Ontario College of Pharmacists
Putting patients first since 1871

PHARMACY CONNECTION

WINTER/SPRING 2021 • VOLUME 28 NUMBER 1
PHARMACYCONNECTION.CA

THE OFFICIAL PUBLICATION OF
THE ONTARIO COLLEGE OF PHARMACISTS

PROVIDING SAFE PATIENT CARE THROUGH SYSTEM AND PROFESSIONAL COLLABORATION

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BOARD OF DIRECTORS

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- Finance & Audit
- Governance
- Screening

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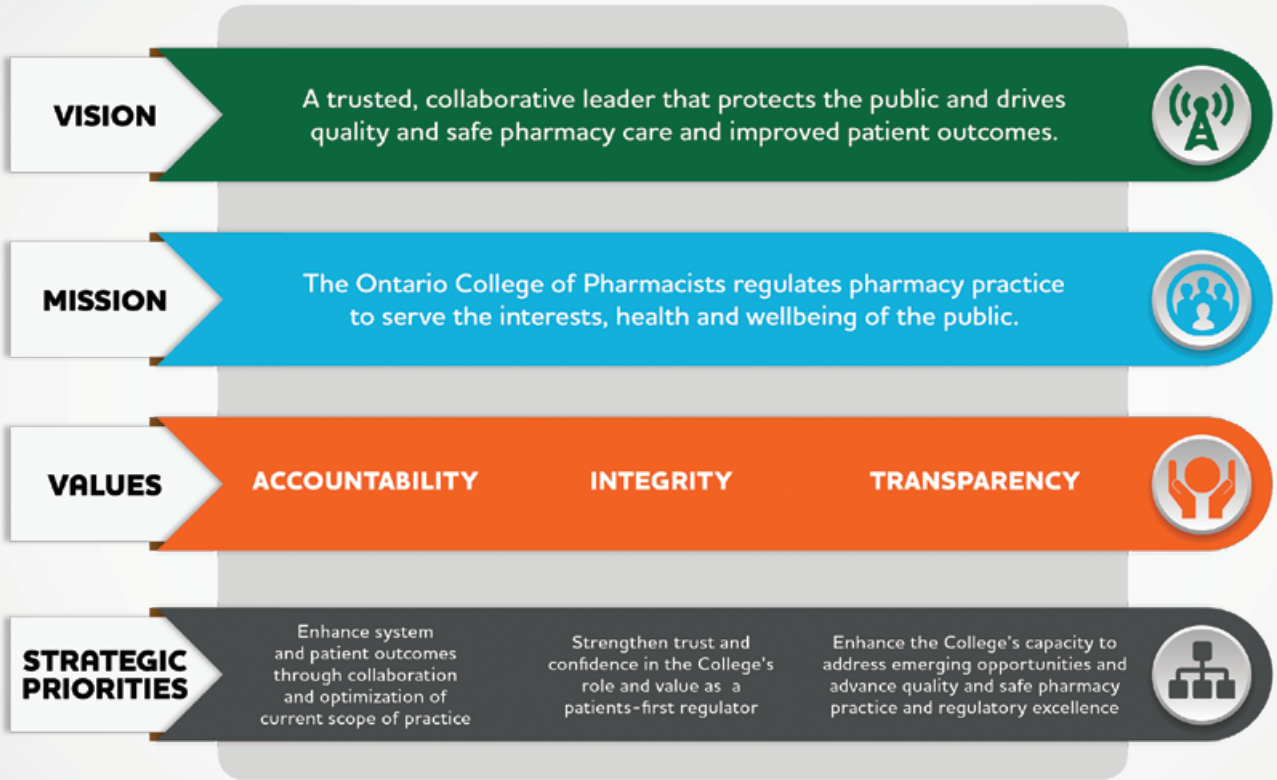
*(2019-2022/2023)**

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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Billy Cheung, R.Ph.,
Board Chair

Dear colleagues,

I want to start my letter by acknowledging your ongoing commitment as pharmacists and pharmacy technicians during this continuing crisis. Your efforts to support the safety of your patients and your colleagues, while still ensuring patient care is provided as an essential service, are a testament to your fundamental dedication to your patients, your communities and your profession. As we move towards the widespread administration of the COVID-19 vaccines, that professionalism and commitment will be needed more than ever.

It is a great honour to serve as the new Chair of the OCP's Board of Directors. As the Board, our role is to ensure the interests of the public are protected and maintained, provide oversight of the College and approve policies and regulations. The Board's work is guided by our Strategic Framework and priorities, which were recently reaffirmed.

I would like to thank our outgoing Chair, Laura Weyland, for her leadership over the past two years, our past Chair, Regis Vaillancourt, and the entire Board for their service to OCP. Their leadership has contributed to many milestones being met at the College, including the implementation of important governance changes, a focused approach on Indigenous cultural competency, the advancement of medication safety programs, and the development of regulations related to expanded scope of practice.

> "Your efforts to support the safety of your patients and your colleagues, while still ensuring patient care is provided as an essential service, are a testament to your fundamental dedication to your patients, your communities and your profession."

While COVID-19 dominates our conversations, we know the day to day care of your patients is just as important as ever. This issue of *Pharmacy Connection* continues to touch on topics that support your practice, including care for patients receiving opioid therapy, implementation of non-sterile compounding standards, prevention of medication incidents, avoidance of confirmation bias and updates on College guidance and resources. As always, we encourage you to stay up to date with the College's communication channels, including the website, e-Connect and social media.

This year we also recognize the College's 150th anniversary. An anniversary presents not just a chance to look at all we have accomplished, but also to re-commit ourselves to our mandate as an organization and look for opportunities to ensure we are doing all we can to contribute to a safe pharmacy environment.

This pandemic is not over yet. But as we transition to the next phase of COVID-19 which includes vaccines, know the College is committed to continuing to work within our mandate to protect patients and support pharmacy professionals. From providing necessary guidance for pharmacy professionals to collaborating with key stakeholders to address challenges in practice, our priority is ensuring patients receive the care they need.

Thank you to all pharmacists and pharmacy technicians for your incredible efforts over the past year.

Sincerely,

Billy Cheung, R.Ph.
Board Chair

MARCH 2021 BOARD MEETING

As recorded following the Board of Directors' regularly scheduled meeting held on March 22, 2021.

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

MARKING OCP'S 150TH ANNIVERSARY AND RECOGNIZING PHARMACY APPRECIATION MONTH

The Board Chair acknowledged that 2021 represents OCP's 150th anniversary. Since 1871, the College has evolved from the leading teaching institute for the profession of pharmacy to become Canada's largest provincial regulator of pharmacy professionals. Throughout this year, the College will be highlighting some major milestones in its history. It will also focus on looking forward in the pursuit of its Board-defined vision of being a trusted, collaborative leader that protects the public and drives quality and safe pharmacy care and improved patient outcomes through its mission and strategic priorities, guided by its values of integrity, accountability and transparency.

In recognition of Pharmacy Appreciation Month, the Board Chair extended the Board's thanks and best wishes to all of Ontario's pharmacists and pharmacy technicians for their vast contributions in serving their communities and providing quality care to thousands of Ontarians every day—particularly in light of the increasingly important role they have played in maintaining care to their patients as an essential service during the COVID-19 pandemic.

The Board viewed a video message from Deputy Premier and Minister of Health, the Hon. Christine Elliott, congratulating the College on its 150th anniversary and commemorating Pharmacy Appreciation Month by thanking pharmacy professionals throughout the province for their dedication to serving Ontarians.

COLLEGE PERFORMANCE MEASUREMENT FRAMEWORK

The Board was presented with OCP's first-ever College Performance Measurement Framework (CPMF), a document introduced by the Ministry of Health to apply a standardized and transparent approach to reporting on the performance of Ontario's health regulatory colleges and to support system-wide quality improvement. Overall, the College meets all of the standards expressed in the CPMF, which aligns with our commitment to accountability, transparency and performance measurement, with opportunities for ongoing improvement articulated throughout the report. The College will submit the CPMF to the Ministry by March 31, 2021 and will post the CPMF and corresponding documents to our website.

REGISTRAR'S REPORT

The College's CEO and Registrar delivered a report to the Board highlighting activities that have taken place since the last meeting, as well as progress on strategic initiatives. The Registrar shared the Q4 2020 Scorecard, which provides a snapshot of the performance of the College against the established objectives for last year, as well a 2021 scorecard that sets out key performance measures and milestones for this year. The redeveloped 2021 Scorecard performance domains now align with the CPMF.

BOARD APPROVES AUDITED FINANCIAL STATEMENTS

Following the recommendation of the Finance and Audit Committee, the Board approved the College's 2020 Audited Financial Statements as prepared by Tinkham LLP Chartered Professional Accountants. The opinion of the auditor is that the financial statements present fairly, in all material respects, the financial position of the College as of December 31, 2020 and its

results of operations and its cash flows for the year then ended in accordance with Canadian Accounting Standards for not-for-profit organizations. A copy of the Audited Financial Statement is available in the Board package.

APPOINTMENT OF 2021 SCREENING COMMITTEE

To support competency-based selection and appointment of Board and Committee participants for the coming Board elections and Committee appointments, the Board appointed the 2021 Screening Committee.

- David Breukelman, Vice-Chair of the Board
- Gene Szabo, Public Director
- Tracey Phillips, Elected Director
- David Collie, Lay Committee Appointee
- Megan Sloan, Lay Committee Appointee

APPROVAL OF GOVERNANCE MANUAL POLICIES

The Board reviewed and approved policies in Section 3—*Policies and Processes Supporting Good Governance* with minor amendments. The Board requested that a statement asking Directors to be conscious of their biases be added to all policies that involve evaluations of others. In addition, the Board approved an amendment to a policy previously approved in December on Screening, Selection and Appointments of Committees.

This is the third section of a series of standalone policies which, once complete, will replace the current Governance Manual. The current manual, in effect since 2014, is comprehensive but lengthy and not easily amended. Additional sections will be brought to the Board for consideration at the June 2021 meeting, with the intention of having all new policies in place in time for the 2021/2022 Board Year Orientation.

DRAFT POLICIES APPROVED FOR PUBLIC CONSULTATION

As part of the College's policy review process that allows for feedback and consideration of additional perspectives which may impact final policy direction, the Board approved the posting of two draft policies for 60-day public consultation periods. The draft policies and feedback forms are available on OCP's Consultations web page.

Virtual Care Policy

In response to virtual care in pharmacy practice becoming an emerging area that is being facilitated by advances in technology, the College has drafted a new policy to outline the practice expectations for registrants providing care to patients using virtual approaches. The policy development was informed by a comprehensive review of pharmacy regulatory authorities across Canada and health professional regulators in Ontario, alongside a review of privacy legislation and guidance from external organizations.

Cross-Jurisdictional Pharmacy Services Policy

To clarify the expectations for the provision of pharmacy services to patients in jurisdictions outside of Ontario, the College has reviewed its Prescriptions – Out of Country policy and its Out of Province Prescriptions fact sheet, and combined the two into a new draft Cross-Jurisdictional Pharmacy Services policy.

LONG-TERM CARE POLICY RETIRED

Following a College review of the Standards for Pharmacists Providing Services to Licensed Long-Term Care Facilities (LTC Standards), the Board accepted the recommendation that the expectations outlined were sufficiently covered in other College standards, policies and guidelines. The Board approved retiring the LTC Standards since they have become redundant over time due to the introduction of more recent applicable standards, policies and regulations.

NEXT BOARD MEETING

The next regularly scheduled meeting will be held on June 14, 2021. Special Board meetings may be called at any time. Please see our website for information on upcoming Board meetings. Board meetings are open to the public and are typically held in the Board Chambers of the College at 483 Huron Street, Toronto, ON, M5R 2R4. Due to public health measures currently in place, Board meetings are being held virtually until further notice. If you plan to attend an in-person meeting or for more information, please contact Ms. Sarah MacDougall, Board and Committee Liaison at boardofdirectors@ocpinfo.com. Links for those who wish to observe a virtual meeting will be posted with meeting agendas. You can also follow highlights from the Board meetings via Twitter.

REGISTRAR'S Reflection

It has now been more than a year since COVID-19 changed the way we all live and work, and as essential healthcare workers, pharmacy professionals have been on the front lines of the pandemic since day one. While the challenge has been enormous, we are beginning to see light at the end of the tunnel in the form of new vaccines to combat this virus. And, once again, pharmacy professionals are being asked to use their skills and knowledge to play a role by helping to vaccinate patients as part of the next phase of the province's COVID-19 Immunization Program.

Earlier this year, the government passed amendments temporarily enabling a registrant of the College who is a Part A pharmacist, intern, registered pharmacy student or pharmacy technician to administer the COVID-19 vaccine, without needing delegations of authority, under the condition they are engaged to do so by an organization or other entity that has signed an agreement with the Minister of Health for this purpose.

