



Ontario College
of Pharmacists
Putting patients first since 1871

PHARMACY & CONNECTION

FALL 2016 • VOLUME 23 NUMBER 4

THE OFFICIAL PUBLICATION OF
THE ONTARIO COLLEGE OF PHARMACISTS



IN THIS ISSUE:

Engage the Patient:

A Conversation with Marshall Moleschi,
retiring Registrar of the Ontario College
of Pharmacists, [page 14](#)

Applying the Code of Ethics in Everyday Practice

New resources available to assist you, [page 11](#)

QUICK CONTACTS

Office of the CEO & Registrar
 registrar@ocpinfo.com
 ext. 2241

Office of the President
 ocp_president@ocpinfo.com
 ext. 2243

OCP Council
 council@ocpinfo.com
 ext. 2243

Pharmacy Practice
 pharmacypractice@ocpinfo.com
 ext. 2285

Registration Programs
 regprograms@ocpinfo.com
 ext. 2250

Member Applications & Renewals
 memberapplications@ocpinfo.com
 ext. 3400

Pharmacy Applications & Renewals
 pharmacyapplications@ocpinfo.com
 ext. 3600

COUNCIL MEMBERS

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

H Christine Donaldson
 (Vice-President)
 H Régis Vaillancourt
 (President)
 K Esmail Merani
 K Tracey Phillips
 L Billy Cheung
 L James Morrison
 L Sony Poulou
 M Faye Kosa
 M Don Organ
 M Laura Weyland
 N Gerry Cook
 N Christopher Leung
 N Karen Riley
 P Jon MacDonald
 P Douglas Stewart
 T Michelle Filo
 TH Goran Petrovic

PM Kathy Al-Zand
 PM Linda Bracken
 PM Carol-Ann Cushnie
 PM Ronald Farrell
 PM Naj Hassam
 PM Javid Khan
 PM John Laframboise
 PM James MacLaggan
 PM Sylvia Moustacalis
 PM Shahid Rashdi
 PM Joy Sommerfreund
 PM Ravil Veli
 PM Wes Vickers
 U of T Heather Boon
 U of W David Edwards

Statutory Committees

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

Standing Committees

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



**Ontario College
 of Pharmacists**
 Putting patients first since 1871

Strategic Framework 2015-2018

Mission

The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care.

Vision

Lead the advancement of pharmacy to optimize health and wellness through patient-centred care.

Values

Transparency ♦ Accountability ♦ Excellence

Strategic Priorities

Core Programs
 Fulfillment of Mandate ♦ Optimize Practice
 within Scope ♦ Inter & Intra
 Professional
 Collaboration

Strategic Initiatives

Patients First
Effective Communications
Continuous Quality Improvement

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

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

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

**PUBLISHED BY THE COMMUNICATIONS
& POLICY DEPARTMENT**
communications@ocpinfo.com



PHARMACY CONNECTION

FALL 2016 • VOLUME 23 NUMBER 4

FOLLOW US ON SOCIAL MEDIA!



www.facebook.com/ocpinfo



www.twitter.com/ocpinfo



www.youtube.com/ocpinfo



[www.linkedin.com/company/
ontario-college-of-pharmacists](http://www.linkedin.com/company/ontario-college-of-pharmacists)

ISSN 1198-354X

© 2016 Ontario College of Pharmacists

Canada Post Agreement #40069798

Undelivered copies should be returned to the Ontario College of Pharmacists. Not to be reproduced in whole or in part without the permission of the Publisher.



CONTENTS

President's Message	4
Council Report	5
2016-2017 Members of Council	7
Code of Ethics e-Learning Modules	11
In the News	12
Conversation with Marshall.	14
Medical Assistance in Dying	20
Reporting Privacy Breaches	22
Patch 4 Patch	23
Universal Influenza Immunization Program	24
Regulatory Amendments	26
ISMP Canada: Analysis on QT-Prolongation	28
Coroner's Report: Transitions of Care	34
Student Experience at OCP	38
Sterile Compounding Standards: What We Heard During Consultation	40
Social Media	41
Close-Up on Complaints	42
Discipline Decisions	44
Focus on Error Prevention: Pediatric Patients	50



Régis Vaillancourt,
O.M.M., C.D., B. Pharm.,
Pharm. D., R. Ph.

President

As I enter my term as President of OCP Council, I'm humbled by the privilege and mindful of the responsibility of ensuring that the College continues to uphold our mandate to protect the public and that our activities ultimately support our vision: *lead the advancement of pharmacy to optimize health and wellness through patient-centred care.*

Supported by our values of transparency, accountability and excellence, the current strategic plan (2015 – 2018) creates a solid framework, which will continue to guide and prioritize the work of the College. With a focus on patients first and a commitment to continuous quality improvement and effective communication, the

overarching objective of the plan is to deliver measured improvement in the safe, effective and ethical delivery of pharmacy services to Ontarians.

This objective has been coined "Moving the Mountain" by our recently retired Registrar Marshall Moleschi (read *Engage the Patient – A conversation with Marshall Moleschi, retiring registrar of the Ontario College of Pharmacists* page 14). A key component to successfully delivering on this strategy has been the College's shift in focus from compliance with rules towards an emphasis on coaching and mentoring to the Standards of Practice and Code of Ethics.

“Our responsibility, as always, must be to remain diligent in our efforts to focus our work on our mandate to serve and protect the public”


Although this shift in focus can be felt in all areas of the College, perhaps the most significant – with respect to directly impacting on enhancements to the delivery of quality patient care – is in the changes that have been made over the past few years to practice assessments.

