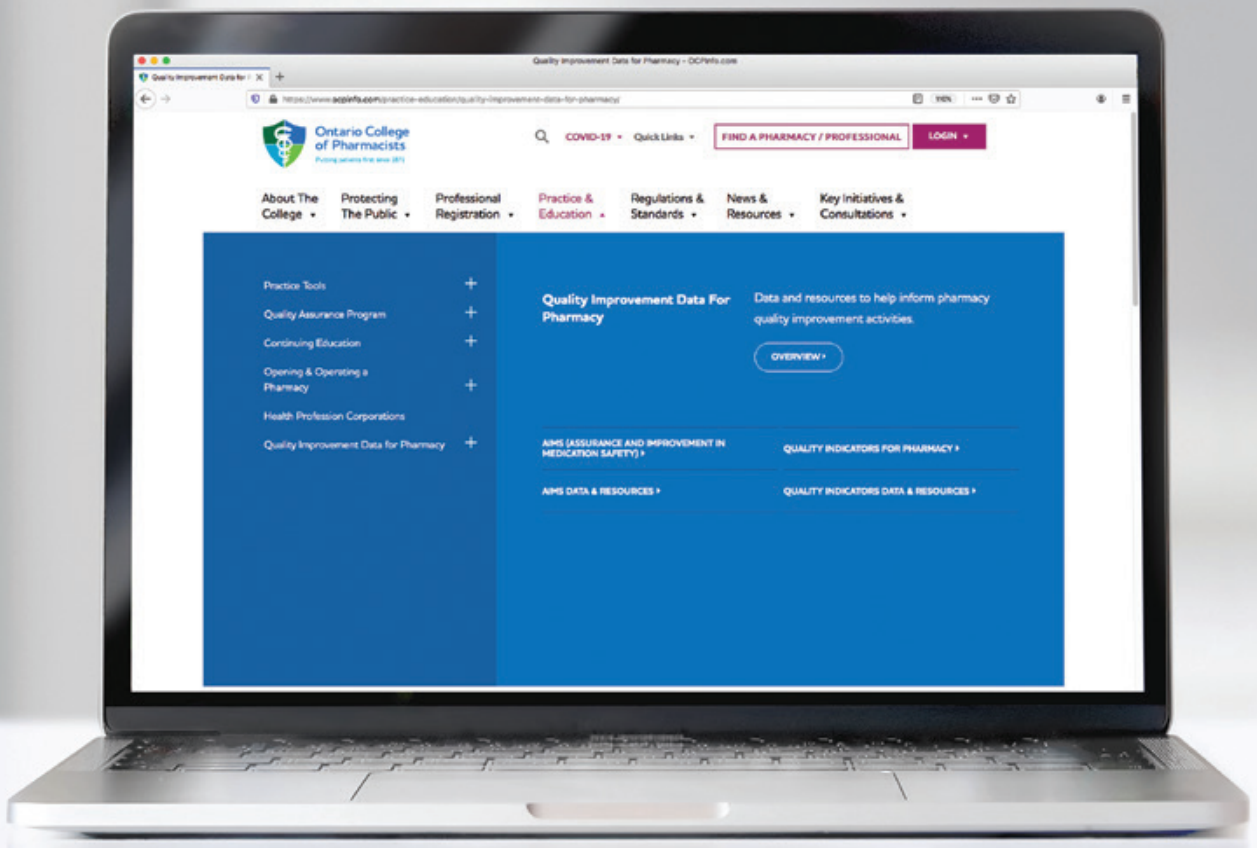
That's why we have launched initiatives such as Quality Indicators for Pharmacy and Assurance and Improvement in Medication Safety (AIMS) that are designed to help registrants assess their practice against regional and provincial data, giving them the necessary information to build continuous quality improvement plans that enhance both patient safety and health outcomes. This data is being shared in a way that helps registrants understand its significance, and where possible, includes practice insights to guide them in how to apply the data within their own pharmacy practice's quality improvement strategies.

Quality Indicators and AIMS data are now being shared on the College website using an interactive tool that allows registrants to access de-identified aggregate information about the way pharmacy care is delivered. It is important to note that the College only has access to de-identified aggregate data to support shared learning and system-based improvements across the province. The College does not have access to information related to a specific pharmacy or pharmacy professional through this program.

You can read more about accessing Quality Indicators and AIMS data on the next page.

For pharmacy professionals, regularly reviewing the data available to them is an important part of continuously examining and improving the quality of care they provide. This is a shared responsibility, and it's one that continues to enhance confidence and trust with the patients we serve. By embracing the importance of using data to improve pharmacy care, we are working together to improve the quality and safety of Ontario's health system.

Sincerely,
Nancy



AIMS AND QUALITY INDICATORS:

Using Data To Inform Quality Improvement

Quality improvement among pharmacy professionals and their teams provides an opportunity to focus on areas that can enhance the way care is delivered to patients. Having access to relevant data can help address those areas and help to inform continuous quality improvement initiatives that can have a positive impact on patient safety and health outcomes.

Successful quality improvement initiatives are data-driven, and registrants and patients need the tools and information to make informed decisions.

One of the keys to improving patient safety and health outcomes is to identify opportunities to share data that are accurate and meaningful and have the necessary context for registrants to be able to make quality improvements in their practice. This is an important part of the College's commitment to accountability and transparency, and to fulfilling our mandate of serving and protecting the public.

The College publicly shares data from a number of sources that allows pharmacy professionals to assess their practice against regional and provincial data, giving them the necessary information to build continuous quality improvement plans that enhance both patient safety and health outcomes.

MANDATORY AIMS (ASSURANCE AND IMPROVEMENT IN MEDICATION SAFETY) PROGRAM

The AIMS (Assurance and Improvement in Medication Safety) Program is a standardized medication safety program that supports continuous quality improvement and puts in place a mandatory consistent standard for medication safety for all community pharmacies in the province. Its goal: to improve medication safety and reduce harm caused by medication incidents.

The AIMS Program enables practitioners to learn from medication incidents, and better understand why they happen and how they can be prevented. Utilizing both a preventative approach through proactive reviews of work processes to identify areas of risk and retrospective reviews of specific medication incidents, pharmacy professionals will be able to identify learnings that will help prevent incidents and near misses and enhance patient safety.

Using AIMS data

The College is evolving new ways to provide registrants with practice insights based on AIMS data. Registrants are encouraged to use the data warehouse within the AIMS Pharmapod platform to review their own pharmacy data and to compare it to provincial results, as well as to use the continuous quality improvement tool as part of their own quality and medication safety improvement plans.

An interactive tool on the College website also provides the ability to view aggregate, anonymous medication incident and near miss data on some of the event recording fields available through the AIMS Program.

QUALITY INDICATORS

To better understand the impact of pharmacy care on patient outcomes, the College, in partnership with Health Quality Ontario (now called Ontario Health), established the first set of Quality Indicators for community pharmacy in Canada. These indicators provide the public with a clearer picture of the overall quality of pharmacy care in Ontario and support quality improvement efforts by pharmacy teams and the College.

An **interactive tool** that reports data from the first three Quality Indicators on appropriateness of dispensed medications, medication-related hospital visits, and transitions of care is now available on the College website.

Registrants are encouraged to use the tool alongside information and data from their own practice to better understand the quality of care they provide. While the data does not provide information about any one pharmacy, the tool helps identify regional and provincial trends that can help registrants and teams focus their efforts when developing continuous quality improvement initiatives in their own practice.

Patient/Caregiver-Reported Experience Measures

The Patient/Caregiver-Reported Experience Measures were developed for community pharmacy in 2019 using a rigorous process led by an expert panel that incorporated feedback from more than 100 patients, 20 corporate executive leaders and 100 frontline pharmacy professionals. To confirm these indicators measure areas of pharmacy care that are important and relevant to patients and caregivers they will be validated before a plan for data collection is developed.

Once the indicators have been validated, the College will undergo user testing and work alongside experts in collecting information from patients and those who own, operate and practice within community pharmacy to develop a data collection plan.

Provider Experience Measures

Measuring the experience of pharmacy professionals is an important part of the Quality Indicators for Pharmacy initiative, and developing these provider experience measures requires broad engagement with registrants. The start of this process was postponed from Spring 2020 in recognition of the pressures experienced in community pharmacy due to the COVID-19 pandemic response. The College continues to monitor the impact of this pandemic on community pharmacy to determine when the process of developing provider experience measures can move forward. At this time, the plan is to launch a working group by the Fall.

Practice Insight:
RECOGNIZING AND RESPONDING TO RED FLAGS

Practice Insight explores incidents reported to the College that present learning opportunities for pharmacists and pharmacy technicians. This ***close up on a complaint*** *highlighted below encourages registrants to reflect on when and how they recognize and respond to red flags in practice.*

A MISSED MEDICATION ON HOSPITAL DISCHARGE RESULTS IN PATIENT HARM

A community pharmacist received a faxed hospital discharge prescription, which was quite faded, for an older patient. The patient's daughter attended the pharmacy to pick up the prescription without the original prescription; she also wanted to wait for the compliance pack instead of having it delivered later. The prescription had a list of 30 medications, including discontinuations, additions and dose changes. The pharmacist failed to add one of the medications to the patient's compliance aid. As a result of not receiving the medication, the patient was readmitted to hospital and experienced serious consequences to their health.

OUTCOME FROM THE INQUIRIES, COMPLAINTS AND REPORTS COMMITTEE

Upon reviewing the complaint, a panel of the College's Inquiries, Complaints and Reports Committee noted that the pharmacist in this case did not pay sufficient attention to ensure accurate dispensing in a situation where both the patient's age and

complex medication regime can be considered *red flags*.

While the panel recognized that the faxed prescription itself was in poor quality, they noted that it was essential for the pharmacist to have taken the appropriate amount of time to diligently and accurately fill the discharge prescription. The panel emphasized that the primary responsibility of the pharmacist is to the safety of the patient. Therefore, the checking process for any prescription must always be performed regardless of time constraints, such as the patient or their agent waiting onsite, and that complex discharge prescriptions require additional diligence. In addition, the panel noted that patients who receive medications in compliance packaging trust the pharmacist to help them manage the drug therapy prescribed by the physician.

In this case, the pharmacist apologized to the patient, and identified strategies to implement in the pharmacy to avoid repeating the incident.

The panel required the pharmacist to complete specified remediation, namely a workshop on medication safety, in addition to issuing an Oral Caution to remind the pharmacist of the importance of taking extra care when preparing compliance packs.

LEARNINGS FOR PHARMACY PROFESSIONALS

Pharmacists and pharmacy technicians have a professional responsibility to take all measures to ensure that the right medication is dispensed to the right patient in the right dose with the correct instructions as intended by the prescriber. The Standards of Practice specifically require that pharmacists apply their medication use expertise

to ensure patients receive the appropriate therapy.

The Code of Ethics requires that pharmacy professionals must be diligent in identifying and responding to *red flag* situations that present in practice. Seniors, especially those with complex medication regimens, should be considered *red flag* or particularly vulnerable patients and proper attention must be provided as potential serious outcomes could occur in this population.

Transitions of care from one setting to another (in this case, from hospital to home) can present risks to patients and require appropriate quality assurance mechanisms in place to prevent harm. See the *Pharmacy Connection* article "Coroner's Inquest into the Death of an Elderly Patient Attributed to Medication Error During Care Transition" for a discussion of specific recommendations for pharmacy professionals.