The importance of collaboration at this juncture cannot be emphasized enough and this is great news for the millions of Ontarians who are expected to want access to the vaccine in the coming months.

I urge all pharmacy professionals to help in the battle against vaccine hesitancy by ensuring you are well-versed in the evidence and only relying upon and sharing credible sources of information about the vaccines. I am pleased to be co-chairing the Ontario campaign for 19 to Zero, a dedicated coalition of healthcare providers, academics, public health experts, behavioural economists, and creative professionals working to understand, engage with, and ultimately shift public perceptions around COVID-19 behaviours and vaccination. The College is a proud participant in this group, and we will continue to explore ways to encourage vaccination against COVID-19 and to support pharmacy's future role in the distribution of the vaccine.

Community Practice Environment

Listening to input from registrants and patients is an important part of how the College makes decisions as the pharmacy regulator in Ontario, and over the past few years we have consistently heard feedback about the practice environment in community pharmacy. Registrants have expressed concerns about workload, the importance of professional autonomy and ensuring an environment that is conducive to maximizing their ability to meet practice expectations and standards. Patients have raised issues with access to care in increasingly busy pharmacies and have commented on the need for adequate staffing.

Safe, quality patient care is a shared accountability for pharmacy professionals and those who own, operate or influence the operation of pharmacy. To address the feedback we have heard, the College launched a Community Practice Environment Initiative with the goal of developing a set of principles to guide the College, community pharmacy owners and operators, professional associations and pharmacy professionals in creating specific solutions and strategies that further strengthen the safety and quality of pharmacy care.

In December, the OCP Board endorsed a set of shared accountability principles that were developed by an Advisory Group of stakeholders with extensive feedback from patients and registrants. The College has now established a working group to translate these principles into provider experience indicators to further the work of the College in developing Quality metrics for the profession. The College also continues to work with the Advisory Group to further explore ways to implement the principles and improve the community practice environment for the benefit of all—with a particular focus on enhancing safety and health outcomes for patients. You can read more about the Community Practice Environment Initiative in this edition of *Pharmacy Connection*, and we will continue to share information throughout the year.

Sincerely,
Nancy

A More Responsive PHARMACY CONNECTION

The College is excited to announce upcoming enhancements to Pharmacy Connection, making it more timely and responsive for our readers.

Starting this summer, Pharmacy Connection will transition to a digital-only publication available on PharmacyConnection.ca. The next edition will be the last to be printed and mailed to subscribers.

By shifting to a fully digital experience, the College can share more information, more frequently, in a way that addresses current issues and questions you may have. This enables the College to introduce many new features and benefits for subscribers, including:

A MORE RESPONSIVE AND FOCUSED PUBLICATION

A digital-only Pharmacy Connection enables the College to publish articles when they are most relevant and timely for you, and not based on a set quarterly publishing schedule.

OPPORTUNITIES FOR ADDITIONAL FEATURES

The digital-only version will allow the College to make use of additional features, including video, infographics and interactive features to enhance the reading experience.

A COMMON READING EXPERIENCE AMONG ALL REGISTRANTS

The majority of registrants already rely on the digital Pharmacy Connection as they have declined the print edition. A single access point to Pharmacy Connection content ensures a common reading experience among all pharmacists and pharmacy technicians.

FRESH, UP TO DATE CONTENT

By the time subscribers receive Pharmacy Connection in the mail, some information may no longer be as timely or as practical as intended. A digital publication allows content to be shared when it is fresh, and for it to be updated with new information as needed.

MORE ENVIRONMENTALLY FRIENDLY

Moving to a digital-only magazine can help prevent the use of more than a million pieces of paper a year, plus the energy and resources required to transport the editions.

EFFECTIVE USE OF COLLEGE RESOURCES

Pharmacy Connection has significant costs associated with printing and mailing, and these costs are only anticipated to rise. The transition to a digital-only version supports the College's commitment to be cost-effective and efficient in all of our activities.

As we work to launch this exciting initiative, we will be engaging registrants to seek their input to help inform what the evolution of Pharmacy Connection looks like.

Once the new PharmacyConnection.ca has launched, we will also continue to seek feedback and make enhancements to support a seamless, engaging experience for pharmacists and pharmacy technicians. Our goal is to provide a publication that provides timely, relevant information that pharmacy professionals can apply in their day to day practice as they deliver safe and quality patient care.

We look forward to unveiling the new PharmacyConnection.ca this summer!

SUPPORTING VACCINE CONFIDENCE AMONG PATIENTS

Pharmacy professionals are an important source of information and education for patients on a wide variety of drugs, health products, medical devices and more. As Ontario moves forward with widespread administration of the COVID-19 vaccines in order to bring about an end to this pandemic, there is an opportunity for pharmacy professionals to be a trusted source of information for their patients and communities.

It is important that pharmacists and pharmacy technicians educate themselves about the COVID-19 vaccines so that they are prepared to address questions and concerns from patients.

There are a number of resources that can help guide conversations with patients and provide supportive evidence of the safety and importance of these vaccines.

PrOTCT Plan for the COVID-19 Vaccine Discussion. This framework from the Centre for Effective Practice helps healthcare professionals approach conversations in a thoughtful manner to build trust while sharing important information.

COVID-19 Vaccines information hub. The Centre for Effective Practice has a COVID-19 vaccines information resource that addresses many questions regarding the vaccines. The *Ensuring Patient Confidence in Vaccines* section lists common questions from patients and then provides a list of key messages to use in responding.

COVID-19 Vaccine Questions and Answers for Health Care Workers on Vaccine Safety. The CANVax CONSIDER Working Group has provided comprehensive answers to questions healthcare workers may have about the safety of the vaccines.

Pharmacy5in5. Pharmacy5in5, at the University of Waterloo, offers multiple resources on COVID-19 vaccines, including infographics for pharmacy professionals and patients, as well as a COVID-19 vaccines quiz.

Government of Ontario. The fact sheet *What you should know about the COVID-19 vaccines* provides simple questions and answers to common questions from the public about COVID-19 vaccines.

19 to Zero. A coalition of experts working to understand, engage with, and ultimately shift public perceptions around COVID-19 behaviours and vaccination. Provides links to tools and resources for healthcare professionals.

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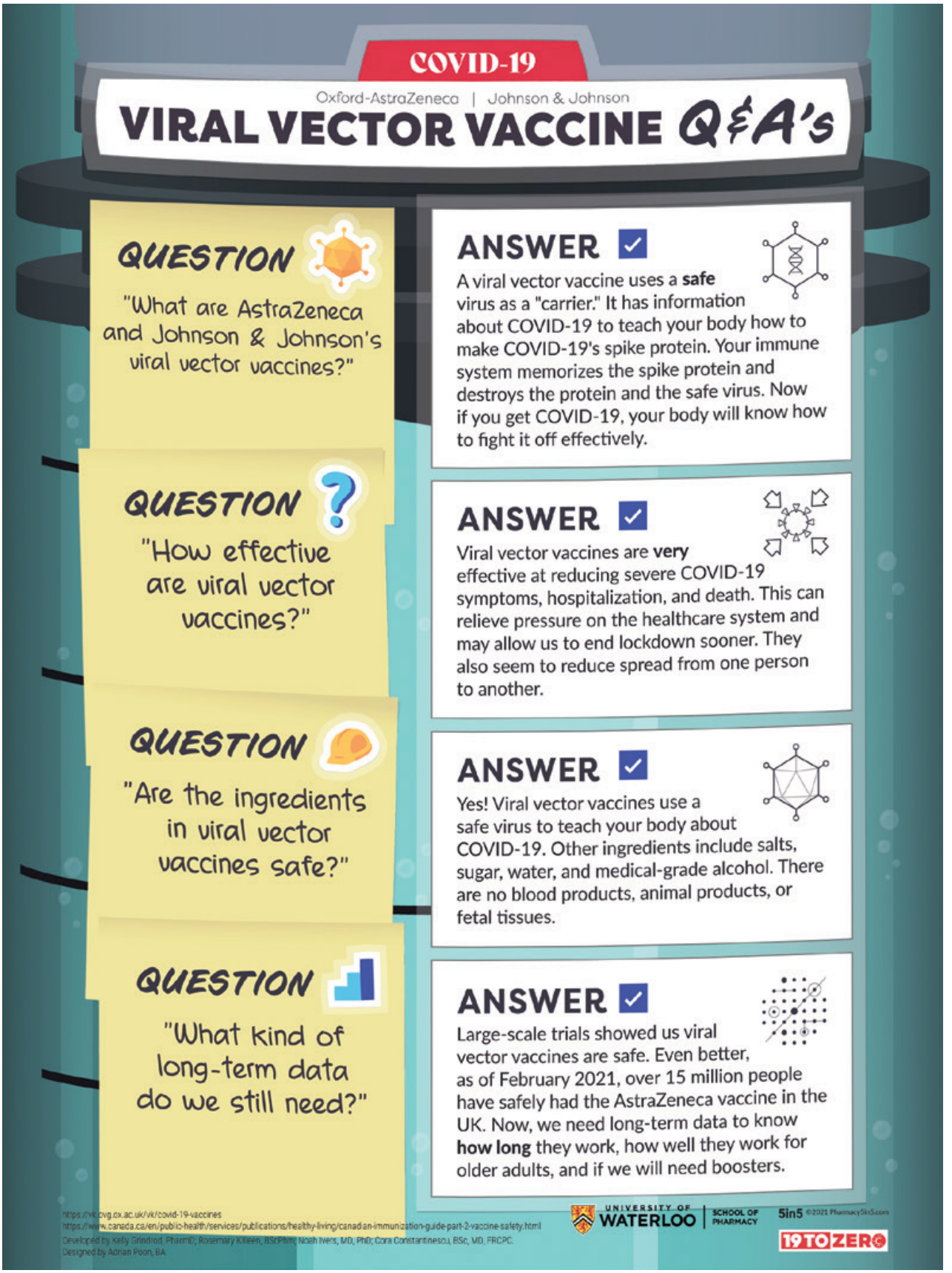

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COVID-19:
Resources for Pharmacists and Pharmacy Technicians

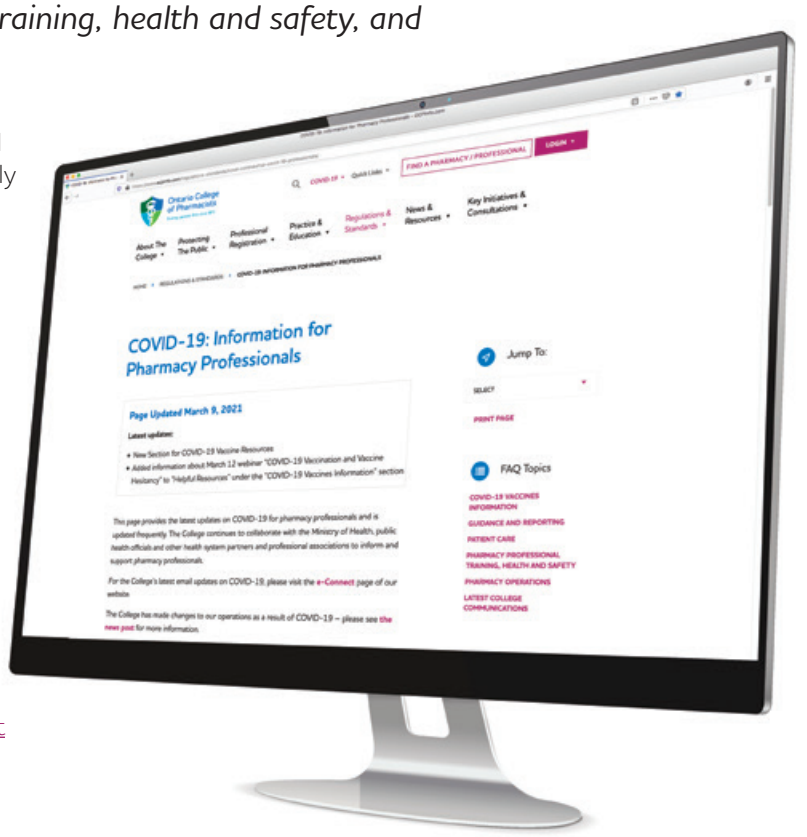
The College continues to update our guidance and resources for pharmacy professionals related to COVID-19, including regarding vaccinations, testing, patient care, training, health and safety, and pharmacy operations.

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 vaccines section with guidance and helpful resources
- COVID testing in pharmacies
- CDSA Section 56 exemption
- Managing opioid agonist treatment, with new guidance documents
- 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 answers to common questions about the program.

THE CODE OF ETHICS: *Non Maleficence*

Healthcare professionals must be diligent in their efforts to do no harm to their patients and, whenever possible, prevent harm from occurring.