Introducing an assessment of individual practitioners, as part

of routine community pharmacy assessments, has allowed the College to engage with pharmacists and pharmacy technicians in their own practice environment: clarifying practice expectations, providing coaching and mentoring, and sharing best practices. With official oversight for hospital pharmacies now in place, the College will soon be introducing individual practitioner assessments to routine hospital assessments as well.

An important part of these pharmacy visits over the coming years will be working with practitioners to understand and become compliant with new standards regarding sterile and

non-sterile compounding (refer to article on page 40). Although appreciative of the challenges that evolving standards can bring to hospitals and community pharmacies, the overriding consideration for the College must be the compliance to standards with the assurance of continuity of care for patients.

The growing complexity of patient conditions and medication therapies, fueled by both real and perceived societal, political and media pressures, will continue to influence the work of the College. Our responsibility, as always, must be to remain diligent in our efforts to focus our work on our mandate to serve and protect the public interest. I look forward to the challenges and opportunities the coming year will bring! 

OCP REGISTRAR SEARCH UPDATE

The executive search for the College's next Registrar is ongoing. It is anticipated that a new registrar will be appointed either late this year or early in 2017.

In the interim, Anne Resnick, Deputy Registrar, has assumed the position of Acting Registrar for the Ontario College of Pharmacists.

SEPTEMBER 2016 COUNCIL MEETING

As recorded following Council's regularly scheduled meeting held at the College offices on September 19th and 20th, 2016.

NEW PRESIDENT AND VICE-PRESIDENT ELECTED BY COUNCIL FOR 2016-2017 COUNCIL TERM

At the September meeting, Mr. Régis Vaillancourt was acclaimed College President and Ms. Christine Donaldson was acclaimed Vice-President for the 2016-2017 Council terms.

Council also welcomed newly elected members Mr. Billy Cheung, Mr. James Morrison and Mr. Sony Poulou (District L), Ms. Tracey Phillips (District K), and newly appointed public member, Ms. Carol-Ann Cushnie (Toronto), to the Council table. Mr. Esmail Merani was re-elected to District K, Ms. Michelle Filo to District T and Mr. Goran Petrovic to District TH.

Elections were also held for Committee Chairs and a full list of 2016-2017 Council members as well as a complete list of Committee Chairs and appointments can be found on the [College website](#).

2017 CAPITAL AND OPERATING BUDGET AND AUDITOR APPOINTMENT

Council reviewed and approved the 2017 budget, which supports the strategic plan (2015 – 2018) developed by Council in March

2015 and the Operational Plan presented to Council in June 2015. The Plan affirms transparency, accountability and excellence as values and codifies Patients First, Effective Communication and Continuous Quality Improvement as strategic initiatives. The 2017 budget reflects the respective expenses in accordance with operational accountabilities.

As a result of continued growth in membership and moderate increases in expenses for 2017, no fee increases are required. Operating expenses are budgeted to equal revenue; capital expenditures will be funded by reserves if no operating surplus materializes throughout 2017.

Council also approved the appointment of Clarke Henning LLP as Auditors for 2016. The auditors were selected in 2014 following an external review of the College's auditing and financial services and the Finance and Audit Committee is satisfied that the firm continues to meet the College's requirements.

REVISION FRAMEWORK FOR QUALITY ASSURANCE AND REGISTRATION REGULATIONS

Council approved frameworks for updating the quality assurance

and registration regulations (see more details on [page 26](#)). This will allow the College to proceed with drafting amendments to regulations that will be outcomes-based, supported by standards, policies and guidelines which can change over time to enable practice evolution.

In the case of Quality Assurance, the regulations require amendments to incorporate a two-part register (part A for those engaged in patient care; and part B for those in non-patient care practice) for pharmacy technicians to align with the current register of pharmacists. With respect to maintaining part A status, Council also approved moving to a requirement that members declare that they have completed sufficient practice to maintain competence in patient care within the member's area of practice, in place of the current hourly practice requirement.

With respect to Registration Regulations, Council agreed to the implementation of a single provisional class of registration for pharmacist and pharmacy technician students and interns and to add a requirement of police background checks as part of the registration process.



STERILE COMPOUNDING STANDARDS AND TIMELINE APPROVED

Council, following consideration of the feedback received through the public consultation process ([see page 40](#)), adopted the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations (NAPRA, 2016)* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations (NAPRA, 2016)* and approved implementation by January 1, 2019.

Preparation of sterile products in Canada currently incorporates many

of the same patient safety and quality assurance requirements as these new standards; however, there are some additional requirements in the new standards, including an onsite quality assurance program, increased oversight, beyond-use-dates and recall procedures.

As some pharmacies may require time to become fully compliant, Council approved a two-year implementation timeline during which pharmacies currently engaged in sterile compounding are expected to review these new standards, identify any gaps in current practice and establish an action plan to reach full compliance on or before January 1, 2019. **Pc**

NEXT COUNCIL MEETING

Monday December 12, 2016

For more information respecting Council meetings, please contact

Ms. Ushma Rajdev, Council and Executive Liaison at urajdev@ocpinfo.com

MEMBERSHIP RENEWAL REMINDER

Online renewal starts in January with a deadline of March 10, 2017

NOTE: no form will be mailed to you, however email reminders will be sent.

Before you begin your renewal you will need:

- Credit Card if paying online
- User ID: This is your OCP number
- Password: If you have forgotten your password, click "Forgot your Password or User ID?" A new password will then be emailed to you.