If a prescription is unclear, pharmacy professionals must be diligent in ensuring they have enough information to safely prepare and/or dispense the prescription, which may include taking more time to complete the prescription and/or seeking additional information from the prescriber. Even if a patient requires a medication immediately, pharmacists may consider options such as dispensing a small amount of necessary medications until the full prescription can be verified.

The College's Guideline on Multi-Medication Compliance Aids requires that pharmacies must have policies and procedures in place, and the appropriate physical space, equipment and trained staff to ensure the safe preparation of compliance packages. This can include, as a best practice, an uninterrupted workflow when preparing and packaging the compliance aid.

The primary focus at all times must be on the well-being and best interests of the patient. Even if the patient (or their agent) is waiting for their prescription, pharmacy professionals must take the time to use their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize the patient's health outcomes.

ASK, LISTEN, LEARN:

Understanding Opportunities to Enhance Care for Indigenous Patients

An Interview with Jaris Swidrovich, Canada's first self-identified First Nations Doctor of Pharmacy

In September 2019, the College's Board approved the adoption of three opportunities to cultivate Indigenous cultural competency amongst non-Indigenous Board members, College staff and registrants. This commitment includes identifying ways to address cultural inequities to improve patient outcomes and highlighting resources for registrants to enhance the care they provide to Indigenous patients and communities.

*As part of this work, the College was pleased to interview **Dr. Jaris Swidrovich**, a member of Yellow Quill First Nation and Canada's first self-identified First Nations Doctor of Pharmacy. Dr. Swidrovich is a clinical pharmacist and an Assistant Professor of Pharmacy in the College of Pharmacy and Nutrition at the University of Saskatchewan. He is dedicated to educating healthcare workers and students on Indigenous topics and reconciliation, in addition to undertaking educational and clinical work related to HIV/AIDS, mental health, and substance use disorders.*

Q: What have you observed about pharmacy and the role of pharmacy professionals when it comes to caring for Indigenous peoples and communities in Canada?

There have clearly been gaps in our education—all the way from kindergarten to becoming a pharmacist. Those gaps are really prevalent. In every presentation I've given over the last few years, over 90% of the audience can't tell me what the Sixties Scoop was, for example.

The Sixties Scoop, as a single example, is directly connected to why so many Indigenous folks are accessing the healthcare system or why they might be in the hospital, or why they might be dealing with depression, anxiety, or substance use, and are therefore presenting to community pharmacy for medication. Those traumas are not even on the radar for many pharmacy professionals.

Terminology is not well known. So, I usually focus a lot on terminology in the presentations I do so we know who we are talking about, as well as move away from that monolithic representation of Indigenous Peoples as one people.

Because Indigenous voices are not well-represented in our profession, there hasn't been an opportunity for change from the inside. It's tough to share Indigenous experiences with professionals when they haven't witnessed it from the inside. Racism is prevalent and that is a big barrier. For many folks in pharmacy, the only Indigenous peoples they see or talk to are the patients they interact with in their professional setting—so those situations subconsciously, sometimes even consciously, become the representation of who Indigenous people are, which is not true. We get a very one-sided image in our walk of life as pharmacy professionals. It creates barriers as it labels everyone else as something different.

Q: When thinking about individual pharmacy professionals, and what they do on a daily basis, are there any examples of how these barriers typically happen?

One barrier is that incorrect terminology can often be used. Another is that there can be assumptions that everything is provided to First Nations patients. Or there can be an idea that Indigenous patients are always struggling—there seems to be this rhetoric that we are living in mayhem. Which is not true, there are absolutely thriving Indigenous communities.

One example I often refer to in order to illustrate barriers to care: patients will present with a status card that enables them to receive payment of their medication under the Non-Insured Health Benefits Program (NIHB). Navigating the NIHB system can be quite a pain sometimes. In cases where a pharmacy professional is frustrated with the NIHB system, that experience can sometimes lead to a negative interaction with the patient; there's a sense of "ugh" or "oh, great" coming from the professional when they know they will need to access the system. So that can lead to a negative experience or exposure.

Our limited understanding, as pharmacy professionals, of Indigenous medicine and practices can create an awkward power imbalance. The concept of cultural safety is addressing and breaking down that hierarchy that exists in healthcare and addressing the inherent power imbalance in our system. When we aren't able to entertain questions or concerns about Indigenous medicine and practices, again we are upholding Western knowledge as superior and either disregarding or de-valuing Indigenous practices and medicines. If a patient feels that their pharmacist doesn't care, this can affect their level of engagement.

Q: What are some things that pharmacy professionals should be thinking about now to address these issues and overcome these barriers and challenges?

There is a lot of learning that needs to happen. Unfortunately we need to fill in those gaps in knowledge of Indigenous peoples and history in Canada that were not presented to us in all of our schooling. That's not the fault of people. For pharmacists who are not aware of terminology, of history, or of best practices, I don't blame them at all because that probably wasn't provided to them. But now the professional responsibility lies with that individual to learn and to make up for those gaps.

The messaging that I share frequently is that pharmacists are the most accessible healthcare professional and often ranked the most trusted. The greatest gaps in health outcomes experienced by people in Canada are between Indigenous and non-Indigenous peoples. So arguably, within the healthcare sector, pharmacy professionals have the greatest opportunity to effect change in this area.

Quite often, pharmacies are the first point of access to the healthcare system as a whole—we are really that gateway. That single interaction can really make or break the healthcare experience for people. In a world and sector where racism is rampant, that's our opportunity to show that we are different, that we care, that we are not racist, that we are anti-racist.

Q: You've mentioned terminology and language a few times as an area for learning and awareness. Why is proper language and naming so important?

If I mis-gendered you, that wouldn't make you feel great because that's not who you are. By using incorrect terminology, you are disregarding someone's identity and sometimes incorrectly labelling someone. Terminology also plays an important role in our pharmacy world because it is only certain First Nations and some Inuit people who have access to Non-insured Health Benefits (NIHB).

Indigenous is an umbrella term; it applies to all of First Nations, all of Métis and all of Inuit. Native and Indian should not be used to describe First Nations people, though some First Nations people may have reclaimed those names or use it in their own way.

You can go more specific than First Nations. For example, I'm Saulteaux but depending on the situation, I may not refer to myself as that. For Métis folks, they are often excluded from the consciousness of people when they say Indigenous—but they are Indigenous peoples. Inuit means "people" and is a collective term for Inuk people.

Q: Knowing the commitment pharmacy professionals in Ontario have to the Code of Ethics and the principles on Justice/Respect for Persons, is there anything that they can and should be doing when applying this principle?

I think it would be difficult to apply those principles in action, if we're not even aware of who in our society is marginalized or why they are marginalized and how and why they need to be treated equitably.

For example, how can you treat a First Nations patient equitably if you don't know what the residential schools were, if you don't know what the Sixties Scoop was, if you don't know that most children in the province who are apprehended are First Nations because of colonial views of what families are supposed to be and how they are supposed to function. We just simply can't fully enact that principle without knowing more.

And also, spending more time asking questions than speaking is a great practice to honour the individuality of people. We need to be able to hear their story and understand who they are without making any snap judgments. Which can sometimes be difficult in a really fast paced pharmacy environment, I get that.

Q: What should organizations, institutions and corporations, from academic institutions, to professional bodies to pharmacy owners and operators be thinking about and doing to help support pharmacy professionals in their role? And how can we increase Indigenous representation in pharmacy?

Number one, more can be done to provide and facilitate education... education always.

Secondly, there should be a concentrated and dedicated effort to recruit, retain and centre Indigenous pharmacy professionals. Sometimes that will need very different practices than how we normally might recruit and reach folks.

We need to take a step back and think about if we are doing things *for* Indigenous people or *with and by* Indigenous people. And it really should be *with and by*.

Even ensuring representation in everything—in images from corporations. I don't recall seeing a visibly Indigenous person in the materials from corporations, regulatory bodies, advocacy groups. The message that current or prospective Indigenous pharmacy professionals receive is that this isn't a place for us. If we don't see ourselves, it is a really quick write off.

There are very few pharmacies on-reserve so that opportunity for us to make an impact in the community is limited when we aren't even there. It is difficult for people to consider pharmacy as a profession if they are rarely or never exposed to it, they don't even see pharmacists and pharmacy technicians in the community.

If we provide more of a presence in both urban and rural Indigenous communities, perhaps those ripples of change will start to be noticed and pharmacy will be on the radar as a potential career aspiration.

Q: Are there any final thoughts that you wanted to convey to Ontario pharmacy professionals?

I would encourage folks to always be curious. By being curious, that would perhaps prompt seeking educational resources or seeking learning or even introspection on their own biases and beliefs that might exist.

I would even just personally thank them for reading my words—it means the world. I'm conscious of and thankful for the platforms that I do have, like this magazine—it's really special. I think about my family members whose voices were just diminished and lost and suppressed. Whereas what I have to say is being uplifted and shared. And I thank all the readers for engaging in this content and area and seeking to learn more.

As part of our commitment to cultivate Indigenous cultural competency amongst non-Indigenous Board members, College staff and registrants, the College is committed to highlighting efforts by pharmacy professionals and others to enhance the care provided to Indigenous patients and communities. Below, students at the University of Toronto's Leslie Dan Faculty of Pharmacy share some of the ways they are educating pharmacy professionals and reducing barriers faced by Indigenous patients.

SPOTLIGHT ON:

University of Toronto Pharmacy Students Bringing Awareness to Healthcare Barriers Faced by Indigenous Patients

By: Max Yaghchi, Past President and Co-Founder of PAIH, and Anjali Patel, Current President of PAIH

Pharmacy Awareness of Indigenous Health (PAIH) is a student-run group at the University of Toronto's Leslie Dan Faculty of Pharmacy. We seek to bring awareness to the healthcare barriers faced by Indigenous patients, to reduce these barriers by improving pharmacy students' Indigenous cultural competence, and to increase Indigenous representation in pharmacy practice. We identify and promote local Indigenous cultural events, share articles regarding Indigenous health on social media, and host health education workshops at Indigenous centres.

PAIH's most recent initiative is the NIHB Optimization Program, which was developed in collaboration with Tiana Tilli from Whole Health Pharmacy Partners, to increase access to eligible over-the-counter (OTC) products for Indigenous patients. NIHB (Non-Insured Health Benefits) is a federally funded health and drug plan for registered First Nations and Inuit patients. This plan covers a wide range of OTC products with some examples being vitamins, analgesics, contraceptives, and nicotine replacement therapy.

Many pharmacy professionals are unaware that NIHB reimburses OTC products with a written recommendation from a pharmacist, allowing Indigenous patients to access OTC products without paying out-of-pocket. Pharmacists are reimbursed for recommending appropriate eligible schedule II, III and U products for patients with NIHB coverage. This program is independent of minor ailment prescribing and is available in all Canadian provinces and territories except for British Columbia, where PharmaCare Plan W is used instead. All members of the pharmacy staff can assist in increasing awareness of this NIHB coverage, both among Indigenous patients and pharmacy professionals.