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

- *Refrain from participating in behaviours/attitudes which could potentially result in harm and utilize their professional judgment to make every reasonable and conscientious effort to prevent harm to patients and society.*
- *Disclose medical errors and "near misses" and share information appropriately to manage risk of future occurrences.*
- *Ensure that the healthcare professional/patient relationship is not exploited for any personal, physical, emotional, financial, social or sexual gain.*
- *Assume responsibility for making reasonable efforts to ensure continuity of patient care when they are unable or unwilling to provide requested pharmacy services.*
- *Raise concerns to the appropriate authority if they reasonably believe human resources, policies, procedures, working conditions or the actions, professional performance or health of others may compromise patient care or public safety.*

LEARN MORE ABOUT NON MALEFICENCE

- Read the Code of Ethics
- Watch the e-Learning Module on Non-Maleficence
- 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*.

Government Expands Select Scope of Practice Activities for Pharmacists

In December, the provincial government passed regulatory changes that give Ontario pharmacists the authority to administer the flu vaccine to children as young as two years old and to renew prescriptions for up to one year.

These regulatory changes, which came into effect December 11, 2020, expand from the previous expectation of pharmacists to be able to administer the flu vaccine to children as young as five and renew prescriptions in quantities of up to six month's supply.

Additional expanded scope activities that are being considered by the government include administering certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration, and pharmacist prescribing for certain minor ailments. The draft regulations for these activities that were submitted to government by OCP are under review and have not yet been approved.

The College is committed to supporting registrants with resources and practice tools to expand their scope of practice safely and with confidence. A list of applicable guidelines and education modules has been developed and posted for your reference on the OCP website.

If you have any questions about expanded scope, please direct them to pharmacypractice@ocpinfo.com.

PRINCIPLES OF SHARED ACCOUNTABILITY

In December 2020, the College's Board of Directors approved a set of Principles of Shared Accountability, developed in collaboration with the College, patients, the profession, pharmacy stakeholders including owner/operators and associations. These principles provide all pharmacy stakeholders with a foundation to guide decision making that supports consistent delivery of safe, high quality patient care within a community pharmacy environment.

In early 2020, the College launched the Community Practice Environment Initiative, which is aimed at understanding confirmed and potential barriers to professional autonomy and patient safety in community pharmacy through thoughtful, respectful and meaningful collaboration and engagement with pharmacy stakeholders. The first phase of this initiative focused on developing principles of shared accountability amongst pharmacy stakeholders. These principles are intended to guide the development of specific solutions and strategies for the sector to further strengthen the quality and safety of pharmacy care, and help position the profession for ongoing success as pharmacy plays an increasingly important role in the health and wellbeing of Ontarians.

Following engagement with the profession and the public, and through the input of a multi-disciplinary advisory group, seven principles have now been developed, and approved by the Board. The following set of principles of shared accountability were developed to enable a community practice environment that supports professionalism and safe, high-quality patient care:

PRINCIPLES OF SHARED ACCOUNTABILITY

Principle 1:
The regulator, proprietors, and pharmacy professionals each have a responsibility to facilitate and promote the delivery of safe, patient-centred healthcare in community pharmacy.

Principle 2:
The regulator, proprietors, and pharmacy professionals have a shared responsibility to educate the public on the role of pharmacy within their health care team, what pharmacy professionals do, and how this is essential for the health and safety of patients.

Principle 3:
The regulator, proprietors, and pharmacy professionals have a shared responsibility to integrate continuous quality improvement within the practice environment, including the use of evidence-based methods, tools and resources along with sharing best practices, to enable the delivery of safe, high-quality patient-centred care.

Principle 4:
The regulator, proprietors, and pharmacy professionals have a shared responsibility for a practice culture that supports the physical and mental wellbeing of pharmacy team members.

Principle 5:
The regulator, proprietors and pharmacy leaders have a shared responsibility to ensure the provision of safe, high-quality care by an appropriate complement of qualified and skilled staff who have the resources and physical environment necessary for managing patient care in accordance with the standards of the profession.

Principle 6:
While performance metrics are a normal business practice in many industries and are used across the health sector, the regulator, proprietors and pharmacy professionals have a shared responsibility to align performance goals and measures in community pharmacy with the best interests of the individual patient as determined in collaboration with the pharmacy professional.

Principle 7:
The regulator, proprietors, pharmacy leaders, and pharmacy and professional associations are committed to ensuring strong pharmacy leadership, and have a shared responsibility to promote leadership development, including skill development for the critical role designated managers have in creating effective pharmacy team dynamics and a positive practice culture.

WHAT'S NEXT?

The College is working with its advisory group on the development of an implementation strategy that will involve each partner playing an important part in the rollout, promotion and adoption of the principles throughout the profession. Please watch for additional details in the coming months through e-Connect about opportunities to learn more about the principles and how they can be applied within community pharmacy practice environments across the province and the role of the College and other organizations in supporting this work including public education.

New and Updated Guidance

The College continually assesses, creates and updates the guidance and resources available on our website to provide necessary information for pharmacy professionals. Please ensure you are subscribed to e-Connect to receive notifications when major updates or additions are made.

Below is a summary of the guidance documents and resources that were updated or added in 2020, including many that were revised to account for specific changes to practice required as a result of the COVID-19 pandemic.

POLICIES AND POSITION STATEMENTS

Authenticity of Prescriptions Using Unique Identifiers for Prescribers

Centralized Prescription Processing (Central Fill)

Faxed Transmission of Prescriptions

Opioid Policy

GUIDELINES AND GUIDANCE

Administering a Substance by Injection or Inhalation

COVID-19 Testing of Asymptomatic Persons in Community Pharmacies – **NEW!**

Initiating, Adapting and Renewing Prescriptions

Prescribing and Providing Controlled Substances During the Coronavirus Pandemic – **NEW!**

Temporary Method for Transmitting Prescriptions via Unsecure Email During COVID-19 – **NEW!**

FACT SHEETS

Delivery of Prescriptions

Destruction of Narcotics, Controlled Drugs and Targeted Substances

Forgery: Management and Reporting of Fraudulent Prescriptions

Key Requirements for Methadone Maintenance Treatment

Narcotic Prescription Part-Fills

Patch for Patch Fentanyl Return Program

Prescriber Registration Status Change

Prescription Expiry

Prescription Transfers

Releasing Personal Health Information

WEBPAGES AND ADDITIONAL RESOURCES:

COVID-19 Page for Professionals – **NEW!**

COVID-19 Page for the Public – **NEW!**

Quick links to the Ministry of Health

Quick Links to the Office of the Information and Privacy Commissioner

PRACTICE TOOLS

Administering Injections

Communication and Education

Decision Making

Documentation

Infection Prevention and Control

Methadone and Buprenorphine

Patient Assessment

Practice Assessments - **NEW!**

NON-STERILE COMPOUNDING PHASE 2:

How to Meet the July 1, 2021 Deadline

It is the College's expectation that pharmacies and pharmacy professionals continue to be engaged in preparing their pharmacy for full implementation of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. Use the fillable checklist to guide activities for each phase of implementation.

COLLEGE OPERATIONS ADVISORS LOOKING FOR COMPLETION OF RISK AND GAP ASSESSMENTS

In Phase 1, which had a deadline of January 1, 2020, pharmacies performing non-sterile compounding were focussed on assessing their risks and gaps, including reviewing the NAPRA standards and guidance documents, completing risk assessments, determining the level of requirements the pharmacy must meet (i.e. A, B or C) and performing a gap analysis between current practice and the level.

As the January 1, 2020 deadline has now passed, College operations advisors will be looking for completion of Phase 1 activities when performing pharmacy assessments (see section 4).

FOCUS ON PHASE 2: TRAINING AND QUALITY ASSURANCE

In Phase 2, the priorities are training and assessment of all personnel engaged in non-sterile compounding, developing and implementing policies and procedures, and creating a quality assurance program. In order to meet the upcoming deadline, pharmacies can:

- **Create Master Formulation Records for each preparation,** including all necessary information to compound the preparation and the assignment of a beyond-use date (BUD) for each preparation. *See Section 6 of the Guidance document and the article on the next page.*
- **Develop policies and procedures** for all aspects of non-sterile compounding. Note that hazardous preparations require additional policies and procedures. *See Section 5.3 of the Guidance document and Section 9.3, 9.4 and 9.5 related to hazardous.*
- **Complete a skills assessment for existing non-sterile compounding/cleaning personnel.** *See Section 5.2 of the Guidance document.*
- **Develop a training program for non-sterile compounding personnel** and ensure there is training on policies and procedures as they are developed. *See Section 5.2 of the Guidance document.*
- **Develop a quality assurance program for personnel to verify ongoing effectiveness of, and compliance with, policies and procedures.** *See Section 7.3 and 7.4 of the Guidance document.*
- **To support the upcoming Phase 3, with a deadline of January 1, 2022, begin developing other components of the pharmacy's quality assurance program.** *See Section 7 of the Guidance document.*

MANY RESOURCES TO ASSIST YOU

- Fillable checklist for each phase of implementation
- Frequently Asked Questions
- Webinar Recording and Slides
- Non-Sterile Preparations Assessment Criteria
- Non-Sterile Compounding Key Initiative and Pharmacy Connection articles

MASTER FORMULATION RECORDS AND COMPOUNDING RECORDS: *What's the difference?*

The NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations require pharmacies to have policies and procedures as well as quality assurance mechanisms in place to achieve the intended outcomes of enhancing patient safety and protecting compounding personnel.

The gap analysis completed in the implementation Phase 1 may have identified that the pharmacy needs to develop or update existing Master Formulation Records in Phase 2. A Master Formulation Record includes **all necessary information and appropriate procedures** to safely compound a specific non-sterile preparation, whereas the Compounding Record is generated every time that preparation is compounded with prescription- (or batch-) specific information that must be verified before it is dispensed.

The non-sterile compounding supervisor is responsible for ensuring that Master Formulation Records are developed, reviewed regularly and updated as needed. When there are changes to the record, compounding personnel must be informed. The table below summarizes and compares the standards, guidance and content for these two types of records. Please remember this is only a summary and the Guidance Document must be read and interpreted as a whole.

STANDARDS AND GUIDANCE

MASTER FORMULATION RECORDS	COMPOUNDING RECORD
Must be kept (in hard copy or electronic format) and be readily available to compounding personnel	Must be kept (in paper-based or electronic form) for each individual prescription and for non-sterile preparations made in batches
Must be developed by regulated pharmacy personnel with adequate experience and broad scientific knowledge	These records should be filed and retained for future reference in accordance with the OCP Guidelines for Record Retention
Must include all necessary information to compound the non-sterile preparation	In cases where there is a marketed drug available, the rationale for compounding should be documented in the patient's file with the appropriate justification
Must be based on scientific data and contain supporting rationale and references	In cases where the preparation was compounded by another pharmacy in accordance with a Central Fill agreement, this should be recorded
Should be kept together	Allow for auditability and traceability, be able to track information related to preparations in the event of a recall
Must be current and reviewed yearly or when new information becomes available	As part of the quality assurance process, this should be reviewed quarterly

SUMMARY OF CONTENT

<table>
<tr><th>MASTER FORMULATION RECORD</th><th>COMPOUNDING RECORD</th></tr>
<tr><td colspan="2">Official or assigned name of the preparation</td></tr>
<tr><td colspan="2">Strength and dosage form of the preparation</td></tr>
<tr><td>Calculations needed to determine and verify quantities of ingredients for quantity produced</td><td>Names and quantities of ingredients used, and calculations performed (if applicable)</td></tr>
<tr><td>Description of ingredients, their quantities and sources (e.g., physical description, DIN, manufacturer, etc.)</td><td>Sources, lot numbers and expiry dates of ingredients</td></tr>
<tr><td>Expected yield</td><td>Total quantity compounded</td></tr>
<tr><td rowspan="2">Compatibility and stability data, including any supporting documentation and references used to determine the beyond-use date (BUD)</td><td>Assigned BUD</td></tr>
<tr><td>Assigned preparation batch number or prescription number</td></tr>
<tr><td rowspan="2">Source or origin of the formula*
• References used to develop the formula
• Date last reviewed and/or updated</td><td>Reference to Master Formulation Record (including any deviations)</td></tr>
<tr><td>Date of compounding the preparation</td></tr>
<tr><td>Special precautions to be observed
• Personal protective equipment (PPE)
• Any specialized training for a specific procedure</td><td>Name of the person who compounded the preparation
Name of the person who approved/verified the preparation</td></tr>
<tr><td>Description of final preparation</td><td rowspan="2">Results of quality control procedures
• Name of the person who performed the quality control procedures
• Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient</td></tr>
<tr><td>Quality control procedures and expected results (e.g., weight range of filled capsules, pH of aqueous liquids, etc.)</td></tr>
<tr><td>Equipment needed to compound the preparation (and any special cleaning instructions)</td><td rowspan="3">* There may be formulations for compounded preparations available in the public domain or for purchase. When considering the use of pre-existing formulations, the Non-Sterile Compounding Supervisor is responsible for ensuring that NAPRA standards for the Master Formulation Record are met and that they are suitable for the conditions and circumstances of the pharmacy's practice, by assessing, modifying, adapting and/or updating them as necessary.</td></tr>
<tr><td>Mixing instructions and methods, which may include:
• order of mixing
• mixing temperatures or other environmental controls
• duration of mixing
• other factors pertinent to consistent replication of the preparation</td></tr>
<tr><td>Packaging and storage requirements
• Type of container used in dispensing
•Sample label</td></tr>
</table>

Since there are similarities between the content of the Master Formulation Record and Compounding Record, some pharmacies may use a copy of the Master Formula as a basis for the Compounding Record. Also, a prescription's dispensing record created may also serve as an outline for the Compounding Record, if the information required by the *Drug and Pharmacies Regulations Act*, s156(1) is suitable for meeting what is required by NAPRA. The College is not directive in how the requirements of the Standards are met, and it is up to the pharmacy to develop policies and procedures taking into account the systems and technology they have in place.