Once you're ready:

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



2016/2017
Council



**Ontario College
of Pharmacists**
Putting patients first since 1871

2016/2017 MEMBERS OF COUNCIL

H Hospital

T Pharmacy
Technician

TH Hospital
Pharmacy
Technician

P

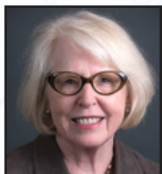
K

L

M

N

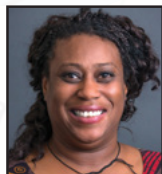
PUBLIC MEMBERS



Kathy Al-Zand
Ottawa



Linda Bracken
Marmora



Carol-Ann Cushnie
Toronto



Ron Farrell
Sundridge



Naj Hassam
North York



Javaid Khan
Markham



John Laframboise
Ottawa



James MacLaggan
Bowmanville



Sylvia Moustacalis
Toronto



Shahid Rashdi
Mississauga



Joy Sommerfreund
London



Ravil Veli
North Bay



Wes Vickers
LaSalle

ELECTED MEMBERS

District H



Christine Donaldson
VICE PRESIDENT
Windsor



Régis Vaillancourt
PRESIDENT
Ottawa

District K



Esmail Merani
Carleton Place



Tracey Phillips
Westport

District L



Billy Cheung
Markham



James Morrison
Burlington



Sony Poulse
Hamilton

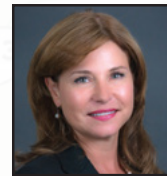
District M



Fayez Kosa
Toronto



Don Organ
Toronto



Laura Weyland
Toronto

District N



Gerry Cook
London



Chris Leung
Windsor



Karen Riley
Sarnia

District P



Jon MacDonald
Sault Ste. Marie

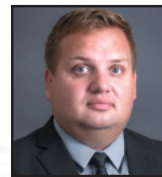


Douglas Stewart
Sudbury

District T/ TH



Michelle Filo (T)
Sudbury



Goran Petrovic (TH)
Kitchener

FACULTY OF PHARMACY



Heather Boon, Dean
Leslie Dan Faculty of Pharmacy
University of Toronto



David Edwards, Hallman Director
School of Pharmacy
University of Waterloo

2016/2017 Committee Appointments

EXECUTIVE

COUNCIL MEMBERS:

Régis Vaillancourt – President & Chair
Christine Donaldson – Vice President
Esmail Merani – Past President
Ron Farrell
Sylvia Moustacalis
Joy Sommerfreund
Laura Weyland

STAFF RESOURCE: CEO & Registrar

ACCREDITATION AND DRUG PREPARATION PREMISES

COUNCIL MEMBERS:

Tracey Phillips (Chair)
Billy Cheung
Michelle Filo
John Laframboise
James Morrison
Joy Sommerfreund

NON-COUNCIL MEMBERS:

Lavinia Adam
Tracy Wiersema
STAFF RESOURCE: Tina Perlman (Acc)
Judy Chong (DPP)

DISCIPLINE

COUNCIL MEMBERS:

Doug Stewart (Chair)
Kathy Al-Zand
Heather Boon
Linda Bracken
Gerry Cook
Carol Cushnie
Christine Donaldson
Dave Edwards
Ron Farrell
Javaid Khan
Fayez Kosa
Chris Leung
Jon MacDonald
James MacLaggan
Esmail Merani
Sylvia Moustacalis
Don Organ
Sony Poulouse
Goran Petrovic
Karen Riley
Shahid Rashdi
Régis Vaillancourt
Ravil Veli
Wes Vickers

NON-COUNCIL MEMBERS:

Chris Aljawhiri
Jennifer Antunes
Ramy Banoub
Jocelyn Cane
Charles Chan
Fel dePadua
Dina Dichek
Debbie Fung
Jim Gay
Jillian Grocholsky
Sherif Guorgui
Andrew Hanna
Rachel Koehler
Andreea Laschuk
Jaime McDonald

Cara Millson
Akhil Pandit Pautra
Chintan Patel
Kelly Pogue
Mark Scanlon
Jeannette Schindler
Connie Sellors
David Windross

STAFF RESOURCE: Maryan Gemus

FINANCE AND AUDIT

COUNCIL MEMBERS:

Javaid Khan (Chair)
Linda Bracken
Gerry Cook
Esmail Merani
Doug Stewart
STAFF RESOURCE: Connie Campbell

FITNESS TO PRACTISE

COUNCIL MEMBERS:

Kathy Al-Zand (Chair)
Carol Cushnie
James Morrison
Goran Petrovic

NON-COUNCIL MEMBERS:

Jocelyn Cane
Mark Scanlon

STAFF RESOURCE: Maryan Gemus

INQUIRIES, COMPLAINTS AND REPORTS (CRC)

COUNCIL MEMBERS:

Laura Weyland (Chair)
Kathy Al-Zand
Linda Bracken
Billy Cheung
Gerry Cook
Carol Cushnie
Christine Donaldson
Ron Farrell
Michelle Filo
Javaid Khan
John Laframboise
Chris Leung
Jon MacDonald
James MacLaggan
James Morrison
Sylvia Moustacalis
Sony Poulouse
Goran Petrovic
Shahid Rashdi
Joy Sommerfreund
Ravil Veli
Wes Vickers

NON-COUNCIL MEMBERS:

Elaine Akers
Kalyna Bezchlibnyk-Butler
Andrea Fernandes
Sherif Guorgui
Frank Hack
Bonnie Hauser
Mary Joy
Elizabeth Kozyra
Curtis Latimer
Dean Miller
Akhil Pandit Pautra
Kelly Pogue
Saheed Rashid

Satinder Sanghera
Richard Sigesmund
Dan Stringer
Asif Tashfin
Tracy Wiersema
Debra Willcox

STAFF RESOURCE: Maryan Gemus

PATIENT RELATIONS

COUNCIL MEMBERS:

Joy Sommerfreund (Chair)
Linda Bracken
Sylvia Moustacalis
Goran Petrovic
Doug Stewart

NON-COUNCIL MEMBERS:

Fel dePadua
STAFF RESOURCE: Anne Resnick

PROFESSIONAL PRACTICE

COUNCIL MEMBERS:

Chris Leung (Chair)
Fayez Kosa
Don Organ
Shahid Rashdi
Karen Riley
Ravil Veli

NON COUNCIL MEMBERS:

Mike Hannalah
Mark Scanlon
STAFF RESOURCE: Tina Perlman

QUALITY ASSURANCE

COUNCIL MEMBERS:

Jon MacDonald (Chair)
Linda Bracken
John Laframboise
Sylvia Moustacalis
Tracey Phillips
Sony Poulouse

NON-COUNCIL MEMBERS:

Tina Boudreau
Mary Joy
Sarah Woodworth-Giroux
STAFF RESOURCE: Sandra Winkelbauer

REGISTRATION

COUNCIL MEMBERS:

Christine Donaldson (Chair)
Carol Cushnie
Michelle Filo
Ravil Veli
Wes Vickers
NON-COUNCIL MEMBERS:
Jillian Grocholsky
Deep Patel
Dean:
Heather Boon
Ontario Pharm Tech Program Rep:
Sharon Lee
STAFF RESOURCE: Vince Bowman

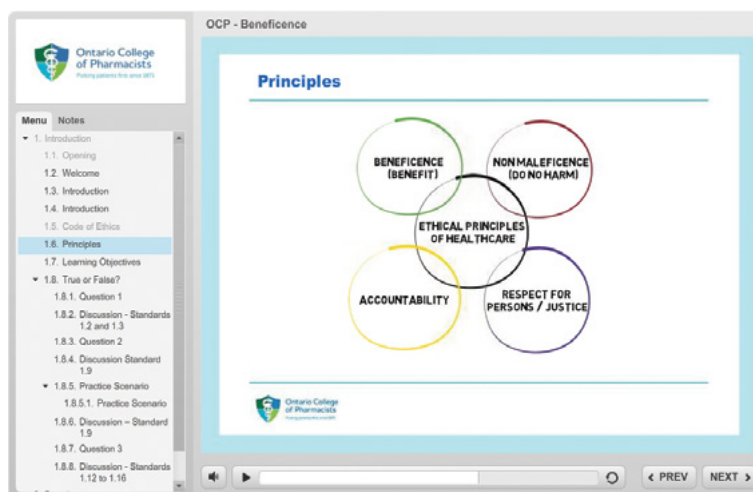
More Resources Now Available to Assist You in Applying the Code of Ethics in Everyday Practice!

The College is pleased to launch additional [e-Learning and video modules](#) as part of a series to assist current and future pharmacists and pharmacy technicians understand and apply the new Code of Ethics in everyday practice.

The series now includes modules dedicated to the principles of Beneficence (to benefit) and Non Maleficence (do no harm) as well as the first of three video practice examples. The role and purpose of OCP's Code of Ethics is to clearly articulate the ethical principles and standards which guide the practice of pharmacists and pharmacy technicians in fulfilling their mandate to serve and protect the public.

Using a variety of fun and engaging learning techniques, such as true and false questions, animated graphics, case studies and video, the modules bring the core ethical principles of healthcare to life and illustrate how the standards within the Code can be applied in everyday practice.

In approving the new Code of Ethics at their December 2015 meeting, Council established a requirement for all current (and new) pharmacists and pharmacy technicians to declare that they have read and understood the Code in 2017. As such pharmacists and pharmacy technicians are encouraged to view these modules as they are released. Over the next few months, additional e-learning and video modules will cover all aspects of the Code and provide a library of resources. **PC**



LIBRARY OF CODE OF ETHICS LEARNING RESOURCES:

- [Code of Ethics Introduction](#) – **Available**
- [Principle of Beneficence \(to benefit\)](#) – **Available**
- [Principle of Non Maleficence \(do no harm\)](#) – **Available**
- Principle of Respect for Persons/Justice – In Development
- Principle of Accountability/Fidelity – In Development
- Professional Boundaries – In Development

VIDEO PRACTICE EXAMPLES:

- [Confidentiality](#) – **Available**
- Continuity of Care – In Development
- Applying Therapeutic Judgement – In Development



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

SEXUAL ABUSE TASK FORCE REPORT

On September 9, 2016, the Ministry of Health and Long Term Care [released](#) the findings of the *Minister's Task Force on the Prevention of Sexual Abuse of Patients and the Regulated Health Professions Act, 1991*. The task force was initially established in December 2014 after a number of high profile incidents of sexual abuse by regulated health professionals.

The task force put forward [34 different recommendations](#). The government has indicated that they will bring forward legislative amendments in the fall that would encompass some, but not all, of the recommendations. Proposed amendments include:

- expanding the list of acts that result in mandatory revocation of a license;
- increasing transparency on what colleges must report on their public register; and
- clarifying the time period after the end of a patient-provider relationship in which sexual relations are prohibited.

The ministry has also indicated that they will, in 2017, look to identify more ways for patients to participate in the complaints, investigation and discipline processes at health regulatory

colleges and enhance knowledge and education among the public, patients and health professionals.

HEALTH CANADA APPROVED NALOXONE NASAL SPRAY

On October 3, 2016, Health Canada approved naloxone (Narcan®) nasal spray for use in Canada as a non-prescription product.

Naloxone nasal spray must now be scheduled at the provincial and territorial level through the National Drug Schedules (NDS) program maintained by the National Association of Pharmacy Regulatory Authorities (NAPRA). A scheduling submission for naloxone nasal spray was received and will be reviewed by the NDS Advisory Committee at their meeting on December 5, 2016. A final recommendation and modification to the NDS will be made by the end of 2016.