PAIH and Whole Health Pharmacy Partners, have developed a pharmacy provider infographic and a patient-facing infographic. These infographics provide guidance on utilizing NIHB's OTC product reimbursement. They can be accessed free of cost on our MDBriefCase page, which has donated resources to host these infographics to ensure that they are accessible for pharmacy providers and clients of NIHB. Our pharmacy provider infographic provides guidance on the billing procedure for OTC product reimbursement. The patient-facing infographic is a tool that allows Indigenous patients to be aware of common eligible OTC products that are covered and to ensure their pharmacy team is aware of NIHB's reimbursement of OTC products.

In the coming year, PAIH will continue to develop health education based on the needs of the Indigenous community, while working to increase Indigenous cultural competence among pharmacists. We will launch a social media initiative to bring awareness to health inequities experienced by Indigenous persons, and to highlight how pharmacists may reduce them through patient care. We also hope to connect virtually with Indigenous persons and organizations to increase our own knowledge of healthcare barriers and to establish what we, as future pharmacists, can do to address them.

To date, all PAIH executives have been non-Indigenous pharmacy students, and our goal is for PAIH to be one day led by a team that truly reflects and represents the Indigenous community. Until then, we will continue to connect pharmacy professionals with resources to enhance their Indigenous cultural competence, and welcome you to follow us on our social media.

NON-STERILE COMPOUNDING:

Training and Facilities Questions

The College addresses some common questions about implementation of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations regarding personnel training and facility requirements. As a reminder, Phase 2 requirements related to personnel training and quality assurance must be met by July 1, 2021. See the Checklist Overview for Phases 1, 2 and 3 on the OCP website.

Phase 2 of the NAPRA Non-Sterile Compounding Standards implementation involves personnel training and skills assessment. What courses does the College recommend? What if we cannot get all the compounding staff trained by July 1, 2021?

Refer to Section 5.2, Table 1, Table 2, Checklist 1 and Table 8.4 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

In Phase 1, the knowledge and skills of non-sterile compounding personnel should have been assessed for gaps to identify training needs and help plan for the work needed in Phase 2 and, ultimately, to fully achieve the standards by January 1, 2022. Depending on the extent of these gaps, it may be appropriate to put into place an intermediary risk mitigation strategy that addresses safety, while providing continuity of care for patients.

There is no requirement in the NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations for personnel to complete a formal, accredited or third-party training program. The

pharmacy manager/department head (or designated non-sterile compounding supervisor) may choose to develop their own training tools and program to suit their specific needs. The intended outcome is that the expertise of personnel responsible for compounding must be commensurate with their assigned duties. The potential need for training is not limited to the compounding processes or technique; personnel must also be educated on policies and procedures, such as those related to attire, personal protective equipment, cleaning, and conduct, which must also be developed during Phase 2.

Refer to Table 8.4 of the Guidance Document for an overview of training topics for each Level (A, B or C), as well as the specific sections relevant to the type of personnel or preparation. Fillable and printable forms for Phase 2 activities can be found on the NAPRA website:

- Checklist 1: Skills assessment checklist for compounding process
- Table 1: Elements to cover in training of compounding personnel
- Table 2: Elements to cover in training of cleaning personnel
- Table 3: Examples of policies and procedures

For registrants interested in exploring external courses, OCP provides a listing of CE resources however the listings are not exhaustive, and inclusion of a course is not to be construed as an endorsement.

We are planning to renovate our pharmacy space to meet Level B requirements. Do we need to move the sink so it is inside the compounding room?

Refer to Sections 5.4.1.4, 9.1.1 and 9.2.1 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

It is a standard of accreditation for all pharmacies to have two sinks or one double sink in the dispensary. These standards must be maintained at all times. Accredited pharmacies engaged in non-sterile compounding must also implement the Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the sink requirements outlined in the accompanying guidance document (GD).

A Level B compounding room requires a sink within the room that meets the requirements of Section 5.4.1.4. If there is a C-PEC in the room for compounding hazardous drugs, Section 9.1.1, consideration should also be given to the placement of water sources and drains so that the operation of the C-PEC is not compromised. These are summarized in the Table below.

Any material changes to the existing accredited area require a Notice of Renovation to be submitted to the College, and an Operations Advisor will be assigned to review the floor plan.

LEVEL	Sink Location	GD Section	Comments
A	• In or close to the compounding area	5.4.1.4	• If the designated compounding area is in the dispensary, the minimum sink requirement for accreditation may serve to meet both sets of standards. • Consider accessibility (for example, compounding volume and number of personnel compared to the available time and space), ease of use, potential for splashing nearby areas, etc.
B	• In the compounding room	5.4.1.4	• If there is a C-PEC, consider Section 9.1.1 and consult supplier regarding proper installation and certification
C	• In the compounding room • Water sources and drains should be located at least 1 meter away from the C-PEC.	5.4.1.4 9.11	• To avoid interfering with required ISO classifications in a Level C room (see footnote 56 for reference to <USP 800>)
All levels	• Clean, potable, hot and cold running water for washing hands and equipment • Preferably made of stainless steel and having touchless control	5.4.1.4	• Plumbing system should be free of defects that could contribute to contamination

How do I determine whether external ventilation is needed for non-sterile compounding?

Refer to Sections 5.4.1.3, 8.2, 8.3, 9.1, 9.1.1, 9.1.2, 9.1.3 and 9.1.5 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

Ventilation (the "V" in HVAC) is an engineering control intended to remove or control contaminants released in indoor work environments by bringing in fresh air. Fans, while they circulate the air, are not suitable for ventilation as they would blow the contaminant around the work area without effectively controlling it. Opening a window or door might allow outdoor air in, however it is not controllable and risks bringing in other contaminants and disrupting the compounding environment.

The Canadian Centre for Occupational Health and Safety (CCOHS) Fact Sheet on Industrial Ventilation may be helpful for background information on this subject. Compounding personnel should know how the secondary ventilation (HVAC) system operates.

The external ventilation requirements differ between Levels A, B and C (see table below).

For storage of other hazardous products (e.g., non-antineoplastics, products that carry a reproductive risk, and final dosage forms) external ventilation is recommended but this may not always be possible.

LEVEL	External Ventilation	GD section
A	• External ventilation is not required for the designated compounding area • Refer to the requirements for all levels of compounding	• 5.4.1.3
B	• External ventilation is not required for the compounding room; however, this room must be well-ventilated or have a ventilated containment device (C-PEC)	• 8.2 • 9.2.1
C	• External ventilation through high-efficiency particulate air (HEPA) filtration is required for compounding and storage of hazardous products, particularly antineoplastic drugs • If this is not possible, the Designated Manager/department head should determine if having redundant HEPA filters in a series would result in adequate protection for personnel	• 9.1.2 • 9.2.1
All levels	• The Standards of Operation require pharmacies to be designed, constructed and maintained to ensure the integrity and the safe and appropriate storage of all drugs and medications; including, the proper conditions of sanitation, temperature, light, humidity, ventilation, segregation and security	

Do we need two separate designated compounding areas for hazardous and non-hazardous non-sterile preparations?

Refer to Sections 9.1, 9.1.1, 9.2.1, 9.2.2 and 9.3 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

It is preferable to have separate areas for compounding hazardous and non-hazardous non-sterile preparations, however, if this is impossible and the same area is used, compounding and/or cleaning personnel must, at minimum, be assured that the area and any reusable equipment has been meticulously deactivated, decontaminated and cleaned to prevent any risk of cross-contamination from the hazardous materials before other preparations are compounded.

Because of the difficulty of removing hazardous product contamination, the surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the non-sterile compounding area should be smooth, impermeable, free from cracks and crevices, and made of non-shedding material. It is strongly recommended that equipment be dedicated for compounding each of hazardous and non-hazardous drugs. Alternatively, disposable equipment should be used, if possible, to reduce the chances of cross-contamination.

The Designated Manager/department head and/or non-sterile compounding supervisor must have policies and procedure in place for the deactivation, decontamination and cleaning required after compounding hazardous non-sterile preparations. As part of the pharmacy's quality assurance program, personnel must be trained and their work routinely assessed to ensure compliance with procedures.

For more information and resources related to non-sterile compounding, including checklists, assessment tools, articles and FAQs, please visit the Non-Sterile Compounding webpage.

STERILE COMPOUNDING:
Third Party Evaluators and Assessment Reminders

THIRD PARTY EVALUATORS FOR EVALUATING THE STERILE COMPOUNDING SUPERVISOR

A third party evaluator is a pharmacist or pharmacy technician with expertise in sterile preparation compounding who is free of any real or perceived conflict of interest with the individual being evaluated. The third party evaluator must be independent (at arm's length) from the facility/pharmacy to ensure an impartial competency assessment.

The third-party evaluator (either a pharmacist or pharmacy technician) must meet the criteria set out in section 5.1.2.4 of the NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations for third-party evaluators.

The compounding supervisor must ensure that the third-party evaluator is qualified and has training that covers the compounding of sterile preparations and certification that his or her competencies (which include the same elements as those of a competency assessment program for compounding personnel) are being maintained, developed and assessed on an annual basis. Any third-party evaluator or model used must mitigate risk and meet the intended outcome of this standard.

The third-party evaluator may perform training and competency assessment at the workplace or at an alternate location.

The College does not recommend or endorse a particular pharmacy professional for this role.

COMMUNITY PHARMACIES WHO ARE ENGAGED IN STERILE COMPOUNDING: KEY REMINDERS

As of January 1, 2019, pharmacies engaged in sterile compounding must be compliant with the Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations (NAPRA) and the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations (NAPRA).

Following recent assessments, College operations advisors have the following reminders for community pharmacies who are engaged in sterile compounding:

- **Full compliance with the NAPRA standards is expected.** In order to support pharmacy compliance with the NAPRA standards, and recognizing that pharmacies may have needed additional time to conduct education and implement infrastructure modifications, the College worked with pharmacies in 2018 and 2019 to support action plans and mitigation strategies. In 2020, it is the expectation of the College that pharmacies are now in full compliance with the standards; therefore, assessment ratings and comments may be different than the educational and informative recommendations provided in 2018 and 2019. The College's assessment tools and approaches are regularly refined through a continuous quality improvement process to ensure that assessments are consistent and completed in a manner that supports compliance with the NAPRA standards, with the ultimate goal of protecting the public's health and safety.

- **College assessments focus on the NAPRA standards.** The College does not assess against USP or other compounding standards – the focus of the assessment is on the NAPRA standards. Pharmacies should use the Hazardous Sterile Preparations Assessment Criteria and the Non-Hazardous Sterile Preparations Assessment Criteria to prepare for their assessments.

- **Requirements regarding Beyond Use Dates (BUD) outlined in the NAPRA standards must be met.** Pharmacy professionals are encouraged to review the Guideline – Extending the Beyond-Use Dates for Sterile Preparations, the *Pharmacy Connection* article "Beyond Use Dating – the North York General Hospital Experience," and Cancer Care Ontario's Beyond-Use Date Recommendations Report to ensure that requirements are met.

- **Hazardous and non-hazardous rooms must be separate for sterile compounding.** The standards require that facilities that compound both hazardous and non-hazardous sterile preparations must have two clean rooms: one for the compounding of hazardous sterile preparations and the other for the compounding of non-hazardous sterile preparations.

Additional information and resources are available on the Sterile Compounding Standards and Implementation Key Initiative on the OCP website.

Ensuring Therapeutic Appropriateness For New And Refill Prescriptions

Recent practice assessments have highlighted the importance of establishing a workflow that ensures that therapeutic checks are being done for both new and refill prescriptions at the pharmacy. Both pharmacy technicians and pharmacists must be aware of their accountabilities for a prescription prior to its release to the patient.