ADDITIONAL REFERENCES

Printable and Fillable template for a Master Formulation Record (NAPRA)

NON-STERILE COMPOUNDING: *Frequently Asked Questions*

If I have a room for non-sterile compounding of hazardous drugs, can I also make non-hazardous compounds in it?

The NAPRA Guidance Document For Pharmacy Compounding Of Non-Sterile Preparations explains that compounding of hazardous non-sterile preparations should occur in a separate room specifically dedicated for this purpose. Also, it is strongly recommended that dedicated equipment is used to compound hazardous preparations. Another option is to use disposable equipment where possible to reduce the chances of cross-contamination.

The level of requirements needed (i.e., B or C) depends more on the risk(s) posed by the hazardous product than on the complexity of the preparations. Drugs listed in the NIOSH[‡] Group 1 (antineoplastic/cytotoxic) require handling in the greater precautions provided by Level C (e.g., a closed-off room under negative pressure, filtered air exhausted to the outside, etc.) to avoid contaminating the environment and to further protect personnel. Similarly, compounding with drugs categorized by WHMIS[‡] as a health hazard that are very irritating to the respiratory tract, skin and/or mucous membranes should also take place in a Level C room.

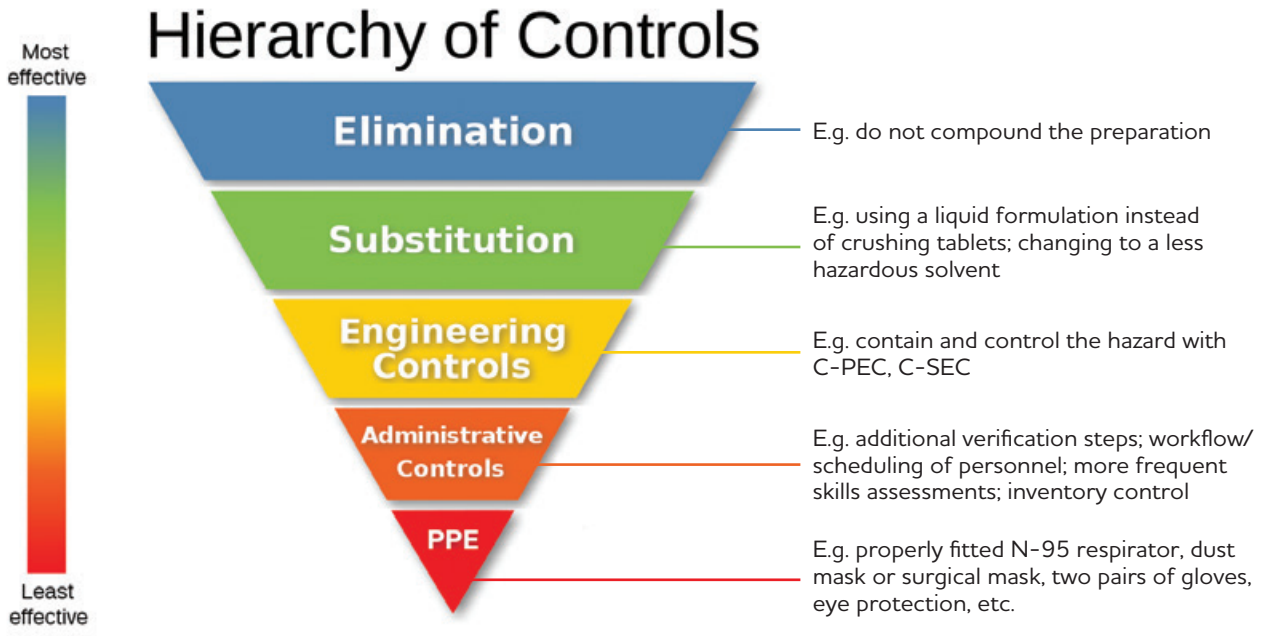
If it is not possible to have a dedicated room for hazardous compounding, at an absolute minimum there should be assurances that the area is meticulously cleaned before non-hazardous preparations are compounded. To prevent any risk of cross-contamination with the hazardous materials, the compounding area, equipment and accessories must be deactivated, decontaminated and cleaned as described in Section 9, immediately after compounding. For *occasional* compounding of *non-sterile hazardous* products, a C-PEC used for sterile hazardous compounding (e.g., Class II BSC or CACI) may be used, provided it is decontaminated, cleaned and disinfected before compounding the non-sterile product and again before resuming sterile compounding in that C-PEC. Policies and procedures for cleaning must be implemented, and personnel must be trained and assessed to ensure they are qualified to perform these tasks.

[†]National Institute for Occupational Safety and Health
[‡]Workplace Hazardous Materials Information System

Section 9 in the NAPRA Guidance Document states that "the compounding of hazardous nonsterile preparations requires safety measures to protect personnel and the environment" and refers to the NIOSH "hierarchy of controls" diagram depicting various levels of controls that can be implemented. Can you explain what this means?

The NIOSH website explains that a hierarchy of controls is "a means of determining how to implement feasible and effective control solutions" to minimize the risk of exposure to occupational hazards. Compounding supervisors should review the descriptions of each level of control. The diagram below (from the November 4th OCP webinar) provides examples of what the various controls might be in the context of pharmacy compounding.

The Guidance Document states that if there are "extra steps that must be taken to mitigate the risks" associated with compounding a particular preparation, these must be documented on the risk assessment along with "references confirming that these steps actually will minimize risks to the quality of the product and safety of personnel." It is the responsibility of the compounding supervisor and manager to evaluate and choose the appropriate 'controls' depending on the type of risk posed by a hazardous product.



Adapted from: https://www.cdc.gov/niosh/topics/hierarchy/default.html

ADDITIONAL RESOURCES

- November 4th webinar and slides
- *Pharmacy Connection* Article:
  - o A Closer Look at Personal Protective Equipment
- Frequently Asked Questions:
  - o As part of our risk assessment, should we follow the WHMIS list or the NIOSH list? I don't understand the difference between the two

EXTERNAL RESOURCES

- Best Practices for the Safe Handling of Hazardous Drugs (WorkSafe BC)
- Prevention Guide – Safe Handling Of Hazardous Drugs (ASSTSAS QC)
- ASHP Guidelines on Handling Hazardous Drugs

Ontario College of Pharmacists
Putting patients first since 1871

150 YEARS

Celebrating 150 years of putting patients first

This year marks the College's 150th anniversary, and in celebration of this milestone, this article in Pharmacy Connection highlights some key milestones and initiatives for the College and the pharmacy profession over recent decades.

We asked past and present Registrars – **William Wensley** (1967 to 1990), **Jim Dunsdon** (1991 to 2000), **Deanna Williams** (2000 to 2011), **Marshall Moleschi** (2011 to 2016) and **Nancy Lum-Wilson** (2017 to present) – for their thoughts on some meaningful OCP achievements and milestones during their tenure. Their views provide an opportunity to reflect on the College's work and mandate to serve and protect the public over the last 150 years.

1967-1990 Registrar: Bill Wensley

• Ontario government introduced the Ontario Drug Benefit Plan. During this time, pharmacists, encouraged by OCP, the Ontario Pharmacists Association, and other groups, pursued patient-oriented practice and continuing education to ensure they maintain a high level of competence throughout their careers.

• Key issues that were being discussed during this time included child-resistant packaging for prescriptions, ownership of pharmacies and physical standards for dispensaries, training for pharmacists, pharmacy assistants and technicians, the categorization and conditions of sale of non prescription drugs, and the Standards of Practice.

• The inclusion of members of the public on College Council was an important change that introduced new and positive healthcare and administrative perspectives.

• The Report of the Pharmaceutical Inquiry of Ontario, a study commissioned by the Provincial Government, was published. The positive observations in the report about the College and pharmacy practice, including suggestions for improvement, and the model of a self-governing profession acting in the public interest, reflected the wisdom of the Committee on the Healing Arts' report 20 years earlier. Both of these prestigious reports confirmed and supported the model of a self-governing profession acting in the public interest.

"I'm proud of the College's and the profession's work in pursuing patient-oriented practice and continuing education leading up to improving and ensuring levels of competence. This work is an ongoing and integral part of College activities."

- Bill Wensley

1991-2000 Registrar: Jim Dunsdon

- OCP led the transition to regulation under the new *Regulated Health Professions Act*, 1991. In addition to increasing public representation on Councils, the new Act also created 16 new health regulatory Colleges.

- OCP requested the government enact legislation prohibiting the sale of tobacco in pharmacies which was achieved through the enactment of the *Tobacco Control Act*, 1994.

- OCP, in collaboration with L'Ordre des Pharmaciens du Quebec, initiated discussions that resulted in the establishment of the National Association of Pharmacy Regulatory Authorities (NAPRA), which was initially formed to facilitate harmonization of drug schedules, and later, pharmacy practice and competencies across Canada.

- Council passed a motion to explore pursuit of the regulation of pharmacy technicians as a separate and independent class of registrant within the College.

"Leading the College and the profession's transition to regulation under the new Regulated Health Professions Act, 1991, while also overseeing a massive construction project to double the square footage of the College,were significant initiatives! The College also assumed a leading role in the development of Pharmacy's first Mutual Recognition Agreement (MRA) which was signed by NAPRA member Colleges in spring, 2000."

- Jim Dunsdon

2000-2011 Registrar: Deanna Williams

- The government proclaimed legislative and regulatory amendments that granted OCP the final authority to formally regulate Registered Pharmacy Technicians and significantly expanded the scope of practice of pharmacists to include limited powers with respect to prescribing and administration of substances by injection and inhalation.

- The College's Quality Assurance (QA) Program and Peer Review process, implemented in 1994, was considered "cutting edge" in Ontario, and was also quickly recognized and widely cited as a model QA program for all regulated professions internationally.

- Council approved a robust public outreach and communication program that in addition to establishing the tagline "Putting Patients First Since 1871," included animated commercials to inform the public about the existence and role of the College.

- OCP demonstrated its commitment to embracing technology, through enhanced internal IT advances, and through Council's approvals of regulatory revisions that would enable new technological advances in pharmacy practice – such as internet pharmacies or remote dispensing – provided Council was satisfied that all new provisions included the controls required to ensure public safety and protection

"I am most proud that the Ontario College of Pharmacists gained an international reputation, and recognition, as a leader in professional and occupational regulation, through the following initiatives: OCP's cutting edge QA program, its bold communication and public outreach efforts, its move from a traditional workplace to a telecommuting platform, and in being the first pharmacy regulator worldwide to formally regulate Pharmacy Technicians as an independent and separate class of registered pharmacy professionals."

- Deanna Williams

2011-2016 Registrar: Marshall Moleschi

• OCP put in place the framework for the approved profession of Pharmacy Technicians, and developed the frameworks for pharmacist prescribing (adapting, renewing and initiating prescriptions), and pharmacist administration of injections for teaching and for vaccinations.

• OCP adopted standards on Sterile Compounding and developed the legislation, standards and framework for the oversight of hospital pharmacies and drug preparation premises.

• OCP built the infrastructure for improving its operations through continuous quality improvement, project planning, and transparency.

• OCP developed and rolled out a comprehensive Code of Ethics complete with ethical principles and engaging learning tools.

"Over the five years that I had the privilege to serve as registrar of the Ontario College of Pharmacists I saw many significant changes to the profession of pharmacy and the College. While all these changes are significant… the most important changes are not just the changes that focus on 'what' one does. The most changes focus 'how' one does what they do. I feel the most important change was the development of the Code of Ethics and its tools that dictate a healthcare professional's ethical duty to patients and society. The Declaration to: 'put patients first,' 'do good,' 'do no harm,' 'protect patients,' take 'responsibility and accountability,' with 'integrity and honour.'