Until NAPRA scheduling is complete, pharmacists may continue to access naloxone through regular distribution channels or U.S. distributors as per [Health Canada's](#) requirements for importing and selling Narcan®. The Interim Order, signed by the Minister of Health on July 6, 2016, authorizes the importation, distribution, and sale of US approved naloxone nasal spray without a prescription.

Pharmacists can dispense any formulation of naloxone available for sale and distribution in Canada, as long as it is in accordance with all of the requirements outlined in the [College's Guidance – Dispensing or Selling Naloxone](#). It is the professional responsibility of a pharmacist to ensure that he or she has sufficient knowledge, skills and abilities to competently deliver any pharmacy service. The College has included links to [external training resources](#) for pharmacists to ensure they are prepared to safely and effectively provide naloxone to a patient or patient's agent.

[The Ontario Pharmacists Association](#) may be an additional source of information regarding sourcing supplies for pharmacy-assembled take-home naloxone kits.

OPIOID ADDICTION AND OVERDOSES

The issue of opioid dependency and overdose is an ongoing concern across Canada. According to data from the chief coroner's office, fentanyl was the number one cause of opioid-related deaths in Ontario in 2015. The number two cause of opioid-related deaths was hydromorphone.

In response to this growing crisis, the government of Ontario, in an October 12 news release—Ontario Taking Action to Prevent Opioid Abuse—revealed a number

of strategies to address opioid addiction and overdose. A few of these include:

- developing evidence-based standards for healthcare providers on appropriate opioid prescribing to help prevent unnecessary dispensing and over-prescribing;
- delisting high-strength formulations of long-acting opioids from the Ontario Drug Benefit Formulary in January 1, 2017;
- expanding access to naloxone overdose medication, available free of charge for patients and their families to help prevent overdose deaths;
- increasing access to Suboxone addiction treatment and improving patient outcomes for those who use this treatment; and
- establishing the Patch for Patch program, which came into effect on October 1, 2016, and

which places new obligations on prescribers, dispensers and patients (for more on Patch for Patch, turn to [page 23](#)).

The full release is available in the Government of Ontario [newsroom](#).

REVISED OVER THE COUNTER ACETAMINOPHEN LABELLING REQUIREMENTS

Health Canada has released a revised labelling standard for over the counter acetaminophen products following stakeholder consultations last fall. The purpose of the revised labelling standard is to ensure “stronger, clearer” labels for over the counter acetaminophen products. Pharmacists should be aware of these new standards to ensure appropriate counselling for patients regarding over the counter acetaminophen products.

The revised standard indicates that:

- a dosing device be included with children’s liquid formulations;

- the principal display panel of product labels include the declaration “Contains acetaminophen” in red text with a white background, in bold, size 10 font;
- labels emphasize the importance of using the lowest effective dose and heeding the maximum daily dose of 4 grams per day, or eight tablets of extra-strength (500mg) acetaminophen; and
- a new template for the Drug Facts Table for acetaminophen products be incorporated – once the requirement for all products to have a Drugs Fact Tables comes into force.

Although discussed during the consultation period, Health Canada decided not to make changes to the maximum daily dose or maximum unit dose for acetaminophen products. **Pc**

CURRENTLY SEEKING FEEDBACK ON NON-STERILE COMPOUNDING STANDARDS

OCP is currently seeking feedback on the Model Standards for Pharmacy Compounding of Non-Sterile Preparations developed by the National Association of Pharmacy Regulatory Authorities (NAPRA). All pharmacists and pharmacy technicians who engage in non-sterile compounding are invited to review these standards and provide feedback.

Comments received during the 30-day consultation, ending Thursday November 17 will be considered by the College for its feedback submission to NAPRA early in December. NAPRA will review the submissions from all pharmacy regulators across the country and determine what changes to make to these draft standards, if any. Once NAPRA finalizes the standards, OCP council will consider the timing of their implementation.

To share your feedback on the standards, visit the [Consultations](#) page on the OCP website.



ENGAGE THE PATIENT

A CONVERSATION WITH MARSHALL MOLESCHI, RETIRING
REGISTRAR OF THE ONTARIO COLLEGE OF PHARMACISTS

By Stuart Foxman

The practice of pharmacy may have evolved over his career, but to Marshall Moleschi the fundamental role has remained the same.

"It really is about how you engage the patient in a respectful way that gives the best therapy and benefit and reduces risk," he says. "That's the essence of being a healthcare professional."

At age 15 Moleschi landed his first part-time job – and gained a window into his future calling. After school, he worked as a stock boy at a pharmacy in Langley, B.C. "The pharmacist was a great guy, respected in the community, and we started to talk about pharmacy as career," recalls Moleschi.

After graduating from the University of British Columbia with his B.Sc., Pharmacy, he worked in community, hospital and long-term care pharmacy settings, as well as in healthcare administration. Moleschi was appointed

Registrar for the College of Pharmacists of British Columbia in 2005, and in 2011 assumed the same role for the Ontario College of Pharmacists.

Among other leadership positions, he has been the President of the Federation of Health Regulatory Colleges of Ontario (FHRCO) and the President of the Canadian Foundation for Pharmacy, and served on the Board of the National Association of Pharmacy Regulatory Authorities (NAPRA).

As Moleschi prepared to retire from the College, he met with Pharmacy Connection to share his reflections. How does he view the achievements and mission of the College? How well are pharmacists and pharmacy technicians providing safe, appropriate, and quality care to Ontarians? And what are his expectations and hopes for the future of the profession?



Pharmacy Connection (PC):
Where do you think the pharmacy profession has seen the biggest changes over the course of your career?

Marshall Moleschi: It used to be all about simply filling a prescription, following orders and being very accurate. By the time I graduated, it was about giving advice, but

someone else made the decisions. What's different today is that pharmacists are asked to make decisions about everything from extending a prescription to doing an adaptation to initiating therapy.