PATIENT ASSESSMENTS ARE CRITICAL FOR OPTIMAL HEALTH OUTCOMES

For every prescription that is dispensed, pharmacists must ask whether the prescription is **therapeutically appropriate**. This means that the **pharmacist** must have assessed the patient and authorized that drug 'x' is the appropriate medication for the patient.

When performed in an efficient, structured manner, patient assessment allows the pharmacist to gather the necessary information to make informed decisions that will help resolve their patient's primary issue and meet their patient's desired health outcomes. Pharmacists are expected to gather relevant information through dialogue with the patient, and review the patient profile. Note that patient profiles need to be maintained; a patient's health is not static and their profile should be reviewed on a regular basis.

An example of a systematic approach to identify problems related to the patient's drug therapy is Alberta College of Pharmacy's Chat, Check, Chart method. Use the "Check" method of four questions to identify potential drug therapy problems and evaluate the appropriateness of therapy for a patient:

I: Is the therapy **indicated?** Understand the indication and if it is still valid (for example, has anything changed with their health status? Was the medication meant for short term use?)

E: Is the therapy **effective?** Understand if the goals of the therapy are being met (for example, are the medications supporting changes in blood sugar?)

S: Is the therapy **safe?** Understand if there are changes in medications or conditions, if monitoring is needed (i.e. blood work), if there are potentially other untreated conditions or if additional therapies could be instituted.

U: Is the patient willing to **use/adhere to the therapy?** Understand the patient's compliance with the drug regimen and schedule.

CASE EXAMPLE:

Patient A has been on pantoprazole for the past 12 months and has presented at the pharmacy requesting a refill on her prescription. The patient has expressed that she is in a hurry as she has an appointment to get to but she just needs this refill. The refill is processed and filled by an assistant. The assistant asks the pharmacy technician to check the prescription as the pharmacist is in the counselling room administering a flu shot to another patient. The pharmacy technician checks the technical aspects of the refill prescription and notes that the patient is on time for this refill. Is this prescription ready for release to patient A?

Answer: No. A therapeutic check by the pharmacist must be completed prior to release to the patient.

Using the Check method to approach patient assessment in this case, the pharmacist would consider:

I = The indication for the pantoprazole and the ongoing appropriateness of continuing therapy. For example, was the patient initially prescribed the pantoprazole along with an NSAID which has since been discontinued?

E = What is the current status of symptoms and has the pantoprazole been effective?

S = What are the risks of continuing the pantoprazole (for example, lower calcium and B12 absorption) versus the benefits (for example, would a lowering of the dose or deprescribing be an appropriate recommendation?)

U = How has the patient actually been using the pantoprazole regardless of how it was prescribed (for example, has the patient been taking it regularly? At what dose? Has the prescriber discussed long term use?)

UNDERSTANDING THE RESPONSIBILITIES OF PHARMACISTS AND PHARMACY TECHNICIANS FOR THERAPEUTIC AND TECHNICAL CHECKS

Under the Standards of Practice for the profession, pharmacy technicians are responsible and accountable for the technical aspects of all prescriptions that they check, both new and refill (i.e. the correct patient, product and prescriber in accordance with the prescription). Pharmacists remain responsible and accountable for the therapeutic/clinical appropriateness of all prescriptions.

Under the Standards of Practice, prior to releasing any medication to a patient, it is the responsibility of the pharmacy technician to ensure that the prescription has been reviewed for therapeutic appropriateness by a pharmacist; a pharmacy technician **cannot** release the product, including for refills, until that therapeutic check is complete. A therapeutic check is required regardless of whether an issue is identified or not. There must be an established process in place at the pharmacy to ensure that the pharmacist's authorization, which can be digital or handwritten, has occurred.

The Designated Manager of the pharmacy must establish a method for identifying the pharmacist and technician responsible for each prescription (new and refill). Although signatures are the traditional method of accepting or declaring responsibility, pharmacy teams may wish to utilize other mechanisms within clearly defined and understood policies and procedures. Electronic and/or paperless workflow processes should consider this requirement.

The pharmacy team is encouraged to develop policies to ensure clear accountability when the pharmacy technician is independently authorizing prescriptions (for example, in reference to compliance packaging using a structured/defined review process.) This can support the therapeutic check authorization process and ensure both a technical and therapeutic authorization is in place for prescriptions prior to the medication being released to the patient.

It is important to note that when the act of dispensing is shared between the pharmacist and a pharmacy technician, each individual must be aware of their own scope as well as the others'. In order to have a collaborative approach when dispensing, a well thought-out process will ensure that the independent functions of the technical check and the therapeutic check are completed and documented by the right individuals each time to optimize patient outcomes. See the Legal Authority for Scope of Practice/Authorized Act chart for specific authorized acts for each profession.

ADDITIONAL RESOURCES

- The Importance of Patient Assessment (*Pharmacy Connection* Spring 2018)
- Pharmacy Technicians – Professional Responsibilities and Standards of Practice (*Pharmacy Connection*, Fall 2016)
- Working Together: Pharmacists and Pharmacy Technicians Are Teaming Up in Ontario to Deliver Patient Care (*Pharmacy Connection* Winter 2012)
- Patient Assessment Practice Tool
- Understanding What a Pharmacy Technician Can Do
- Frequently Asked Questions from Pharmacy Practice (*Pharmacy Connection*, Winter 2018)
- Legal Authority for Scope of Practice/Authorized Act chart
- Chat, Check, Chart – Alberta College of Pharmacy

Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
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Unauthorized Access to Methadone in a Community Pharmacy Contributes to Death

- *Ensure that methadone preparation and storage areas are always supervised by pharmacy staff, with no opportunity for unauthorized patient access.*
- *Store methadone in a secure manner, out of public view.*
- *Reconcile narcotic inventory more often than every 6 months, and conduct daily inventory counts and reconciliation for frequently dispensed controlled substances, such as methadone.*
- *Educate staff to recognize an individual experiencing a mental health crisis and empower them to follow up their concerns with the patient and relevant health care providers.*
- *Ensure accessibility to an emergency preparedness protocol to guide staff in circumstances such as an opioid overdose and/or a patient presenting with suicidal ideation.*

Methadone, a full opioid agonist, is most frequently used as an evidence-based pharmacotherapy for individuals living with an opioid use disorder. Methadone has a narrow therapeutic index and an inappropriate dose can lead to serious harm.[1,2] As part of an ongoing collaboration with a provincial death investigation service, ISMP Canada received a report describing the death of an individual who ingested a large amount of methadone that had been inappropriately accessed in a community pharmacy. This bulletin highlights the contributing factors identified in the incident analysis and suggests strategies to improve methadone security in community pharmacies.

INCIDENT DESCRIPTION

A patient was receiving buprenorphine-naloxone (available as Suboxone or a generic) from his regular community pharmacy for opioid use disorder treatment. On the day of the incident, the patient jumped over the dispensary counter into the unattended staff-only area, took a bottle containing methadone, and began drinking the methadone liquid directly from the container. Pharmacy staff immediately called police and emergency medical services (EMS) and attempted to stop the patient from drinking more methadone.

During transport to the hospital, the patient was alert and conversing with paramedics. Once at the hospital, the patient's condition began to deteriorate rapidly. Despite intubation, administration of naloxone, and other interventions, the patient died the next day because of multi-organ failure due to acute methadone toxicity.

Read the Full Safety Bulletin at ISMP-Canada.org READ MORE

Be Prepared for Emergencies at the Pharmacy

Emergencies can happen at the pharmacy. It's important to have plans in place to be able to respond in an appropriate and efficient manner that supports the health and safety of everyone involved.

The recent *ISMP Canada Safety Bulletin: Unauthorized Access to Methadone in a Community Pharmacy Contributes to Death* highlighted an incident where an individual died after ingesting a large amount of methadone that had been inappropriately accessed in a community pharmacy.

Among the recommendations made by the Office of the Chief Coroner of Ontario following this death was the importance of having an emergency preparedness plan for situations that may occur in the pharmacy.

ELEMENTS TO CONSIDER IN AN EMERGENCY PREPAREDNESS PLAN

The following are situations that pharmacies may wish to include in their emergency preparedness plan. Note that this is not an exhaustive list; Designated Managers/pharmacy managers will need to consider unique characteristics of their pharmacy when preparing their plan. First aid training materials will also often provide a list of potential emergency situations where a response may be required.

- Recognizing and responding to a mental health crisis (see the *Pharmacy Connection* article "Suicide Risk Assessment and the Role of the Community Pharmacist" for additional resources)
- Recognizing and responding to an opioid overdose, including where to find naloxone and how to administer it (see the Opioid Practice Tool for more resources, including those for patients and families)
- Recognizing and responding to emergency medical situations, such as injuries, heart attacks and anaphylactic shock, including where to find supplies/treatments that may be needed (i.e. AED, epinephrine auto-injectors, first aid kit)
- Identifying information that may be needed for first responders (i.e. medical conditions, treatment

provided, pharmacology of medication that may have been ingested)

- Responding to a robbery or break and enter (see the *Pharmacy Connection* article "Safety and Security for Pharmacies: Preventing Robberies")
- Responding to natural disasters in the community (i.e. fires, floods), such as facilitating access to medical records and critical medications and collaborating with other healthcare providers/ authorities

It is critical that all pharmacy staff are trained on emergency preparedness protocols upon commencement of work at the pharmacy and that the plan is readily available and accessible to all staff in the pharmacy.

An emergency preparedness plan can also be part of larger business continuity planning (see the Ontario Pharmacists Association Pharmacist's Guide to Pandemic Planning for resources.) With the ongoing COVID-19 pandemic, pharmacy managers may also need to plan for key issues such as:

- Ensuring the most up to date public health guidelines are reflected in pharmacy processes/ operations
- Reviewing ongoing information and updates from the College, government, and others
- Managing potential risks to pharmacy staff and patients (including drug shortages, lack of accessibility/availability of prescribers, occupational health and safety)
- Managing personal protective equipment supplies, usage and training
- Managing staff absences and any changes required to pharmacy operations (i.e. changes in hours of operation)

Emergency plans should be reviewed regularly and updated as necessary.

THE IMPORTANCE OF FIRST AID TRAINING

It is a requirement of the NAPRA Model Standards of Practice for Canadian Pharmacists for pharmacists who provide patient care to **maintain valid certification in first aid and CPR**, at a level equivalent to the St. John Ambulance or Canadian Red Cross Standard First Aid & CPR/AED Level C.

As a self-regulated health professional, it is the responsibility of the individual pharmacist to determine the applicability of this standard to the nature of patient care being provided in the context of one's specific working environment. Pharmacists should apply professional judgment to make this determination with the best interest, benefit, and safety of the patient considered first and foremost.

While First Aid and CPR training is not a requirement of the NAPRA Models Standards of Practice for Canadian Pharmacy Technicians, pharmacy technicians are strongly encouraged to obtain and maintain this certification.

For more information about this requirement, please visit the College's First Aid Requirements for Pharmacy Professionals webpage.

COMMUNITY PHARMACY AND PRIMARY CARE:

Working Together to Support Patients with Depression in Northern Ontario

As a regulator increasingly focused on health system and patient outcomes, the College is committed to working with stakeholders to enable a collaborative approach to healthcare. The College recognizes the important role that pharmacy professionals play in the broader healthcare system, and has embedded a systems-focus in many of its key initiatives, including Quality Indicators, AIMS and the work to enable expanded scope of practice for pharmacists.