- Marshall Moleschi

2017-Present Registrar: Nancy Lum-Wilson

• OCP continues to evolve into an organization that better utilizes data and evidence to help guide our work and decisions. The College is constantly looking at how we can better use data and information to more effectively report on the performance of pharmacy and its impact on patient and health system outcomes, as well as our own progress and performance as a regulator. One example is the College's Assurance and Improvement in Medication Safety (AIMS) Program, designed to reduce the risk of patient harm caused by medication incidents in, or involving, Ontario pharmacies. OCP has developed an interactive tool that allows pharmacy teams and other stakeholders to view aggregate, anonymous medication safety data available through the program.

• OCP has developed quality indicators for community pharmacy that are system- and patient-outcomes focused, and is the first pharmacy regulator in the world that has done so. These quality indicators help the College, pharmacy professionals, and the health system better understand the impact of pharmacy care on patient outcomes and make evidence-informed decisions to improve the quality of pharmacy care in Ontario.

• OCP's approach to partnership and consultation has strengthened the organization's impact on the entire healthcare system and drives the College's mandate to serve and protect the public interest.

• OCP has adopted governance reform that reflects best practices in regulatory governance and strengthens public confidence in our work.

"I think the greatest achievement is the transformation that is currently underway. We are transforming the College into a data-driven and evidence informed organization, using data to better understand our work and the impact that the profession, and we, as a regulator, have on the healthcare system."

- Nancy Lum-Wilson

A Collaborative Effort to Protect and Serve Patients

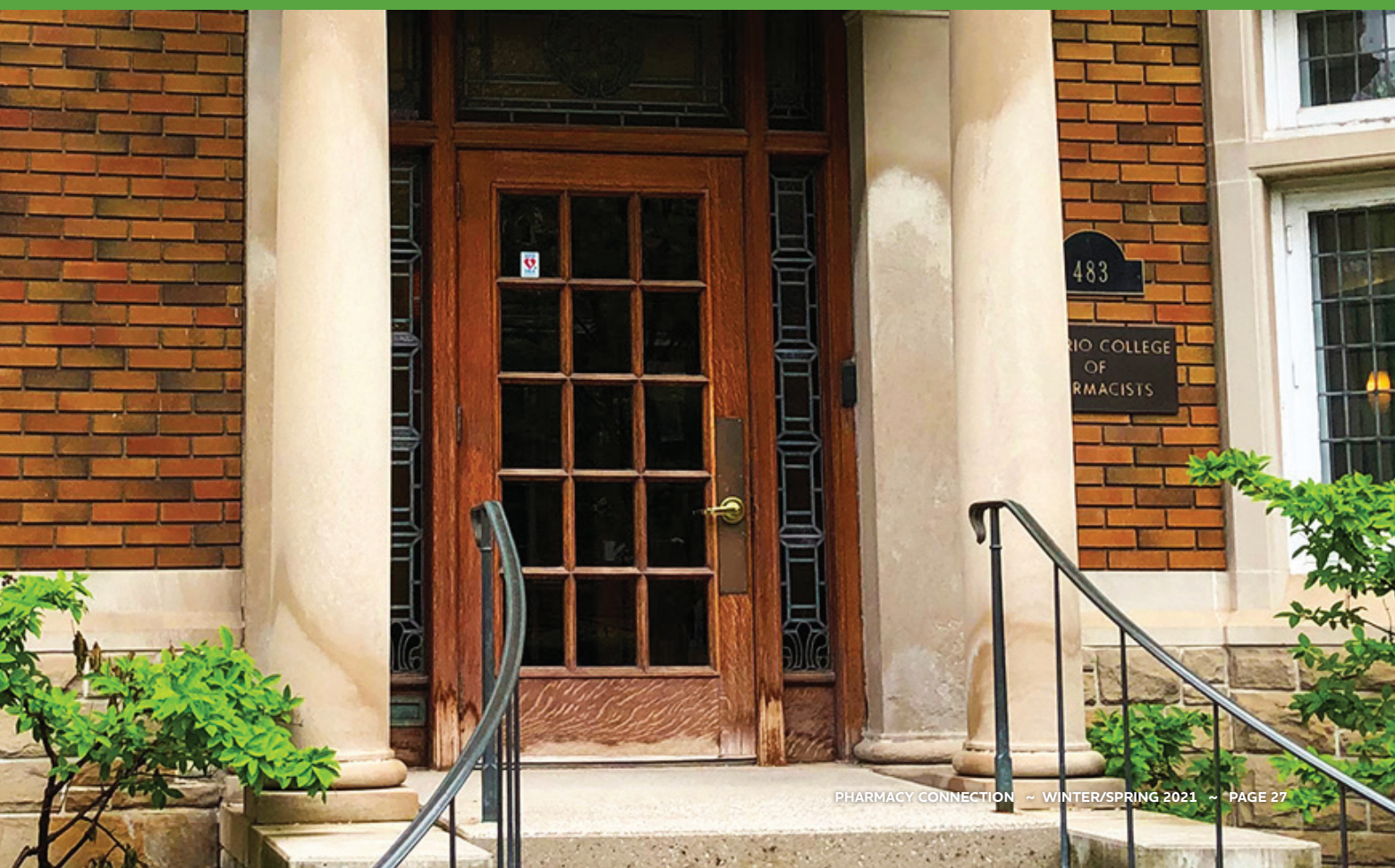
While a great deal has changed in the pharmacy profession since 1871, one constant has remained – our focus on putting patients first.

Until 1953, the College was both the regulating body for the profession and had responsibility for the education and training of generations of Ontario pharmacists, laying the foundation for the evolution of the profession in the second half of the 20th century and beyond. When the College transferred its teaching functions to the University of Toronto's Faculty of Pharmacy, it focused its mandate on serving and protecting the public and holding Ontario's pharmacists—and eventually pharmacy technicians—accountable to the established legislation, standards of practice, code of ethics and policies and guidelines relevant to pharmacy practice. Part of that role includes ensuring that community and hospital pharmacies within the province meet certain standards for operation and are accredited by the College.

This work would not be possible with the dedication and commitment of College staff, leadership, Board and Committee members, government and other stakeholders within the broader healthcare system who have helped develop a regulatory framework here in Ontario that is respected around the world. And, of course, a special thanks is extended to all of the pharmacists and pharmacy technicians who continue to contribute to safe and quality patient care and engage with the College to advance our public interest mandate.

We look forward to ongoing engagement with all of these groups as the College looks forward to embracing exciting new opportunities to promote quality and safety and to continuing to put patients first, together.

The College would like to thank the former Registrars who generously provided their input for this piece, as well as Diana Spizzirri and Deanna Yee for their assistance in preparing this article.



5 Things Pharmacy Professionals Should Know About INFORMED CONSENT

Prior to administering a treatment – whether for therapeutic, preventative, diagnostic or other health-related purposes – informed consent must be obtained from the patient in accordance with O. Reg 202/94 under the Pharmacy Act, the Health Care Consent Act (HCCA) and the Code of Ethics.

The province's *Personal Health Information Protection Act* (PHIPA) is not discussed in this article, as consent in PHIPA is related to the collection, use and disclosure of personal health information by health information custodians.

Pharmacy professionals should be familiar with key elements of the legislation governing informed consent to treatment that are most relevant to the provision of pharmacy services and patient care. This article provides an overview of these elements, and registrants are reminded to refer to the legislation for full details. Where applicable, Standards of Practice and principles from the Code of Ethics are also included.

1) Informed Consent

O. Reg 202/94 under the *Pharmacy Act* requires a pharmacy professional to receive an informed consent from the patient, prior to administering a substance by injection or inhalation or performing a procedure on tissue below (piercing) the dermis.

The Health Care Consent Act sets out the requirements for a patient's consent to treatment to be informed. Accordingly, the pharmacy professional must first provide information to the patient about the:

- Nature of the treatment.
- Expected benefits of the treatment.
- Material risks of the treatment.
- Material side effects of the treatment.
- Alternative courses of action.
- Likely consequences of not having the treatment

The extent of information provided is a matter of professional judgement, based on what a "reasonable person in the same circumstances would require in order to make a decision about the treatment." The pharmacy professional should confirm the patient's understanding and respond to any requests for additional information. Confirmation that informed consent was received must be noted in the patient record in accordance with the regulations and Documentation Guidelines.

It is a Standard of Practice for pharmacists to give patients the information they need to make decisions about their care in a way they can understand and to respond to patient's questions.

Similarly, technicians who provide patient education should respect the patient's right to make their own, informed, decisions about their care.

To support the patient's informed decision-making, the Code of Ethics expects pharmacy professionals to provide relevant and sufficient information regarding the potential risks and the most frequent/serious side effects associated with the medication therapy or pharmacy service.

2) Elements of Consent

According to the *Health Care Consent Act*, for a patient to consent to a proposed treatment, the consent must:

- Relate to the treatment
- Be informed
- Be given voluntarily
- Not be obtained through misrepresentation or fraud

The Code of Ethics expects registrants to respect the patient's autonomy and their right to be an active decision-maker in their care. Registrants must be honest in dealing with patients and not influence, persuade or pressure them to accept pharmacy services.

3) Express or Implied Consent

Consent to treatment may be express or implied. Express consent is explicitly and clearly provided, either verbally (orally) or in writing. Alternatively, a pharmacy professional may determine that implied consent is provided, based on the patient's action(s) or inaction in the circumstances at hand. When consent is implied or given verbally, the pharmacy professional should document this on the patient record.

4) Capability and capacity

The capability of a patient to give consent is contingent on their mental capacity to understand why and for what the consent is for, and depends on particular treatment and/or point in time. Pharmacy professionals can rely on the presumption of capacity unless they have reasonable grounds to believe otherwise. Subsequently, there is **no minimum age of consent** in Ontario

Pharmacy professionals have an ethical obligation to respect the right of a competent minor to provide informed consent and make decisions about their healthcare.

5) Withdrawal of Consent

A patient may refuse to give, or withdraw, their consent at any time. Otherwise, pharmacy professionals can presume that consent to a treatment includes consent to the continuation of, or adjustments in, the treatment, if the above factors do not significantly differ.

ADDITIONAL RESOURCES

Guideline – Administering a Substance by Injection or Inhalation

Guideline – Initiating, Adapting and Renewing Prescriptions

Documentation Guidelines

UNDERSTANDING, MANAGING AND RESPONDING TO COMPLAINTS

The Ontario College of Pharmacists' legislated mandate is to serve and protect the public by holding registrants accountable to established legislation, Standards of Practice, Code of Ethics and other policies and guidelines related to pharmacy practice. Registrants of the College (also known as Members) include Pharmacists, Pharmacy Technicians, Pharmacy Interns, and Pharmacy Students.

The College's Complaints and Reports process exists to protect the public, but it also provides registrants with opportunities to evaluate and improve their practice. A complaint may be filed against a registrant if a patient, caregiver, another healthcare provider or a member of the public has concerns related to the care or services provided by the registrant. This article outlines the College's complaints process, establishes how the College names registrants in complaints, and provides guidance on the prevention and management of complaints.

COMPLAINTS PROCESS

A complaint file is created once the College receives information regarding a concern in writing through the College's Online Complaint Form or another form of media (e.g., email, a mailed letter, or a fax). A complaint submission must identify the Complainant and the registrant(s) involved, and it must clearly outline the concern. The College **does not** accept anonymous complaints. In cases where the information required to initiate a complaint is not available, the College will ask the Complainant for additional information. The College may also request information and records from a community pharmacy's Designated Manager or a hospital's Pharmacy Manager to identify the registrant(s) involved in the concern(s).

If more than one registrant is named in a complaint, each registrant receives their own complaint file and the complaints will be investigated in parallel. Registrants will have an opportunity to review and comment on the responses provided by other registrants involved in the complaint. The College's complaints process is confidential, so registrants are expected to maintain the confidentiality of their Complainant and any other registrant(s) involved. College staff fully and impartially investigate each complaint.

The *Pharmacy Act, 1991* establishes the role and responsibilities of the College's registrants based on their registration class and is used by the College in considering which registrant to name in a complaint. Registrants may proactively prevent complaints by learning about the duties and responsibilities expected of them and by reviewing past complaint and discipline cases. Another strategy that registrants may utilize to prevent complaints is to actively identify, assess, prioritize and manage risk during practice.

For example, at clinical verification and product check, registrants may identify high-alert medications and ensure that they receive independent checks, mandatory patient education, follow-up calls, and adequate handover of care during staff change to mitigate risk. Proactive management and effective communication may prevent a medication incident from escalating to a complaint, and the following framework can be utilized for this strategy.