PC: When you first arrived in Ontario, you introduced this idea of navigating the grey. What does that mean?

Moleschi: Essentially it means that we're not an assembly line. There's not always a black and white answer. We need to treat each patient as a specific person, and figure out what we can deliver to benefit that patient. It also stressed the role that pharmacists have as decision makers and emphasised the point that a decision to do nothing is in fact a decision.



Marshall is recognized by OCP staff members Rob van Doorn and Connie Campbell for his years of dedicated service and leadership in furthering the mandate of the college to serve and protect the public interest.

PC: Navigating the grey seems to stress the importance of being a thinking profession that is accountable for decisions. How do the rules fit in?

Moleschi: It's not just about following rules. In order to fully support patients' needs, pharmacists and pharmacy technicians must utilize their full scope and consistently practice to their Standards of Practice and Code of Ethics.

This means applying all of your knowledge, skills and abilities to each individual patient's circumstance and making decisions that optimize their health outcomes. When each of us chose to become a healthcare professional, this is what we committed ourselves to: putting the interests of patients first.

PC: What has been the most important focus of the College during your tenure as Registrar?

Moleschi: It has really been to our mandate – to serve and protect the public and enhance the delivery of quality care to Ontarians. Our approach has been a strategy coined "Moving the Mountain"

which is really about all practitioners, regardless of role or practice setting, getting just a little bit better.

It's meant a shift in the College's focus or approach as well. If we look at practice assessments as an example, we've moved away from simply a 'checklist' of adherence to 'rules' to an assessment and evaluation of actual practice with the objective of 'coaching and mentoring' practitioners to enhance their delivery of pharmacy services.

PC: What is the intent of this shift in focus?

Moleschi: I hope that we've helped create an environment that's conducive to supporting pharmacy professionals in being decision-makers and using their knowledge, skills and abilities to help make patients better. This is the value that pharmacists and pharmacy technicians bring, not just to individual patients, but to the healthcare system as a whole.

We see in the hospital setting, for example, how pharmacists, enabled in part by pharmacy technicians, have moved from being the drug distribution professional to being

very clinically involved. Overall, we're the medication experts, and that adds tremendous value, whether in a hospital or community practice.

PC: From a regulatory standpoint, what supports this shift?

Moleschi: We've moved from very prescriptive regulation language to more outcome-based. Regulations no longer list all the details. They list the outcomes, and we can get the details into policies or guidelines to allow greater flexibility as patient and societal needs evolve.

PC: What are the public's expectations of healthcare regulation?

Moleschi: The public expects oversight. Regulatory bodies need to reflect the needs of society and ensure the standards for the delivery of safe, effective and ethical care are being met. In doing this, Colleges have a huge obligation to be transparent and accountable. Without that we lose public confidence.

PC: Has that expectation presented new opportunities for this College?

Moleschi: Yes. We were recently given oversight for hospital pharmacies. This came about as the result of a reported incident of under-dosing of chemotherapy medication in a number of hospitals in Ontario. The public was understandably concerned and our College was able to step in and work with government to provide appropriate oversight to better protect the public.

PC: That has represented one move forward in the role of the College during your time as Registrar. What other big changes stand out, and how have they helped the profession and, ultimately, patients?

Moleschi: The ongoing integration of pharmacy technicians – working to their full scope – has enabled pharmacists to shift more time towards their patients and work with them to ensure the appropriateness of their medication to optimize their health. This continues to be a work in progress but is a critical step to maximizing the value that pharmacy professionals can bring to patients.

PC: You mentioned the importance of transparency in regulation, which is a focus of the Ministry of Health and Long-Term Care. What does transparency mean to you?

Moleschi: To me it's being understandable, whether to the public, media or a healthcare professional. Things can't be hidden and buried under a bunch of jargon or a mass of information. If someone wants to

find and understand our processes, it needs to be accessible and clear.

PC: Over your career, you have served on or worked closely with other bodies, such as FHRCO, NAPRA, the Advisory Group for Regulatory Excellence, and the Canadian Council for Accreditation of Pharmacy Programs. How important has it been to build these ties?



In September, Marshall was awarded the Canadian Foundation for Pharmacy Lifetime Achievement Award. This award is given to those who have demonstrated dedicated service to the professional for more than 20 years and have made a significant impact on the practice and advancement of pharmacy. [Pictured outside the OCP offices in Toronto; Dave Edwards, President, Canadian Foundation for Pharmacy (left) with Marshall Moleschi, CEO & Registrar, Ontario College of Pharmacists]



Moleschi: Extremely important. If we have a good understanding of each other and emphasize our commonalities, we can make better decisions together. The relationship building really helps to have that understanding of what healthcare is all about.

PC: The strategic priorities, set out in the College's Strategic Plan, talk about things like Patients First and Continuous Quality Improvement. How does that play out?

Moleschi: We're striving for excellence, which, along with transparency and accountability, is a core value of the College. No matter what current task or work we are engaged in we can never lose sight of the 'big picture' – to put patients first. Our strategic plan deals with fulfilling our mandate through commitment to a culture of continuous quality improvement.

So we're always looking for ways to enhance our programs and processes – whether it's about changes to entry-to-practise and

practice assessments or evolving how we process complaints or conduct investigations. The objective is to find more effective and efficient ways to serve our mandate.

PC: When issues and queries come to the College, what's important in the way you assess that information and respond?

Moleschi: As a regulatory College, we are more often than not dealing with a question of professional conduct. Although understanding what in fact happened is essential, our focus is often around intent – understanding why someone might have done what they did. Was it to serve the best interests of the patient? We don't just look at applying the rules, but consider intention. Sometimes you must do the 'right' thing, simply because it is the 'right' thing to do – even if the rules do not explicitly lead you there.