OCP recently partnered with Ontario Health (North) and Ontario Health (Quality) to develop a systems approach to enable collaboration between primary care and community pharmacy to improve care for patients with depression.

In northern regions there are unique challenges which serve as barriers to treating patients with mental health disorders. These include low health care provider-to-population ratios, travel time to reach service providers, local demand for services, and percentage of repeat hospital stays for patients with mental illness. Strengthening the integration of primary care and community pharmacy will help to provide care across the continuum and better support patients with depression.

This project aimed to develop and test a model demonstrating the benefits of provider collaboration in delivering care for patients in two northern communities (Sudbury and Espanola). This model, aligned to the Ontario Health (OH) Quality Standard for Major Depression, involves primary care practitioners asking patients to connect with their community pharmacist who provided regular follow-up and monitoring as well as additional supports regarding adjunct therapies for self-management.

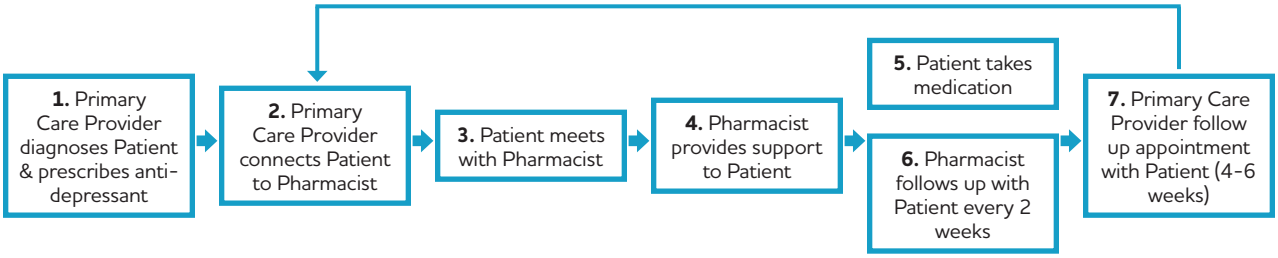
A shared model assists professionals to contribute in a meaningful way to patients and the system by providing the right level of support in an accessible location to achieve healthcare goals and, in some cases, improve access to care.

The role of the College was to help the project partners navigate regulatory responsibilities of pharmacy professionals in designing and implementing the model and to demonstrate support for pharmacies to participate in these types of quality improvement approaches in their own communities.

FOCUSING ON THE FIRST SIX WEEKS OF CARE

In this model, the pharmacist would meet with the patient, after receiving a prescription from the primary care provider, to assess their health status, discuss their health and well-being, and provide appropriate education on their prescription as well as any additional recommendations regarding their health (i.e. services in their local community, non-medication supports). The pharmacist follows up with the

patient at two weeks and four weeks after dispensing to assess their health status, discuss their adherence and response to the medication and offer support in terms of suggesting adjunct therapies or community resources. Throughout this process, the pharmacist is encouraged to communicate with the primary care provider as needed (i.e. updates on the patient health status, recommendations for changes to medication, additional supports provided). Pharmacists were provided with a toolkit of resources to guide their discussions with patients.



RESULTS FOR PATIENTS, PROFESSIONALS AND THE DEVELOPMENT OF FUTURE MODELS

Throughout and after implementation of the model, patients, primary care providers and pharmacists were asked to contribute to measurement and evaluation. The majority of patients felt that the additional supports were helpful and would recommend them to friends and family. Participating healthcare professionals found that the collaboration between primary care providers and pharmacists was helpful to patients. Overall, it was demonstrated that there was value in working in this sort of collaborative quality improvement model to support good outcomes for patients.

Key enablers of the success of the model included establishing new relationships and engaging upfront with primary care providers, adapting staffing at the pharmacy to allow pharmacists to take on this role, and facilitating access to health records, such as through the ClinicalViewer.

As a next step, the toolkit will be shared to enable others to adapt the model to their practice. It is anticipated that this process, whereby community pharmacies and primary care collaborate to implement Ontario Health Quality Standards, could be adapted to other conditions such as COPD and diabetes. It could also be applicable to Ontario Health Teams, where community pharmacists can play a role in a team-based model of care.

ACCESS PATIENT INFORMATION THROUGH CLINICAL VIEWERS IN ORDER TO SUPPORT BETTER PATIENT CARE

Pharmacies are able to access provincial patient information through secure, web-based clinical viewers hosted by Ontario Health (either ConnectingOntario ClinicalViewer or ClinicalConnect.)

Patient information provided through the clinical viewers includes:

- Medication information (publicly funded dispensed drugs, dispensed monitored drugs, pharmacy services)
- Laboratory results (from the Ontario Laboratories Information System)
- Discharge summaries (from the Acute and Community Care Clinical Data Repository)

The dynamic view of patients' health information provided by the clinical viewer can both support the work of pharmacy professionals in delivering counselling, support and treatment, and contribute to better patient care.

There is no cost to pharmacies to participate. To sign up for access to the clinical viewer, the pharmacy's Director Liaison or Designated Manager must complete a request to "Onboard My Organization" on the Ontario Health website for either ConnectingOntario Clinical Viewer or ClinicalConnect.

WORKING TOGETHER TO SUPPORT PATIENTS:

One Pharmacist's Experience with the Community Pharmacy and Primary Care Model

Lynn Halliday is a pharmacist at Espanola Clinic Pharmacy who participated in the project. Below, she shares her experience as well as advice for pharmacists who may want to integrate a similar quality improvement approach in their pharmacies.

How did you engage with primary care providers as part of this project? And what advice would you have for pharmacists who want to build more collaborative relationships with primary care providers in their community?

Since our pharmacy is in the same space as the physician offices, I mostly "marched" back to talk with our physicians in person whenever issues arose. Initially the head of the Family Health Team hosted a meeting with all of the physicians to explain the project and I was allowed to present the pharmacy perspective of this project. This was terrific because I was able to get first hand input from them and to discuss what they wanted feedback on and how they wanted to receive it. There was some questioning at this meeting about the need for pharmacists in the project and this gave me a terrific opportunity to present the case for collaboration with pharmacy.

My advice for other pharmacists is to make opportunities to speak directly with their main physicians about how best to communicate with them, whether via email, fax, memos or phone calls then try your best to keep the information short, to the point and given in the manner that they wish to receive it.

What were some of the benefits you saw for your patients as a result of this approach?

My patients felt that they were cared for, because I would call them. They were usually glad to receive these calls especially since their condition often made them feel neglected, sad and alone. Establishing relationships is so important to people. In addition, the longer the patient took their medication properly, the better they felt. When they had problems due to the medications, I was there to help them to problem solve the issues, thereby keeping them on their medication when they otherwise would have stopped.

What was the time commitment to participate and how did you integrate it into your workflow?

This required very little extra time, since counselling on new prescriptions is standard and I follow up with many new prescriptions anyway and already have a process in place. For the timeframe of the actual project I had to record the patients enrolled and activities on a spread sheet, this was a matter of five minutes per day.

I think that each pharmacist can do follow ups by learning to use the pharmacy management system to alert and record. I used my system (we have Kroll) to document both my follow up appointments and responses to these calls. Then I used my standard Professional Opinion form to inform physicians of any issues or adaptations that occurred as a result of the calls. Using the Professional function in Kroll, I was able to record the initial interview with my patient and schedule a follow up. Once I completed the follow up call or visit, I then used the follow up tab to record pertinent details, which then recorded to the original interview note with a new date. Learning how to use this function was an important "take-away" that I have now applied to other medication documentation.

Being organized is the key. Making follow up phone calls can be a bit time consuming, but with organization it can be done in the slow moments, during regular flow. I try to print the list of follow up calls for the day at the beginning of my shift, then I work my way through the list when I get quiet dispensing moments. I save the calls to students and working patients for nights and weekends.

Did you identify any other key learnings or changes to your practice as a result of taking part in this project?

It's important to have the right resources in one place to help patients cope with this illness and support discussions with them. For example, a community "help" chart with contact or program names that I can recommend to patients who need support.

Even though this project has ended, I will informally continue to do follow ups with this group of patients and also with others as needed.

This design could be adapted to many different diseases and can fit into the normal flow of the pharmacy. The partnership of the primary care provider and the pharmacist allows the provider to initiate therapy and the pharmacist to help keep it going. Pc

Ontario College of Pharmacists

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MEMBERSHIP RENEWAL REMINDER

RENEWAL PROCESS OPENS IN LATE **JANUARY 2021**

NOTE: No form will be mailed to you, however email reminders will be sent. If you fail to pay your fees by March 10, 2021, a penalty will apply.

Before you begin your renewal of your registration you will need:

- Credit Card
- User ID: This is your OCP number
- Password: If you have forgotten your password, click "**Forgot your password**"

Once you're ready:

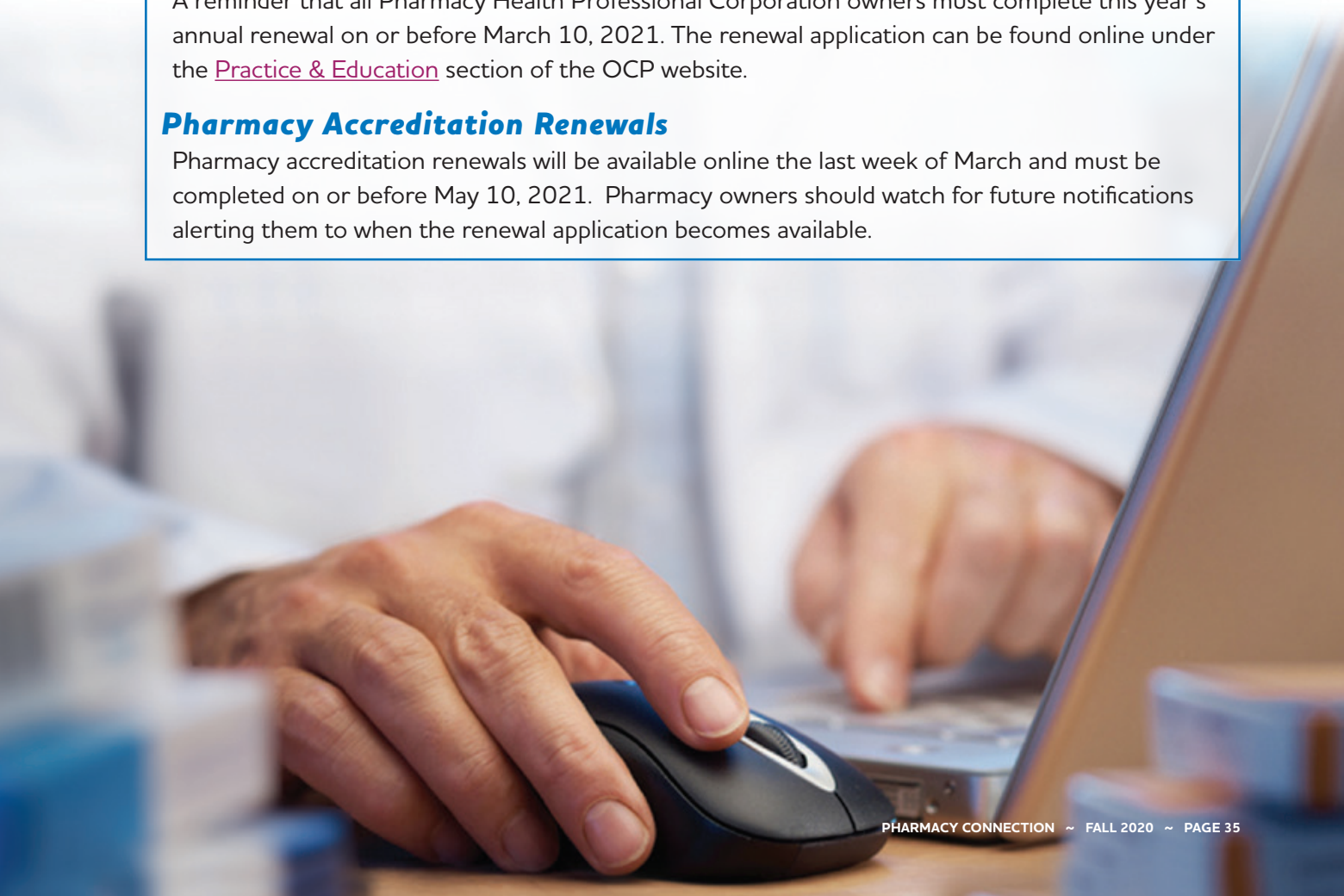
- Go to www.ocpinfo.com and click on "**Login**" and then click on "**My Account**"
- Enter your User ID (your OCP number) and your password
- Once you have successfully logged in, click on "**Annual Renewal**"