Several resources regarding the complaints process have been developed by the College, including a web page, an infographic, and a video

MANAGEMENT RESPONSIBILITIES

While each pharmacy professional has an individual responsibility in providing high quality patient care, a pharmacy's Designated Manager is additionally responsible for the supervision and training of regulated and unregulated pharmacy staff. Unregulated pharmacy staff includes pharmacy assistants, pharmacy clerks, pharmacy technician students, cashiers, volunteers, and other pharmacy employees that are not registered with the College. Furthermore, the pharmacy's Designated Manager is also responsible for developing, applying, and monitoring compliance with the policies and procedures followed by regulated and unregulated

TOP THREE CATEGORIES OF COMPLAINTS IN 2020

Communication/service	38%
Dispensing	29%
Business practices	12%

staff. A Designated Manager may be named in a complaint, even if they were not physically present when the incident occurred, if the pharmacy's policies and procedures contributed to the incident.

Similarly, a pharmacy's Designated Manager may be named in a complaint related to unregulated pharmacy staff, even if the Designated Manager was not physically present when the incident occurred. The College's expectation is that the Designated Manager trains unregulated staff to a degree in which they can provide high quality pharmacy services without direct supervision. To prevent concerns regarding unregulated pharmacy staff, Designated Managers are encouraged to develop and facilitate a training program for new staff. Designated Managers may also provide regular reviews and retraining sessions if they feel that their pharmacy's policies and procedures are not consistently utilized by regulated and unregulated pharmacy staff.

RESPONDING TO COMPLAINTS

If a complaint is filed, registrants are encouraged to cooperate with the College in compiling pharmacy documents and submitting statements for the Inquiries, Complaints and Reports Committee (ICRC) to review. By consistently documenting patient education, clinical/technical decision-making process, and medication incidents, registrants will be able to provide the College with key information related to the complaint.

As part of the College's Assurance and Improvement in Medication Safety (AIMS) program, pharmacy professionals are expected to record all incidents and select near misses in the AIMS Pharmapod Platform. Furthermore, registrants are encouraged to analyze these incidents to develop strategies aimed at preventing similar incidents in the future. The College **does not** have access to a pharmacy's incident level data recorded in the platform. However, if a registrant wishes to submit information regarding an incident/near miss which is the subject of a complaint they may do so by providing a copy of the incident/near miss form available on the AIMS Pharmapod platform. Alternatively, registrants may use any form that captures the necessary incident details to be provided to the College; an example is the College's Dispensing Errors Incident Form.

Some registrants find it helpful to proactively take part in remedial education tailored to the concern mentioned in the complaint, and a record of this education's completion may be submitted for review by the ICRC.

If registrants need extra time to respond to a complaint, they may request an extension. Registrants may seek legal counsel at any time during the complaints process and in the review of an ICRC decision by the Health Professions Appeal and Review Board (HPARB). As well, registrants may access services and resources provided by the Ontario Pharmacy Health Program (OPHP) if they are experiencing stress or mental health issues during the complaints process or at any other time..

REPORTING INFORMATION

If anyone has a concern about the conduct or competence of a pharmacy professional, they can report information to the College without filing a formal complaint. Information reported should include details of the concerns, the name of the pharmacy professional, as well as the reporting individual's contact information. The College will assess the concerns and take appropriate action. The individual who reported the information may be contacted and asked to provide additional information. Generally, that individual will not be engaged in the process and will not receive notification of the outcome. During the course of an investigation, their identity may become known to the pharmacy professional being investigated. Like Complaints, Reports cannot be submitted anonymously.

Practice Insight: AVOIDING CONFIRMATION BIAS

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 recognize and prevent confirmation bias.

A MISINTERPRETATION OF A HANDWRITTEN PRESCRIPTION RESULTS IN THE WRONG MEDICATION BEING DISPENSED

A handwritten prescription was presented to a community pharmacy. The pharmacy assistant entered the prescription into the computer system and the pharmacist verified the prescription, including comparing the original prescription against the hardcopy (dispensing record) in accordance with procedures at the pharmacy, before dispensing to the patient. The patient experienced significant symptoms after taking the medication. Upon visiting their physician two weeks later, it was discovered that the patient had been dispensed the wrong medication.

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 dispensed the wrong medication after making an error in the interpretation of the physician's handwriting and that the pharmacy assistant made the same misinterpretation as well when entering the prescription. The name of the

intended prescription medication and the name of the medication that was actually dispensed had significant differences in spelling, however they are both generally used to treat a similar medical condition, with a similar strength and dose regimen.

The panel observed that a contributing factor to this error was confirmation bias. They advised that pharmacists must examine each prescription without any assumptions that what has been entered into the system is correct and appropriate for the patient. Any additional checks in the process were rendered ineffective by the confirmation bias.

The pharmacist was reminded that if there is any confusion or lack of clarity relating to a prescriber's handwriting, then it is their responsibility to contact the prescriber to confirm the prescription. It was the panel's observation that the pharmacist did not work carefully enough to ensure the accurate dispensing of the medication to the patient.

The panel required the registrant to complete a Specified Continuing Education or Remediation Program, specifically a workshop on medication safety.

The decision of the panel was reviewed at the Health Professions Appeal and Review Board (HPARB) and was upheld. The HPARB panel recommended that the College provide registrants with further information on the issue of confirmation bias.

LEARNINGS FOR PHARMACY PROFESSIONALS

The Standards of Practice require that pharmacists apply their medication and medication use expertise while performing their daily activities. This includes ensuring that prescriptions received are complete as well as ensuring that a final check of prescribed products is performed. While the exact nature of this final check is left to the judgment of the pharmacy professional and pharmacy, it is essential that the potential issue of confirmation bias is taken into account.

Pharmacy professionals must be aware of the potential for confirmation bias. Confirmation bias is defined as the tendency to see what you expect to see or what you are familiar with, while not looking for information which is contradictory[1]; it can occur at any point in the medication-use process.[2]

Handwritten or verbal orders, lack of drug or patient information (i.e. indication for use), similarity in spelling/patterns in naming, and storage location (i.e. storing similarly named medications in close proximity) may contribute to risk of confirmation bias, especially when dealing with look-alike/sound-alike medications[2]. Additionally, certain technology solutions could contribute to confirmation bias. For example, having the scanned original prescription and the hardcopy side by side on the screen could lead to the copy being read before the original. Drop down lists within pharmacy software often group drugs with similar names in close proximity, which can lead to look-alike/sound-alike mix-ups, as the professional sees the medication they are most familiar with[2].

Possible actions that can be taken to reduce confirmation bias include: being aware of similar names, educating pharmacy staff about the potential of confirmation bias, consulting the patient's medication history to identify potential errors, considering all aspects of the prescription for appropriateness and asking the patient open ended questions about their understanding of the medication they were prescribed[1].

The Code of Ethics requires pharmacy professionals to utilize their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize health outcomes for patients. If there is any doubt as to the contents of prescription, such as related to a prescriber's handwriting, it is the obligation of the pharmacy professional to follow up with the prescriber to confirm the prescription.

RESOURCES FOR PHARMACY PROFESSIONALS

- ISMP Canada Safety Bulletins
- Pharmacy Connection – Focus on Error Prevention columns
- Continuing Education for Pharmacists: Practice Skills – Safety and Quality
- Continuing Education for Pharmacy Technicians: Practice Skills – Safety and Quality

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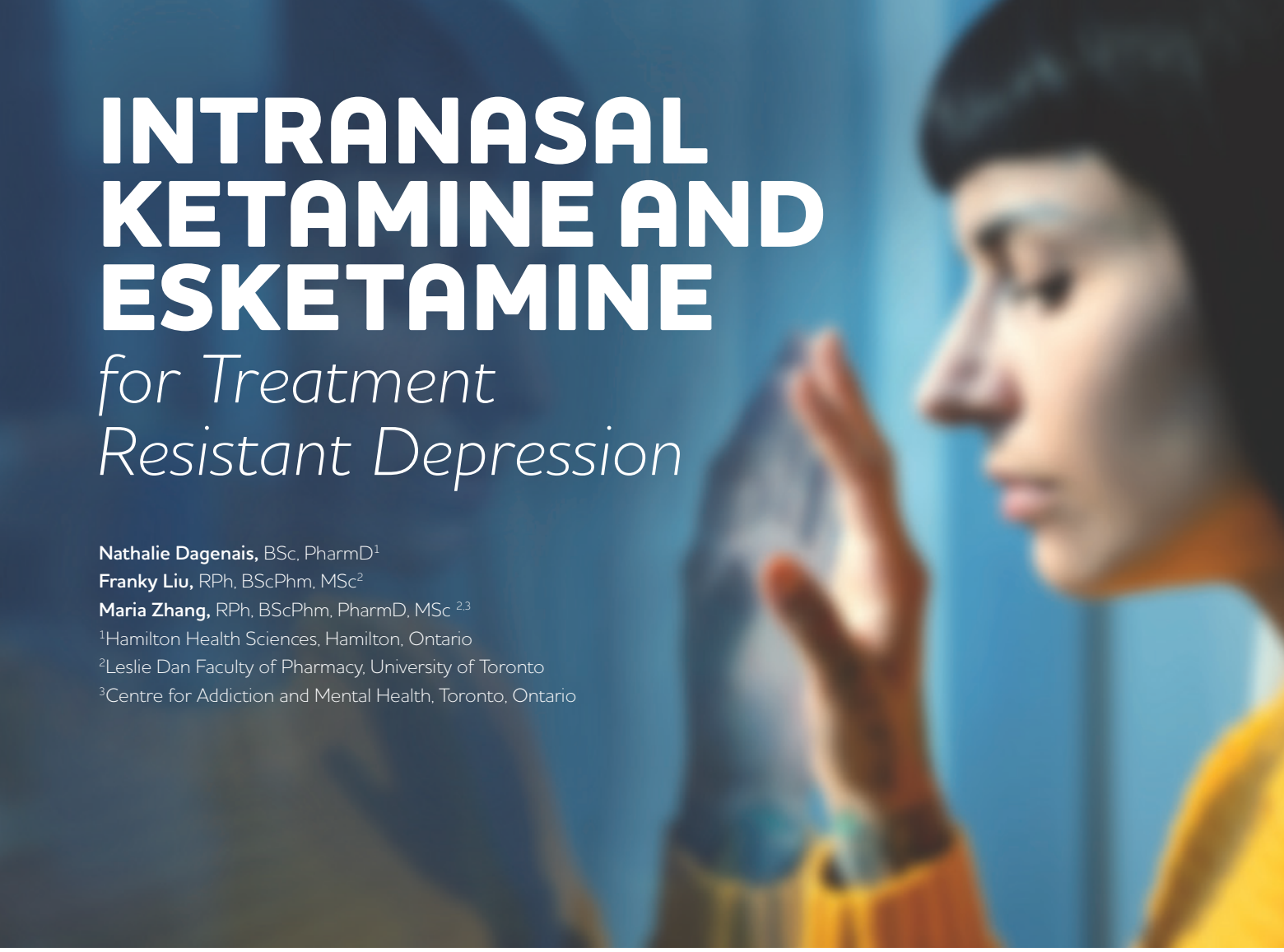
[1]Pharmacy Connection. Focus on Error Prevention (Summer 2018): https://pharmacyconnection.ca/focus-on-error-prevention-summer-2018/

[2]ISMP Canada. ISMP Canada Safety Bulletin Volume 12, Number 9: https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-09-ConcernedReporting-BisoprololandBisacodylMixups.pdf



INTRANASAL KETAMINE AND ESKETAMINE *for Treatment Resistant Depression*

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BACKGROUND

Depression is the leading cause of disability worldwide, affecting over 298 million people globally[1, 2]. While its treatment is multimodal, with medications frequently a cornerstone, current pharmacotherapies are limited by delayed onset of clinically significant antidepressant effects and significant relapse rates[3]. In fact, approximately one-third of individuals with major depressive disorder will experience treatment-resistant depression (TRD), defined as a suboptimal response to two or more appropriate trials of antidepressant therapy[4]. To address these gaps in treatment, there has been growing interest in the use of ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, as well as its newly marketed stereoisomer, esketamine. With the increased use of these agents in hospital and community settings, pharmacists play an invaluable role in optimizing treatment selection, and monitoring medication effectiveness and safety.

KETAMINE AND ESKETAMINE IN TREATMENT RESISTANT DEPRESSION

The 2016 Canadian Network for Mood and Anxiety Treatments (CANMAT) guideline lists intravenous ketamine infusions as an 'experimental treatment' reserved for the acute management of TRD in academic depression treatment centres[5]. Most of the evidence for this recommendation stems from single doses[6, 7], though newer evidence suggests that repeated ketamine infusions may prolong the duration of antidepressant response[3, 4, 8, 9]. Currently, the optimal dose, frequency, and safety of repeated infusions beyond four weeks remain unclear[4, 10]. Despite its inclusion in the CANMAT guidelines, intravenous ketamine remains largely inaccessible for those with TRD. Understandably, there is much interest in non-parenteral forms of ketamine, including intranasal delivery. There are a variety of important clinical, pharmaceutical, operational, and legal considerations that a pharmacist should evaluate when considering compounded intranasal

ketamine. These considerations should be taken in context of the recently available, patented-delivery intranasal esketamine.