As I've already mentioned, decisions in healthcare are rarely black and white. When pharmacy

professionals reach out to us with questions like "How do I do this?" our role is not to provide a definitive answer but rather a framework that supports their decision-making.

PC: How do you see the role of pharmacy professionals continuing to evolve?

Moleschi: I believe pharmacists and pharmacy technicians have the potential to be navigators for patients. Not just in being the medication expert, but in being a portal to the healthcare system.

There is a huge role to be played here by pharmacy professionals. Particularly in community practice, patients are continuously struggling to understand their medications and navigate the healthcare system.

It would mean, of course, that all healthcare professionals would need to function as a true team, working together in a patient-centred care model that enables pharmacy professionals to add even more value to that team. The outcome would be that the

healthcare professional with the most appropriate skillset would be readily accessible to help that patient.

PC: What might that mean for the role of regulatory colleges?

Moleschi: We'll also need to function more as a team of health regulators to support the healthcare system and, ultimately, individual patient health outcomes. We're already starting to do that in the hospital sector because it's so interdisciplinary.

PC: In supporting the best health outcomes for patients, the staff at the College comprises a vital team too. How would you describe the role and the contributions of the people who work at the College?

Moleschi: I am very appreciative of all that the staff have done, how they're committed to our mission and vision, and exercising the values in all that we do. I was very fortunate because one of the first things I realized when I started with the College was that the culture and talent of the team here was very strong. Over the years I think we have built on that strength and grown as a learning and thinking organization.

PC: What kind of culture have you tried to foster within the College to support that?

Moleschi: I want the people who work at the College to think of how they can make a difference, no matter their role, and be empowered to take action. A culture that supports change, asks a lot of questions, and is not afraid to make mistakes. Because that is how you learn and grow.

As I've already mentioned, in the end we need to be a learning and thinking organization. We're making a conscious effort to model or mirror the expectations of this College with the expectations we are asking of the professionals and places we regulate.

PC: Healthcare roles and regulation always transform. You've seen it as a practitioner yourself and as a Registrar. Are members of the pharmacy profession receptive to their evolving scope and the expectations of them?

Moleschi: It is certainly no secret or surprise that our profession is slow to evolve. I think all healthcare professionals become a little uncomfortable when you're pushing the envelope. But it's how

a profession grows. We need to dig deep, find those ways to get over ourselves and confidently own our role as medication experts on the healthcare team.


PC: What are your wishes for the profession over the years ahead?

Moleschi: I hope that pharmacists and pharmacy technicians are delivering true value for their patient – using all of their knowledge, skills, and abilities to make a difference to health outcomes.

PC: What's next for you?

Moleschi: Spend time with family and friends, and do the things I love, like photography, golf and skiing. I'll be moving to Kelowna, BC. Hopefully, I can still be engaged in healthcare in a voluntary way, and serve on boards.

PC: Why was the time right to step down as Registrar?

Moleschi: It's satisfying to say I've done the best that I can do. It's time for a new generation of leaders to come forward and make a difference. 



College Staff bid farewell to Marshall at his retirement party on September 21

MEDICAL ASSISTANCE IN DYING

Frequently Asked Questions



On June 17, 2016, the federal government enacted amendments to the Criminal Code of Canada (the "Criminal Code") to include circumstances under which medical assistance in dying (MAiD) is permitted.

Pharmacists and pharmacy technicians are now exempted from criminal liability when dispensing a prescription that is written by a medical or nurse practitioner for the purposes of providing MAiD in accordance with applicable federal legislation, provincial or territorial legislation, standards, policies or guidelines.

The College has developed a [guidance document](#) to assist pharmacy professionals to comply with legal obligations and professional expectations with respect to MAiD.

Supplementing this, the College recently developed FAQs to address the more common questions arising in practice. The FAQs will be continuously reviewed and revised to ensure pharmacy professionals have access to all necessary and relevant information. Current frequently asked questions include:

1. What are the protocols?

Medical and nurse practitioners will exercise their professional judgment to determine the appropriate

drug protocol for the patient based on individual circumstances and drug availability. The goals of any drug protocol for medical assistance in dying include ensuring the patient is comfortable, and that pain and anxiety are controlled.

Standardized Prescription Protocols have been developed by other jurisdictions for the purpose of MAiD. The Standardized Prescription Protocols are examples of drug protocols being used in other jurisdictions that pharmacy professionals may wish to consult when aiding in MAiD.

Pharmacists are encouraged to engage in a collaborative process with the medical or nurse practitioner as early as possible, once they are aware that the patient has initiated a request for MAiD. Where a pharmacy professional has received a MAiD prescription for a specific patient and requires additional resources to support him or her in the preparation of the drug protocol, the pharmacist may contact a College Practice Consultant at pharmacypractice@ocpinfo.com.

Information on the publicly funded drug protocols is provided on the *August 10th Notice from the Executive Officer: Reimbursement and Claims Submissions using the Health Network System relating to Drugs for Medical Assistance in*

Dying and FAQs for Pharmacists which can be found at the [Ontario Public Drugs Programs](#) website.

2. Where do I get the ingredients to compound oral drug protocols?

Manufactured tablets should not be used when compounding oral drug protocols due to excipients and variable bioavailability of the active ingredient. Pharmacy professionals are required to use Active Pharmaceutical Ingredients (API) when compounding MAiD oral drug protocols.

APIs are the substances in pharmaceutical drugs that are responsible for the beneficial health effects experienced by consumers. An example of an API is the acetaminophen contained in a pain relief tablet.¹

Pharmacy professionals should enquire with normal distribution channels (e.g. wholesaler or chemical supplier) to determine whether they supply API products.