Health Professional Corporation Renewals

A reminder that all Pharmacy Health Professional Corporation owners must complete this year's annual renewal on or before March 10, 2021. The renewal application can be found online under the Practice & Education section of the OCP website.

Pharmacy Accreditation Renewals

Pharmacy accreditation renewals will be available online the last week of March and must be completed on or before May 10, 2021. Pharmacy owners should watch for future notifications alerting them to when the renewal application becomes available.



BIOSIMILARS AND BIOLOGICS:

Navigating the Uncertainty in Ontario

Kathy Vu[1,2], **Daniela Gallo-Hershberg**[1,2], **Sean Hopkins**[1]

1. Ontario Health (Cancer Care Ontario)
2. Leslie Dan Faculty of Pharmacy, University of Toronto

BIOLOGICS AND BIOSIMILARS

A biologic is a complex protein molecule created inside a living cell. This living cell can be a human or mammalian body, a bacterial cell or a cell line from a mammal. For instance, insulins, filgrastim (Neupogen®, Grastofil®, Nivestym®) and peg–filgrastim (Neulasta®, Lapelga®, Fulphila®, Ziextenzo®) are produced in E. Coli cells. Larger monoclonal antibodies are produced in mammalian cells like Chinese Hamster Ovary or mouse myeloma cells. Examples of this are denosumab (Prolia®, Xgeva®), infliximab (Remicade®, Inflectra®, Renflexis®), adalimumab (Humira®) and trastuzumab (Herceptin®, Ogivri®, Trazimera®, Herzuma®). These living cells can produce the exact same protein – in the exact same amino acid sequence – required to produce the biologic. Changing a single amino acid or a small number of amino acids makes a completely different medication; for example, the only difference between human insulin and insulin aspart is a single proline amino acid being replaced by aspartate in the 51–amino acid structure. Changing 5 out of 165 amino acids in erythropoietin (Eprex®) results in the creation of darbepoetin (Aranesp®). Both of these changes created dramatically different medications.

A biosimilar is a biologic drug that is highly similar to a biologic drug that was already authorized for sale (reference biologic). Biosimilars are also known as "subsequent entry biologics" or "follow up biologics" in some jurisdictions. The biosimilar has the identical amino acid sequence as its reference biologic. A biosimilar may enter the market after the expiry of the patent and data protection of its reference biologic. There are no expected clinically meaningful differences in efficacy and safety between a biosimilar and its reference biologic.

Biologics and biosimilars exhibit an inherent variability in how the living cells complete the manufacturing of the biologic (and biosimilar) molecule. This inherent variability means that there is not a single identical molecule for a biologic (or biosimilar) product, but that there are multiple molecules manufactured and included in the final product. These are called glycoforms – the biologic and biosimilar must maintain the number and ratios of glycoforms

ARE YOU PREPARED TO COUNSEL THIS PATIENT ON BIOSIMILAR PRODUCTS?

Marvin is a 64-year-old male with advanced, stage 4 colorectal cancer. He is currently receiving chemotherapy with FOLFOX and bevacizumab every two weeks and has received this treatment for the past two months. He is tolerating his treatment well but did experience two episodes of febrile neutropenia despite a dose reduction. His oncology team will be starting him on filgrastim with future treatments. He is responding well to his treatment and is considered to have stable disease with no major impact on his activities of daily living.

Today, Marvin is in the clinic to receive his FOLFOX and bevacizumab cycle #5. His clinic pharmacist stops by to give him his supportive care prescriptions as well as an information sheet on biosimilars. The pharmacist explains that his bevacizumab is being switched to a biosimilar due to a change in funding policy. Additionally, his filgrastim is also considered a biosimilar. Marvin is concerned about the use of biosimilars instead of the brand name product. Are you, as a pharmacist, prepared to counsel Marvin and address his questions and concerns?

in the approved product within a specified range. This results in no two biologic batches being identical to each other but instead are comparable, and the biosimilar manufacturer needs to maintain this comparability to its reference product.

Biosimilars work in the exact same way as their reference biologic. They have been shown to be analytically comparable to their reference biologic, and large clinical trials have demonstrated that there is no difference in the clinical activity of the biosimilar in indications approved for the reference biologic. These same clinical trials have also shown that there is no difference in the immunogenicity between the reference biologic and the biosimilar – patients do not develop a greater amount of antibodies to the biosimilar when compared to the reference biologic.

Biosimilars are not new products. Europe has been using the same biosimilars that are coming to Canada for more than 10 years. In Europe, there has not been a single biosimilar removed from the market due to concerns about efficacy or safety nor has there been any reported issues about biosimilars. Pharmacists should be confident that when their patient is either started on a biosimilar or changed from the routine use of a biologic to the routine use of a biosimilar, that there will not be any difference in the safety or effectiveness. This article will outline some considerations related to clinical operations, patient safety and patient education to help guide your discussions with patients like Marvin.

CLINICAL OPERATIONS CONSIDERATIONS

The pan–Canadian Pharmaceutical Alliance (pCPA) and Cancer Care Ontario (now part of Ontario Health) collaborated to lead the pan–Canadian Oncology Biosimilars Initiative (pCOBI), which is a cancer–specific strategy that recognizes the unique considerations for the implementation of oncology biosimilars. A national Clinical Operations Working Group (COWG) developed position statements aimed at guiding organizations' and jurisdictions' implementation of biosimilars throughout the entire clinical operations process flow. The full Position Statements for the Implementation of Oncology Biosimilars from the pan–Canadian Operations Working Group can be found on the Ontario Health (Cancer Care Ontario) website. The following are highlights that also apply to community pharmacies dispensing biosimilars.

Procurement and Receiving

- Biosimilars are to be considered as look–alike, sound–alike (LA/SA) products for patient safety.
- Pharmacies are to use the unique Drug Identification Number (DIN), or item number to distinguish biosimilars from reference biologic drugs at procurement.
- Biologics and biosimilars are to be entered as separate drug database entries to allow for tracking utilization, financial impact, and other data.
- In cases of drug shortages where Health Canada allows the use of a biosimilar from an international jurisdiction that does not use the same nomenclature, the product is to be entered as a separate drug entry using Canadian nomenclature.
- To prevent confirmation bias, staff should first look at the drug product received and then confirm against the packing slip (and not vice versa).

Storing

- Biosimilars are to be considered as LA/SA products for operational safety.
- Auxiliary labels are to be placed on reference biologics and biosimilars. The auxiliary labels used for biosimilars are to follow LA/SA guidance.
- When storing biosimilars, LA/SA shelf–talkers and

stop signs can be used to alert pharmacy staff.

- Pharmacies are to physically separate biosimilars from the reference biologic, and/or from similar–looking products (either by physical location, refrigerator, or physical separation within the refrigerator). If the biosimilar is stored in the same refrigerator or physical location as the reference biologic, or similar looking products, then the biosimilar should not be stored in alphabetical order by international non-proprietary name (INN), also known as the generic name. The reference biologic and biosimilar could be kept in alphabetical order by brand name.

Verification

- A prescription for a biosimilar should specify a brand for a specific indication. If this is not the case, a collaborative approach should be taken to determine the intended brand to dispense.

Preparation

- LA/SA products, including reference biologics and biosimilars, should have the DIN or manufacturer, lot and expiry recorded, regardless of whether institutions have an electronic or manual system.
- When using compounding labels, the DIN or manufacturer, lot and expiry should be recorded.

Labeling

- The label is to include both the INN and brand name.
- To best identify the product, the product is to be labeled first with its INN, followed by its brand name [e.g. filgrastim (Grastofil®)].

PATIENT SAFETY CONSIDERATIONS

The introduction of biosimilars is not expected to pose an increased risk to patient safety and the typical processes that occur within a pharmacy regarding patient safety issues will continue with biosimilars implementation.

To enhance patient safety from the perspective of ensuring the patient receives the intended product, the naming convention should be addressed. According to their Notice to Stakeholders "Health Canada has decided that biologic drugs, including biosimilars, will be identified by their unique brand name and non-proprietary (common) name, without the addition of a product-specific suffix. Both the brand name and non-proprietary name should be used throughout the medication use process so that biologics that share the same nonproprietary name can be distinguished by their unique brand names." In an ideal state, both the unique brand name and non-proprietary (common) name should be used throughout the medication use process (i.e. prescription, pharmacy computer system, prescription vial label). However, there may be limitations in the current pharmacy software with character limits and label size that makes this recommendation unrealistic at this time. These are barriers that should be noted and enhanced to ensure patient safety in the future as more biosimilars are expected to be marketed in Canada.

PATIENT EDUCATION MATERIALS

As part of the pan-Canadian Oncology Biosimilars Initiative, the national Education Working Group produced various resources for both patients and healthcare providers. As there are likely many resources available on the internet, it is important to ensure that the information provided to patients and caregiver is evidence-informed and consistent amongst all healthcare providers.

REFERENCES

Cancer Care Ontario. Position Statements for the Implementation of Oncology Biosimilars from the pan-Canadian Clinical Operations Working Group, August 2019. Available at: https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/60296. Accessed January 19, 2020.

Notice to Stakeholders – Policy Statement on the Naming of Biologic Drugs. Health Canada, 2019. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-notice-to-stakeholders-drugs-naming-of-biologics.html. Accessed January 20, 2020.