INTRANASAL ESKETAMINE

In May 2020, Health Canada approved intranasal esketamine (SPRAVATO®) for the treatment of "major depressive disorder in adults who have not responded adequately to at least two separate courses of treatment with different antidepressants, each of adequate dose and duration, in the current moderate to severe depressive episode." The medication is to be used in combination with a selective serotonin or norepinephrine reuptake inhibitor[11]. While the product continues to be reviewed for its cost-effectiveness in Canada and in the United Kingdom, draft recommendations from the UK are negative as there are doubts regarding esketamine's true efficacy[12, 13]. Notably, studies compared esketamine simultaneously with an oral antidepressant started de novo, with a matching placebo and an oral antidepressant. This comparator is not reflective of how treatment-resistant depression is typically managed (i.e., an antidepressant augmented with lithium or an antipsychotic, electroconvulsive therapy, and/or psychotherapy)[13]. Additionally, given the mandatory monitoring period of two hours post medication administration, significant operational issues exist in its implementation.

Table 1: Comparison of intranasal ketamine and esketamine

<table>
<tr><th></th><th>Compounded intranasal ketamine</th><th>Parenteral ketamine for intranasal administration</th><th>Intranasal esketamine (Spravato®)</th></tr>
<tr><td>Commercially available product?</td><td>No</td><td>No. Active pharmaceutical ingredient itself is commercially available but not formulated specifically for intranasal administration</td><td>Yes, inclusive of drug and delivery device</td></tr>
<tr><td>Indicated for treatment resistant depression?</td><td>No</td><td>No</td><td>Yes</td></tr>
<tr><td>Prescribing restrictions?</td><td>No</td><td>No</td><td rowspan="2">Yes, only prescribers and pharmacists who have enrolled in the manufacturer's program are permitted to prescribe and dispense the medication.</td></tr>
<tr><td>Restrictions in medication distribution</td><td colspan="2">No restrictions beyond what is typically expected of narcotic drugs.</td></tr>
<tr><td>Patient access</td><td colspan="2">Following a prescription, patient can pick up the medication from a pharmacy of their choice and then self-administer the medication unsupervised</td><td>Following a prescription, clinic staff must pick up the medication from an authorized retailer. Patient self-administers the medication under the mandatory supervision of a health care provider.</td></tr>
<tr><td>Approximate drug cost (decreases with time as frequency of administration wanes)</td><td>Variable, ranges to approximately $100 for 30-day supply; does not include cost of atomizer</td><td>Variable, approximately $100 to $120 for 30-day supply; does not include cost of atomizer</td><td>Approximately $5000 for first month</td></tr>
<tr><td rowspan="3">Monitoring</td><td colspan="2">No mandatory clinical monitoring by a health care provider</td><td>Mandatory monitoring for 2 hours post-dose by a health care provider</td></tr>
<tr><td>Should be tracked as a general non-methadone controlled compounded substance via the Ontario Narcotic Monitoring System (manual process), using Pseudo-DIN 09857417</td><td>Is tracked as ketamine via the Ontario Narcotic Monitoring System using DIN assigned to parenteral ketamine product</td><td>Is tracked as esketamine via the Ontario Narcotic Monitoring System</td></tr>
<tr><td colspan="3">Effectiveness: measures of antidepressant effect (e.g., Patient Health Questionnaire-9, Quick Inventory of Depressive Symptoms)
Safety: Dissociation, blood pressure, heart rate, nausea/vomiting, changes in mental status, vertigo, sedation, suicidal ideation, substance use disorder, ulcerative or interstitial cystitis, cognitive impairment</td></tr>
</table>

INTRANASAL KETAMINE

Pharmaceutically, intranasal absorption is complicated by high inter- and intra-individual variability, differing with drug formulation, delivery device, insufflation technique and individual patient factors. Intranasal absorption is further limited by administered fluid volume: doses should be divided into 0.1 mL sprays with a maximum volume of 0.3-0.5 mL per nostril to avoid being swallowed and subject to first-pass metabolism[14–16].

With a commercially available racemic isolate available, pharmacy professionals should exercise careful professional judgment before proceeding with product formulation: these factors could include consideration for continuity of care; market availability or shortage of products and/or excipients; or compelling socioeconomic factors.

If compounding intranasal ketamine is deemed necessary, it must be compounded from powder or parenteral solution and manually assembled into a syringe fitted with an atomizer, which introduces further variability. Studies examining intranasal ketamine have exclusively used commercially available parenteral ketamine solution[17, 18].

If intranasal ketamine is to be inhaled from a solution compounded from powder, rather than the commercially available parenteral formulation, pharmacy professionals should consider the following when deciding to compound a ketamine preparation:

1. Ketamine as an active pharmaceutical ingredient refers to a racemic mixture of two stereoisomers of (R)-(-)-ketamine and (S)-(+)-ketamine that exist in approximately equal proportion, with distinct medicinal chemical, pharmacodynamic and pharmacokinetic profiles that may complicate replicability in dosage form preparation and therapeutic effect[19].

2. Ketamine is listed as a drug in the Narcotic Control Regulations under the Controlled Drugs and Substances Act and should be adjudicated through the province-wide Narcotic Monitoring System (NMS)[20]. If it is compounded from a powder without a DIN, it must be submitted using the general **non-methadone** compounded controlled substance pseudo-DIN (09857417)[21].

3. Special attention to isotonicity and pH are required to ensure patient acceptability and pharmaceutical elegance. For instance, ketamine is a weak organic base that is soluble in low pH. Excipients selected, particularly preservatives, should be chemically compatible to prevent inadvertent precipitation, dose variability and irritation to nasal mucosa[22–24]. In this regard, preservative addition is generally expected due to its aqueous formulation.

4. Compounders should observe the requirements outlined in both the USP 795 chapter on Nonsterile Preparations (which lists nasal preparations for local applications)[25] and NAPRA guidance documents when setting beyond-use dates and assigning lot numbers[26].

5. Compounders should maintain a robust quality assurance program as part of NAPRA's Model Standards for Pharmacy Compounding of Non-sterile Preparations; compounders may also consult the USP <795> for nonsterile preparations chapter on quality assurance for guidance on factors to observe[25]. Documentation should include rationale for excipient choice and/or omission, references to published formulae (if applicable), and quality control parameters which may include pH, mass analyses and/or organoleptic analyses[25, 26]. These records should be easily retrievable should any clinical issues arise, which could include adverse reaction management and reporting, therapeutic efficacy assessment or assessing batch variance.

Compounding is typically reserved for situations where "there is a therapeutic need or lack of product availability" and should not duplicate "an approved drug product"[27]. Arguably, with esketamine's Canadian market entrance, the use of intranasal ketamine, particularly to address treatment-resistant depression, will diminish.

Given the significant burden of illness and caveats in the effectiveness of current antidepressants, there is much interest in non-traditional pharmacotherapies for depression. With their novel mechanism of action and potential efficacy in TRD, ketamine and esketamine have emerged as medications of high interest. However, the quantity and quality of evidence supporting the use of these products vary depending on the formulation, route of administration, and/or dosage form. Pharmacists in all direct patient care settings will need to use their clinical judgment, knowledge of pharmaceutics, and patient care skills to ensure the safe and rational use of these emergent therapies. Pc

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A New Opioid Prescription: WHAT SHOULD YOU CONSIDER?

In conducting community pharmacist practice assessments, the College's practice advisors have noted that there is an opportunity for pharmacists to ensure they are considering clinical guidelines or recommendations regarding opioid therapy and applying them to their practice consistently. This article is intended to walk through what a pharmacist should consider when deciding whether to dispense and how to communicate/educate the patient.

SCENARIO A patient of your pharmacy presented a new prescription for OxyNeo® 40mg Sig: ii bid for severe chronic arthritis. This prescription is intended to be a switch from their current prescription for HydroMorph Contin® 18mg Sig: i bid. The patient also had a prescription for a benzodiazepine.

What Can You Consider When Assessing this Prescription and Communicating with the Patient?

GUIDELINES AND RECOMMENDATIONS

What updated recommendations regarding opioid prescribing/dispensing could influence how you assess this prescription and communicate to the patient?

What is the Morphine Milligram Equivalents (MME) of the new prescription? Does it present risks to the patient (i.e. conversion errors between the current and new prescription)? Does it reflect best practices in opioid stewardship?

KEY RESOURCES

- 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain (MAGICapp)
- Opioid Manager Toolkit
- Every Pharmacist is an Opioid Steward: Putting the 2017 Canadian Opioid Guideline into Action (*Pharmacy Connection*, Spring 2019)
- Quality Standard: Opioid Prescribing for Chronic Pain

RISK FACTORS FOR OVERDOSE OR OTHER HARMS FROM OPIOID USE

Is the prescription being co-dispensed with benzodiazepines? If so, what risks does this present to the patient and how can they be mitigated?

Can you proactively offer naloxone? How can you communicate the need for naloxone while being sensitive to concerns or assumptions patients have about naloxone and who it is for?

KEY RESOURCES

- OPA – Pharmacist Clinical Tool for Initiating Naloxone Discussions
- CAMH – Preventing Opioid Overdose Fact Sheet
- Benzodiazepine Use – CEP
- Naloxone module - Pharmacy5in5

PATIENT ASSESSMENT AND EDUCATION

What is the indication for therapy? Does that indication affect how you could optimize the therapy?

What other therapies have been tried? Are there alternative and complementary treatments or strategies that could help (e.g. physiotherapy)?

How does the patient rate their pain? Does the patient understand how their opioid use could contribute to the pain or other symptoms they may be having?

KEY RESOURCES

- Checklist for Starting or Continuing a Trial of Opioid Therapy – Section A of Opioid Manager
- Pharmacists Virtual Communication Toolkit: Engaging in Effective Conversations About Opioids (NAPRA)
- Assessing Opioid Prescriptions module – Pharmacy 5in5
- Opioid Policy

COLLABORATION WITH THE PRESCRIBER

What information should you provide the prescriber about your approach to this prescription, your communication with the patient and your overall recommendations?

How else can you be involved in working collaboratively with the prescriber to support this patient?

KEY RESOURCES

- Tapering – Section E of Opioid Manager
- Opioid Tapering Template - CEP

DOCUMENTATION, MONITORING AND FOLLOW UP

How will you monitor and follow up with this patient to assess whether their medication needs have changed? Do you have an approach for keeping the conversation going with this patient regarding their opioid use?

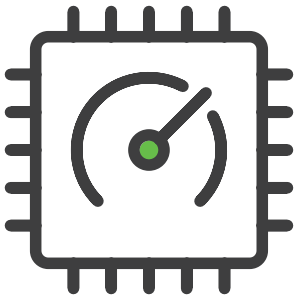
What is your documentation strategy for this patient so that all pharmacists at the pharmacy are aware of what has been discussed and the next steps?

How does your pharmacy's dispensing of opioids compare to others in your area as per the Quality Indicators for Pharmacy?

KEY RESOURCES

- Documentation – Essential to a Patient's Continuity of Care (*Pharmacy Connection*, Fall 2018)
- Quality Indicators for Pharmacy Data and Resources

College Performance Measurement Framework



The College was pleased to have been amongst a group of regulators actively engaged in the development of the Ontario Ministry of Health's new College Performance Measurement Framework (CPMF), designed to strengthen the accountability and oversight of regulatory colleges by ensuring they are meeting their fiduciary duties and serving the public interest, and at the same time helping colleges improve their performance. Beginning this year, all Ontario healthcare regulators are reporting on a number of indicators that are part of the CPMF.

The CPMF reinforces the College's approach to fulfilling its mandate of serving and protecting the public interest through the collection, analysis and transparent reporting of data—with the goal of using that data to continually improve our performance as an accountable health regulator. In fact, starting in 2021, the College is aligning its Performance Scorecard to the domains within the CPMF to create a consistent, standardized approach to reporting performance.

The CPMF measures the College's work in a number of domains, including governance, system partnerships, information management, regulatory policies, suitability to practice, and overall measurement and reporting on regulatory program activities such as those related to quality assurance, registrant competency and conduct processes. The information collected and reported in the inaugural report to be published online will inform future iterations of the framework and promote a better understanding of the activities of all the health regulatory colleges in the province.

Going forward, the College will be evolving the annual report to effectively complement the CPMF. Future editions of the annual report will continue to focus on the ways the College is meeting its legislated mandate, its objects and its Board-defined strategic priorities, while the CPMF data will be reported in a parallel publication. As the College transitions to the new format, it has published a separate document for 2020 that includes historic numbers for some of the data provided in this annual report to provide a transparent view of trends over the past several years.

The College's CPMF has been posted on its website under About the College >Performance and Accountability.