Biosimilar biologic drugs in Canada: Fact Sheet. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html. Accessed Jan 20, 2020

Ontario Health (Cancer Care Ontario) YouTube Playlist - Biologics and Biosimilars - https://www.youtube.com/watch?v=bPY8NkbotGY&list=PLRNynXKCayZWorBE3mgAS7_mwJmDH1pr4. Accessed March 11, 2020

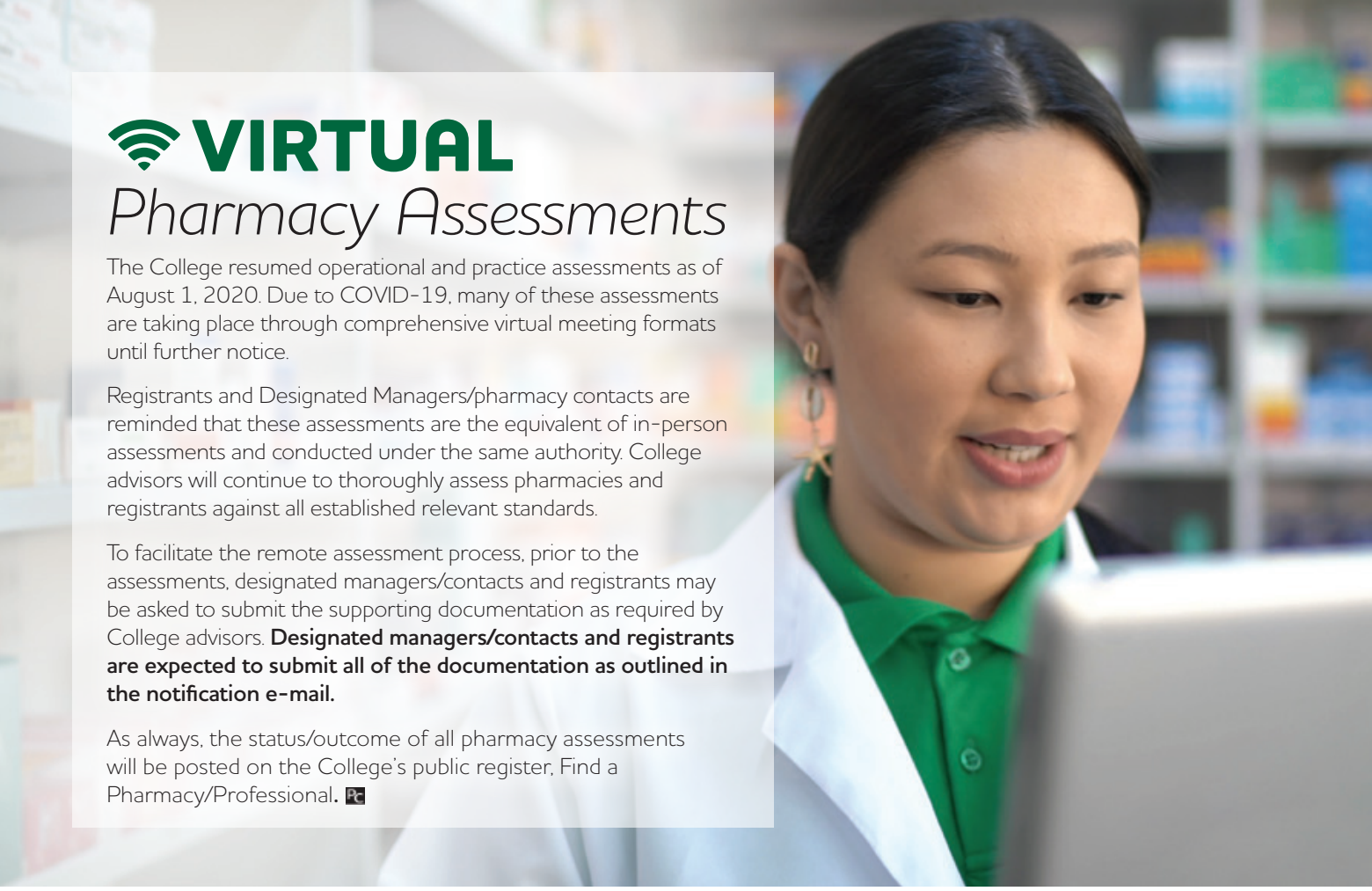
New Designated Manager
E-LEARNING MODULE

The College recently released an interactive and engaging Designated Manager (DM) e-Learning module, which provides an overview of key responsibilities and expectations of the DM. It is recommended that both current DMs and pharmacists who are considering the role in the future complete this module.

In addition to covering relevant points from legislation, Standards of Operation, Standards of Practice, practice policies and guidelines, and the Code of Ethics, the module is divided into the following sections: Managing the Premises, Equipment and Systems, and Managing the Personnel.

The module includes case studies and interactive quizzes to encourage engagement and retention of information. To view other e-Learning Modules from the College, visit the e-Learning Modules page on the OCP website.

ACCESS THE DESIGNATED MANAGER (DM) E-LEARNING MODULE NOW



VIRTUAL *Pharmacy Assessments*

The College resumed operational and practice assessments as of August 1, 2020. Due to COVID-19, many of these assessments are taking place through comprehensive virtual meeting formats until further notice.

Registrants and Designated Managers/pharmacy contacts are reminded that these assessments are the equivalent of in-person assessments and conducted under the same authority. College advisors will continue to thoroughly assess pharmacies and registrants against all established relevant standards.

To facilitate the remote assessment process, prior to the assessments, designated managers/contacts and registrants may be asked to submit the supporting documentation as required by College advisors. **Designated managers/contacts and registrants are expected to submit all of the documentation as outlined in the notification e-mail.**

As always, the status/outcome of all pharmacy assessments will be posted on the College's public register, Find a Pharmacy/Professional.

What Do Upcoming Changes to the College's Registration and Quality Assurance Regulations Mean for You?

In order to update the current approach to registration and quality assurance, the College has submitted proposed amendments to Regulation 202/94 (under the Pharmacy Act) to the Ministry of Health. It is anticipated that the government will approve these in the coming year.

The proposed amendments will allow for a more efficient registration process and an enhanced approach to quality assurance in the interest of patient health outcomes and safety.

To help applicants, students, interns, pharmacists, pharmacy technicians and supervisors understand what the changes mean for them, the College has put together an Upcoming Changes to the College's Registration and Quality Assurance Regulations webpage, including FAQs.

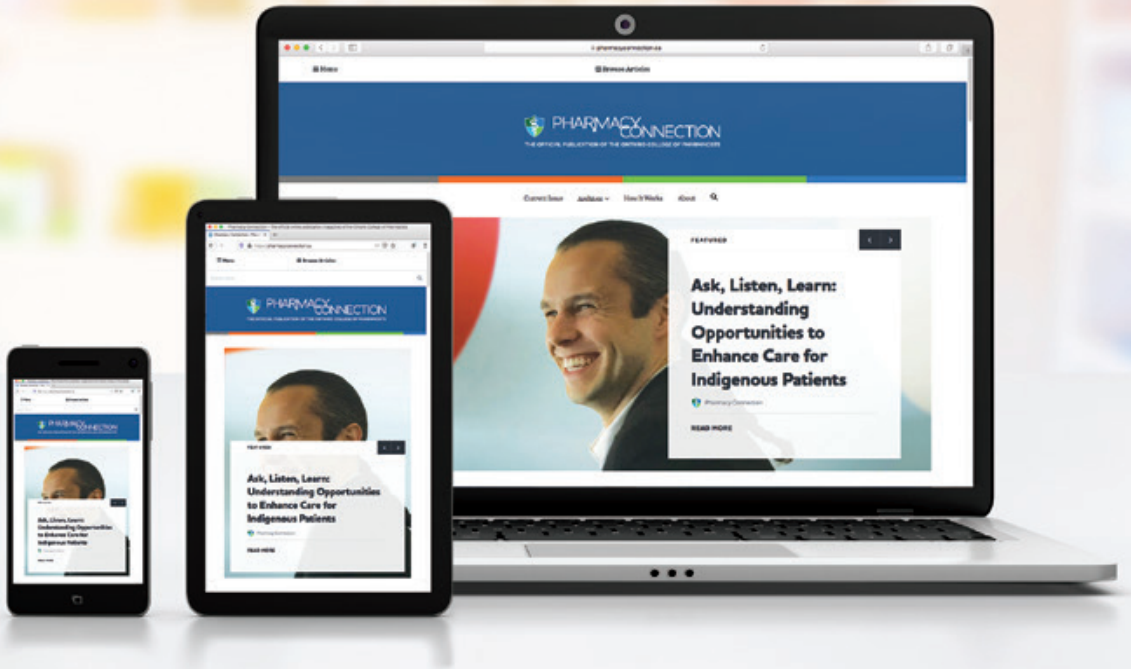
The FAQs address concerns and questions related to impacts on:

- Currently registered pharmacy students
- Students currently studying in a pharmacy technician program
- Currently registered pharmacy interns
- Supervisors of pharmacy students and/or pharmacy technician applicants
- Currently licensed pharmacy technicians
- Currently licensed pharmacists

Please visit the webpage to understand any effects on registration status and quality assurance activities once the regulations are approved.

PHARMACY CONNECTION.ca

is the digital home of the College's quarterly magazine.



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Articles can be easily shared on social media or by email and individual articles of interest can be printed.

Have feedback? Let us know how we can improve your experience with PharmacyConnection.ca at **communications@ocpinfo.com**.

Want to help the environment?
You can opt out of receiving a print copy by emailing **pconline@ocpinfo.com**.

DISCIPLINE DECISIONS

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 public register and CanLii.

LIST OF FALL 2020 DECISIONS:

Maria Musitano (OCP #108758)

George Politis (OCP #68632)

Chris Popoola (OCP #204452)

Ashit Shihora (OCP #109452)

Hussain (Azouz) Al-Yasery (OCP #607011)

Maged Ghobrial (OCP #613350)

Ewa Polak (OCP #207848)

Donghyun (Tony) Kim (OCP #625722)

Mourcos Shenouda (OCP #612220)

Tiffany Czilli (OCP #606992)

Thi Vuong (OCP #90913)

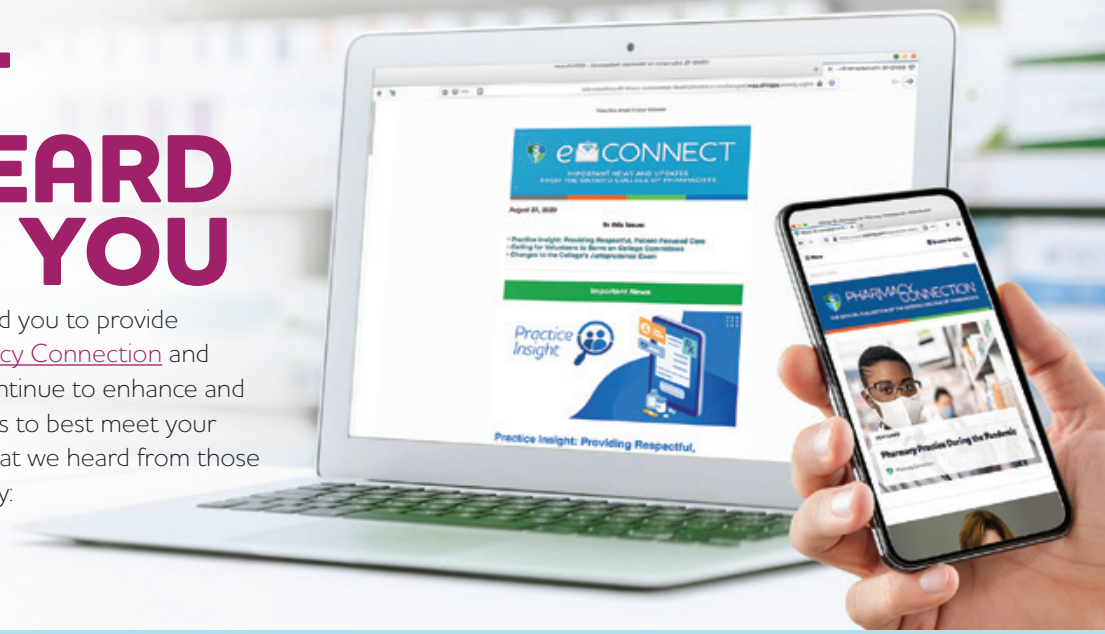
Abadir Nasr (OCP #218265)

Nermin Iskandar (OCP #603693)

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.