Ontario College of Pharmacists

Putting patients first since 1871

150 YEARS

2020 Annual Report

Trusted to lead. Inspired to serve. Driven to protect.

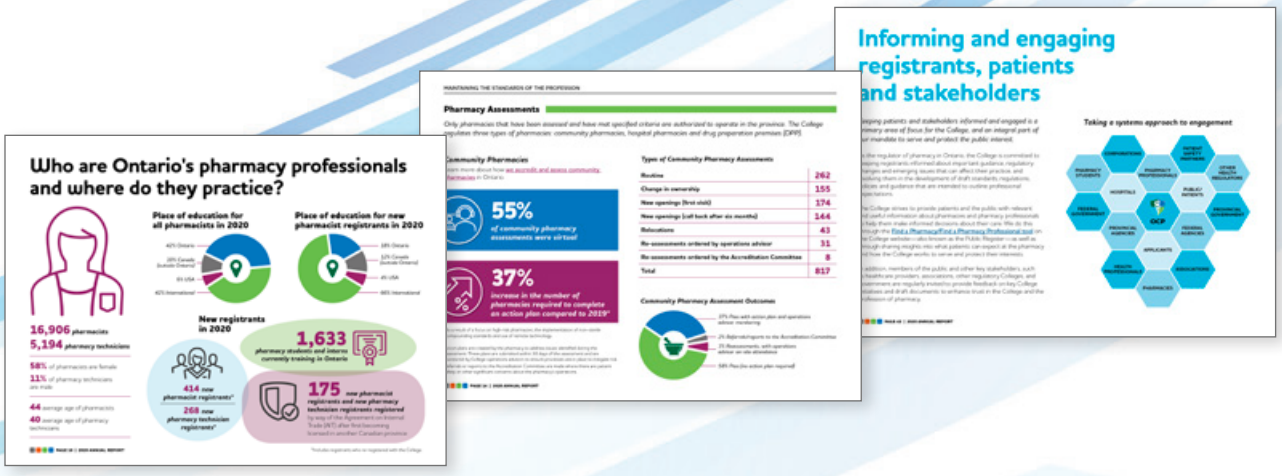
The College recently published our 2020 Annual Report.

The report provides updates on our statutory responsibilities as well as highlighting how we are working to deliver our vision, mission, values and strategic priorities. Read the report to access data about the College's core programs and learn more about our progress in enhancing system and patient outcomes, strengthening trust and confidence in the College, and enhancing our capacity to address emerging opportunities.

Read the 2020 Annual Report

Including the financial information, supplementary data document and links to discipline decisions from 2020.

LEARN MORE



Ontario College of Pharmacists
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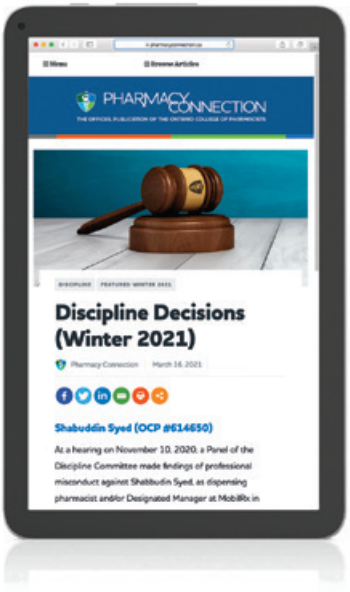
7 REASONS TO CONNECT WITH OCP ON SOCIAL MEDIA

1. Get tips and advice on how to maximize your pharmacy experience (patients) and get practice resources to help you provide better patient care (pharmacy professionals)
2. Stay informed on key projects the College is involved in that directly impact you
3. Learn about our new open consultations as soon as they're posted
4. Stay up-to-date with the latest pharmacy regulatory news and updates
5. Get important reminders of key dates and events
6. Be the first to know when we develop a new helpful tool or resource, such as a video or an infographic
7. Get access to helpful resources we have curated and share on our social media channels from other organizations

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 WINTER 2021 DECISIONS:

Shabuddin Syed (OCP #614650)
Yong Lin (OCP #217337)
Kaushil Shah (OCP #612689)
Shaukatali Mangalji (OCP #65757)
Murad Al Hasan (OCP #604660)
Kochupalanilkunnathil Varghese (OCP #72427)
Leisa Barrett (OCP #208964)
Guirguis Abdou (OCP #613067)
Maged Guerguis (OCP #622569)
Amir Girgis Boktor (OCP #603444)
Hong Hong Xie (OCP #618878)
Shirish Shah (OCP #68179)
Andrew Besada (OCP #610659)
Member "Z"

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.

A Proactive Approach to Medication Safety:
THE PHARMACY SAFETY SELF-ASSESSMENT (PSSA)

ALL COMMUNITY PHARMACY DESIGNATED MANAGERS MUST COMPLETE THE PSSA BY DECEMBER 31, 2021

What is the PSSA?

The PSSA is an informative quality improvement tool that allows for the proactive identification of areas of potential risk within a pharmacy's work processes and provides a baseline understanding of a pharmacy's medication safety rating. This information is then used to plan improvement activities and monitor the impacts of those improvements over time as they work to enhance patient safety.

Who should complete the PSSA?

The PSSA is to be completed by all community pharmacy Designated Managers. It should be done in collaboration with the entire pharmacy team to ensure seamless implementation of the identified opportunities for improvement.

When should the PSSA be completed?

The PSSA should be completed before December 31st, 2021, for the first time, and then at least once every two to three years. If there is a significant change to the pharmacy it can be completed more frequently. Overall, the PSSA takes only a few hours to complete and does not need to be completed at one time.

Where can the PSSA be completed?

The PSSA is available on the AIMS Pharmapod platform and can only be accessed through a Designated Manager's Pharmapod account. For login inquiries see the AIMS contact information box to the right.

Why should the PSSA be completed?

The PSSA is a mandatory component of the AIMS Program, which acts as a foundational assessment of a pharmacy's work processes which could translate into medication incidents or near misses. This is a great opportunity for pharmacy managers to engage their pharmacy team towards creating a culture of safety.

PSSA RESOURCES

- Pharmacy Safety Self-Assessment Overview
- PSSA User Guide

AIMS PROGRAM UPDATES

- The AIMS e-training modules are available on both the OCP website and the AIMS Pharmapod platform
- After completing each module, registrants can print a certificate of completion to confirm they have reviewed the content. This certificate of completion may be kept for your own records and does not need to be submitted to the College

AIMS CONTACT INFORMATION

Account activation and Designated Manager changes
pharmacyapplications@ocpinfo.com

Technical or account log-in issues
success@pharmapodhq.com

AIMS Program standards and expectations AIMS@ocpinfo.com or Website

Pharmacy staff with login issues
Contact the Designated Manager

AIMS **Assurance** and **Improvement** in **Medication Safety**

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

The following is an example of a near miss that took place in a community pharmacy setting. The analysis of the near miss is presented to highlight the learnings that can come from such cases along with possible quality improvements that a pharmacy team may implement into their practice to prevent future recurrence and patient harm.

The College's expectations under the mandatory Assurance and Improvement in Medication Safety (AIMS) Program are described in the second section titled "Applying the AIMS Program to This Near Miss". The AIMS standards are outlined and applied to the incident to highlight how pharmacy staff can incorporate continuous quality improvement into their pharmacy setting using this worked example.

FOCUS ON ERROR PREVENTION

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

*Pharmacists and pharmacy technicians must be aware that pediatric doses can be stated in one of two ways – either as mg/kg/**dose** or mg/kg/**day**. This lack of standardization coupled with the vulnerability of the pediatric population makes it essential that pharmacy professionals use extra care when assessing and confirming indications and doses for pediatric prescriptions.*

CASE:
Rx:
Amoxicillin 250mg/5ml Suspension
Sig: 80mg/kg BID for 7 days.
Weight: 10kg

The above preprinted prescription for a fifteen-month old child was taken to a local community pharmacy.

The pharmacy assistant entering the prescription into the computer input the dosage as 80mg/kg/dose.

The direction for use was therefore entered as 16mls (800mg) twice daily for seven days.

Upon checking the prescription, the pharmacist confirmed the indication for use as acute otitis media which was printed on the prescription.

An appropriate reference was consulted and the recommended dose for otitis media was confirmed to be 80mg/kg/**day**, not per **dose** as entered.

The directions for use were therefore corrected to 8mls twice daily for seven days.

POSSIBLE CONTRIBUTING FACTORS:
- The computer generated prescription provided the incorrect dose (80mg/kg)
- The pharmacy assistant entering the prescription did not clarify the dosing with the pharmacist which led to the entry of the prescription as written (i.e. 800mg BID x 7 days)

RECOMMENDATIONS:
- Instruct staff to always collect and record the patient's age, weight and the indication for use when accepting prescriptions for pediatric patients.
- Confirm whether the weight provided is in pounds or kilograms. An estimate of the child's weight based on their age may be used to double check.
- The child's age, weight, the indication for use and recommended dosage regimen should always be used to ensure that the appropriate drug and dosage are being dispensed.
- Double check all pediatric doses for appropriateness as these patients are at an increased risk of experiencing harm.
- Be aware of the potential for error due to the failure to convert pounds to kilograms, as the patient's weight is usually provided in pounds while dosages are usually stated per kilogram.
- Wherever possible, a second individual should independently complete the calculation without prior

knowledge of the results of the first calculation.

- Though computer generated prescriptions can minimize medication errors due to illegible handwriting, be aware of the potential for incorrect pediatric dosages.
- Always take the necessary steps to clarify any ambiguous aspect of a prescription.
- Educate the prescriber of the potential for error and recommend a change in printing format if possible.

Suggest that the software vendor be contacted for assistance.

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.

APPLYING THE AIMS PROGRAM TO THIS NEAR MISS

This incident provides an opportunity to examine what pharmacy professionals are required do as part of the Assurance and Improvement in Medication Safety (AIMS) Program when they identify a medication incident or near miss.

Under the AIMS Program, pharmacy professionals must *anonymously*:

- **Record** incidents and near misses to the AIMS Pharmapod platform in a timely manner,
- **Analyze** the incident or near miss to identify possible contributing factors and the root cause,
- **Document** plans to minimize the likelihood of the incident recurring by generating learning points and action items for implementation by the pharmacy team,
- **Share** learnings from the near miss or medication incident with all pharmacy staff

All of the above elements are equally important in helping to reduce the risk of a medication incident or near miss from reoccurring in the future and leading to patient harm. Details on each of the above elements and the overall AIMS Program expectations can be found on the AIMS webpage and within the Supplemental Standards of Practice: Mandatory Standardized AIMS Program in Ontario Pharmacies.

RECORD

Standard
The near miss and associated details must be anonymously recorded in the AIMS platform.

Recording the incident helps the pharmacy to monitor trends and devise actions plans. It also contributes to aggregate data that is used to identify trends and disseminate learnings for pharmacy professionals across the province with the goal of preventing similar incidents in the future.

Application of Standard

When the near miss is identified, it is expected that the details are recorded in the AIMS Pharmapod platform as soon as possible. The incident form guides users through a variety of questions including, "What happened?" (i.e. incident type). In this case the appropriate selection would be "incorrect concentration or strength".

ANALYZE

Standard
The analysis of the near miss takes place in a timely manner to identify contributing factors.

This allows for the determination of an action plan to implement appropriate steps to minimize the likelihood of recurrence of the incident in the future.

Application of Standard

The CQI tools in the AIMS Pharmapod Platform (i.e. risk matrix and 5 whys tool) can be used to assist with incident analysis and will appear once the near miss is entered into the platform. The whole pharmacy team, particularly anyone who may have had a part in the near miss, should be involved in the analysis.

DOCUMENT

Standard
Documentation of the following elements is expected: action plans and quality improvements implemented.

Once the incident has been analyzed it is expected that pharmacy staff document continuous quality improvement plans, such as specific actions that are to be taken in response to the near miss.

Application of Standard

The recommendations outlined in Ian Stewart's article are examples of action plan items to be documented in the AIMS Pharmapod platform either under "Learning Points" or "Actions". Once documented, these actions or learning points are visible to all staff who have access to the platform which facilitates implementation and follow-up.

SHARE LEARNINGS

Standard
Communicate near misses to all staff, encourage open dialogue on medication safety, monitor CQI plans and improvements implemented.

Application of Standard

In addition to discussing the importance of collecting specific information for pediatric prescriptions, an agreed upon process should be used to implement the CQI recommendations. For example, a process to ensure that prescription indication and patient weight is collected and recorded on each pediatric prescription received.

AIMS PROGRAM CONTACT INFORMATION

ISSUE	CONTACT
Account activation and DM changes	pharmacyapplications@ocpinfo.com
Technical or log-in issues	success@pharmapodhq.com
AIMS program standards and expectations	Website or AIMS@ocpinfo.com
Pharmacy Staff with log-in issues	The Designated Manager

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