WHAT WE HEARD FROM YOU

The College recently asked you to provide your feedback on Pharmacy Connection and e-Connect in order to continue to enhance and improve these publications to best meet your needs. Here's some of what we heard from those who completed our survey:



94% ***find Pharmacy Connection and e-Connect helpful in maintaining and enhancing their practice and the care they provide to patients***

The **TOP 5** *Most Helpful and Relevant Content In Pharmacy Connection:*

1. Focus on Error Prevention
2. Key initiatives
3. AIMS and medication-related incident content
4. Practice Insight
5. Trending pharmacy practice topics

73% find PharmacyConnection.ca easy to use and navigate

91% feel e-Connect is relevant to their daily practice

80% agree or strongly agree that e-Connect is a valuable resource to stay abreast of key College initiatives and activities relevant to them

72% agree or strongly agree that e-Connect helps them provide better patient care

WHAT'S NEXT?

The College will be using the feedback received through the survey to make enhancements to its communication products to help ensure that it is providing timely and relevant information to registrants to support their practice.

COVID-19:
Resources for Pharmacists and Pharmacy Technicians

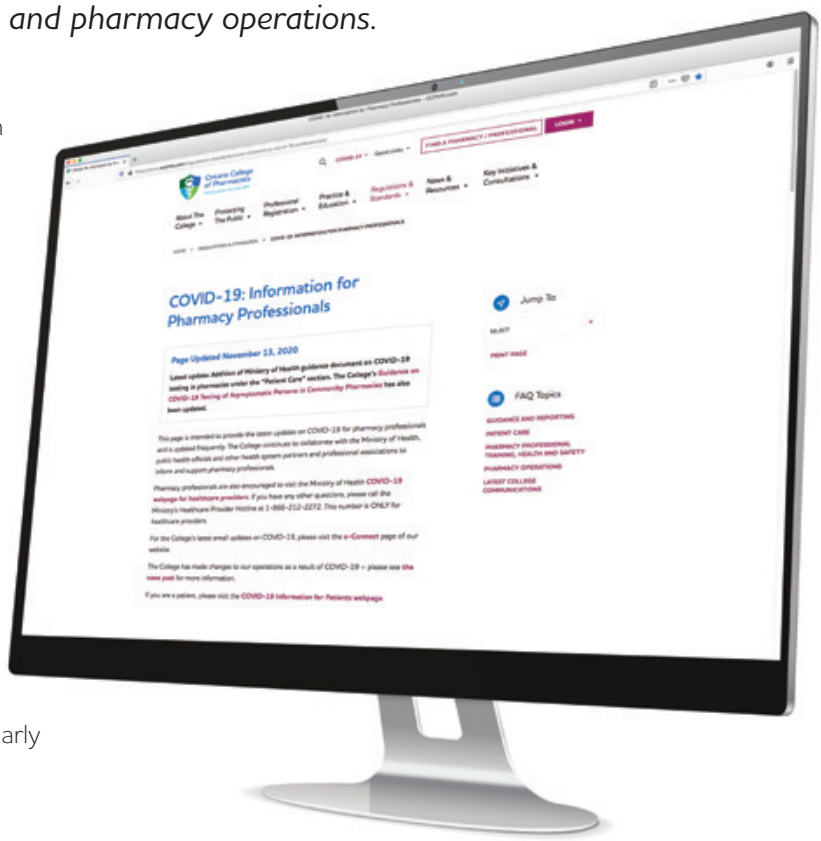
The College continues to update our guidance and resources for pharmacy professionals related to COVID-19, including regarding patient care, training, health and safety, and pharmacy operations.

In response to the many questions received from registrants, new information is regularly added to the COVID-19: Information for Pharmacy Professionals page.

Topics covered on this page include:

- COVID-19 testing
- CDSA Section 56 exemption
- Infection prevention and control
- Wearing masks
- Mental health support
- Managing Opioid Agonist Treatment (OAT)
- Informing the College of temporary pharmacy closures
- And more...

Please continue to check back on the COVID-19: Information for Pharmacy Professionals page regularly for updates and ensure you read the biweekly e-Connect email newsletter.



ONTARIO PHARMACY HEALTH PROGRAM – SUPPORTING REGISTRANTS WITH MENTAL HEALTH OR SUBSTANCE USE CONCERNS

When pharmacists and pharmacy technicians are dealing with mental health and substance use challenges, including addiction, stress, anxiety, depression or other conditions, the College's goal is to recognize those challenges and support individuals to access the resources they need so that they can practice in a safe manner.

One of the ways that the College has facilitated this support is through a partnership with Lifemark Health to establish a program specifically for pharmacy professionals called the **Ontario Pharmacy Health Program**. This program can be accessed directly by pharmacy professionals in a confidential manner without involvement from the College.

For more information, please visit the Ontario Pharmacy Health Program website and read the Pharmacy Connection article "Making Mental Health a Priority for Pharmacy Professionals" for common questions about the program.

FOCUS ON ERROR PREVENTION

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

Pharmacists and pharmacy technicians must be aware of the potential and impact of errors of omission, where the appropriate action is not taken. For example, a much needed drug is not provided to a patient or there is a delay in providing the drug.

This often occurs when a non-prescription drug is prescribed as the following case highlights.

CASE:

Rx:
Metronidazole
500mg four times daily for 14 days

Bismuth subsalicylate
300mg four times daily for 14 days

Tetracycline
500mg four times daily for 14 days

Omeprazole
20mg twice daily for 14 days

A sixty-four year old patient with multiple comorbidities had been taking omeprazole 20mg once daily for dyspepsia.

Following a consultation with her family doctor, the above prescription was faxed into her community pharmacy for processing.

The metronidazole and tetracycline were prepared and dispensed as prescribed. The bismuth subsalicylate was not covered by the patient's insurance likely because it is a non-prescription drug. The pharmacist made the decision to not process the prescription for bismuth subsalicylate as it can be bought over the counter without the need of a prescription.

The patient's insurance also declined to pay for the omeprazole as the patient received thirty tablets ten days earlier. The omeprazole was therefore "logged" into the patient's medication records.

The patient later called and asked the pharmacy to deliver her medications. As a result, only the metronidazole and tetracycline were delivered to the patient.

The pharmacist had intended to call the patient for counselling after the medications were delivered, but did not make the call before the end of his shift. As a result, the patient did not initiate the bismuth subsalicylate and continued to take omeprazole once daily versus the twice daily as prescribed.

Three days later, the patient visited the pharmacy to discuss another issue. During this visit and subsequent discussion with the pharmacist, the error of omission was discovered.

POSSIBLE CONTRIBUTING FACTORS:

- Initiation of a medication regimen that was unfamiliar to the patient.
- The bismuth subsalicylate was not processed as a prescription and was not placed in the pickup drawer with the other medications.
- The pharmacist had intended to speak directly with the patient regarding the bismuth subsalicylate and omeprazole dose increase at pick up. However, the patient requested the medications be delivered.
- Lack of patient counselling and a system to ensure counselling takes place on all delivered medications.

RECOMMENDATIONS:

- Ensure that a thorough patient assessment is completed, including determining whether the medication regimen as prescribed is appropriate for the patient and their condition.
- Policies and training should direct staff that all of the medications in the prescription should be kept together prior to packaging, counselling, and pickup/delivery.
- Develop a system to ensure all patients are made aware of prescriptions being called in or faxed in by their physician. In many instances, patients are unaware that the prescription had been processed and ready for pick up.
- Consider processing prescriptions for non-prescription drugs as prescribed. This will ensure that the patient receives the correct drug and directions for use. Some pharmacy management systems have functionality that allows for inclusion of non-prescription products in the patient record and drug utilization review (DUR).
- For medications not being processed as a prescription, retrieve the medication from the shelf and place in the pick-up drawer with clear directions for use for the patient to follow.
- Develop a system to ensure all medications being delivered are counseled with documentation.
- Ensure patients are made aware of any change in dosing even if no medication is being dispensed due to "early refill". Appropriate documentation must take place.

Please continue to send reports of medication errors in confidence to Ian Stewart at: ian.stewart2@rogers.com. Sharing your experience can prevent similar occurrences at other practice sites.

Please ensure that all identifying information (e.g. patient name, pharmacy name, healthcare provider name, etc.) are removed before submitting.

AIMS Assurance and Improvement in Medication Safety

A PATIENT SAFETY AND QUALITY IMPROVEMENT PROGRAM OF THE ONTARIO COLLEGE OF PHARMACISTS

APPLYING THE AIMS PROGRAM TO THE FOCUS ON ERROR PREVENTION INCIDENT

Under the Assurance and Improvement in Medication Safety (AIMS) Program, pharmacy professionals must anonymously record incidents and near misses to the AIMS Pharmapod platform, document appropriate details a in timely manner, analyze the incident to identify causal factors, determine ways to minimize the likelihood of recurrence, and share the incident and learnings with all pharmacy staff. All of these elements are equally important in helping to reduce the risk to patients in the future.

The incident detailed on the previous page provides an opportunity to examine what pharmacy professionals must do as part of the AIMS Program when they identify a medication incident or near miss.

ANALYZE

The pharmacist should make a list of contributing factors they could identify for why the incident happened (see the list of possible contributing factors above). A review of existing processes can be done to identify gaps and inform any changes to processes. The pharmacist can also bring forward suggestions to prevent recurrence. The Designated Manager of the pharmacy and the pharmacy team should also be a part of this process.

DOCUMENT

Details of the incident, including communication with the patient following discovery of the incident, must be documented in a timely manner to support accuracy.

There should also be documentation of any continuous quality improvement plans, such as specific actions that are being taken in response to the incident (i.e. developing a process to ensure counselling occurs for all deliveries, creating a checklist on how to manage over the counter medications that have been prescribed).

RECORD

The incident must be anonymously recorded in the AIMS platform. Recording the incident not only helps the pharmacy, but it also contributes to learnings for pharmacy professionals across the province as the aggregate data can be used to identify trends and learnings that could prevent incidents like this in the future.

SHARE LEARNINGS

In the next staff meeting, or in small groups at the start of the shift, the importance of ensuring patient counselling for deliveries could be discussed. The team could also review specific suggestions (see the Recommendations above) and determine how they could be implemented. For example, a staff member might have an idea of how best to ensure that prescribed over the counter products are appropriately documented and placed with the other medications for pick up.

FOLLOW UP

Once the above steps are completed and some time has passed to allow for implementation of the action items identified as part of the Analyze and Share Learnings activities, the Designated Manager should review the action plan, which had been entered into the AIMS platform when the incident was recorded, to evaluate whether the changes have been maintained, and whether they were effective.

This action plan and outcomes should be reviewed again with the pharmacy team at the next opportunity.

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