3. What types of "syringes and tubes" are needed for the iv protocol?

Medical supplies required will be determined by the drug protocol prescribed. The pharmacist is encouraged to collaborate with the medical or nurse practitioner to

identify specific supplies required.

4. How do I prepare the mixture?

Compounding requirements for the preparation of each drug protocol will be determined by the protocol selected. The College is able to provide members with examples of protocols from other jurisdictions, but it is up to the professional judgement of the pharmacy professional to determine the most appropriate compounding formulation. Pharmacy professionals are encouraged to work collaboratively with other practitioners, both inter and intra-professionally, as required to determine the best option for each individual patient.

5. What type of coordination and communication is required when dispensing a prescription for MAiD?

The provision of MAiD requires the involvement of multiple health practitioners. Coordination and communication among all health professionals involved in the provision of MAiD is essential.

Early engagement between the prescriber and the pharmacy will help ensure that required medication and supplies are available in a timely manner.

Where the patient will be self-administering medication to end their own life, the College of

Physicians and Surgeons of Ontario has encouraged the physician who prescribed the medication to communicate proactively with the patient and their family to establish a process to be undertaken following death. This may include identifying: any individual(s) who will be present at the time of death; the practitioner who will certify death; and the individual who will notify the Coroner once death has occurred.

6. How do I counsel the patient on how to store/take?

It is important that the pharmacist counsel the individual picking up the medications regarding the stability, storage requirements and any other details supporting the efficacy and administration of the preparations. Stability, storage requirements and details regarding efficacy and administration of a preparation will be specific to each drug protocol.

After counseling the patient or their agent, the pharmacist is encouraged to assess whether the patient understands the information provided, as well as the benefits and risks of the drug therapy.

Pharmacists are also encouraged to discuss the return of unused products to the pharmacy for disposal in a safe, legal, and environmentally sound manner with the patient or his/her agent.

7. Can a hospital supply a community pharmacy with iv meds?

If a community pharmacy is having difficulties sourcing medications for an intravenous MAiD prescription, purchase from a hospital pharmacy is permitted to support individual patient care.

8. What pharmacies are offering MAiD dispensing?

Any pharmacy with the required resources to safely and effectively prepare a compounded drug protocol (if necessary), and where the pharmacy professionals have the appropriate knowledge, skills and judgement, can offer to aid in providing MAiD.

In circumstances where a pharmacist declines to assist in MAiD on the basis of a conscientious objection, he or she is required to, in accordance with their Code of Ethics (Standard 2.13), provide the patient with an effective referral to a non-objecting alternate provider where the patient can receive the desired services in a timely manner.

As with any pharmacy service where a pharmacist has declined to provide a service on the basis of a conscientious objection, that pharmacy should have a process in place prior to receiving a request for that service to ensure that the patient can be directed to an alternate provider in a timely manner. ¹

¹ Active Pharmaceutical Ingredients – Good Manufacturing Practices – Questions and Answers. Health Canada. Retrieved on September 9, 2016 from <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogués/actingre-question-eng.php>

FOLLOW
THE GUIDELINES

REPORTING PRIVACY BREACHES:

New Obligations for Regulated Health Professionals

Pharmacists and pharmacy technicians should be aware of new reporting obligations under the [Personal Health Information Protection Act \(PHIPA\)](#), which took effect in June 2016.

PRIVACY BREACHES AND NOTIFICATIONS

The purpose of PHIPA is to establish rules for the collection, use and disclosure of personal health information and prevent the unauthorized use or disclosure of personal health information, or the loss or theft of personal health information. This includes the implementation of both administrative and technical safeguards and practices to ensure the privacy and security of personal health information.

In the event of a privacy breach, the responsible health information custodian (HIC)—the person with custody and control of the records—must notify the individual(s) affected at the first reasonable opportunity. If you are not the responsible HIC yourself, but rather an agent of the HIC, you

must report the incident to the custodian as soon as possible.

When the custodian notifies a patient of a privacy breach, they must also inform the patient that they can make a complaint about the breach to the Information and Privacy Commissioner of Ontario.

It is recommended that HICs voluntarily report privacy breaches to the Commissioner, as once additional regulations are passed such reporting will be mandatory.

OBLIGATION TO REPORT TO REGULATORY COLLEGES


Health information custodians are also required to report actions taken in response to privacy breaches to the appropriate regulatory college. This means that if you, as a custodian, take any disciplinary action against a regulated healthcare professional relating to their unauthorized collection, use, disclosure, retention or disposal of personal health information, you must report that fact to their regulatory college. This applies even in situations where the

individual resigns, is suspended or has their employment terminated. The notice to the College must be given in writing within 30 days of the disciplinary action or resignation.

OTHER CHANGES TO PHIPA

In addition to these new obligations to report privacy breaches, the following changes have been made to PHIPA:

- The maximum fines for privacy offences have doubled from \$50,000 to \$100,000 for individuals and from \$250,000 to \$500,000 for organizations.
- The limitation period for prosecutions of privacy offences has been removed.
- The respective responsibilities of health information custodians and agents have been clarified.

A framework for a province-wide system of electronic health records has been introduced but is not yet in force. 

More information on the protocol in the case of a privacy breach is available from the Office of the Information and Privacy Commissioner of Ontario or <https://www.ipc.on.ca/health/>

PATCH 4 PATCH

ADDRESSING MISUSE OF NARCOTICS AND MONITORED DRUGS

THE FENTANYL PATCH RETURN PROGRAM

In the latest step taken by the Ontario government to address issues related to narcotics and addictions, the regulations under the *Safeguarding our Communities Act* (*Patch for Patch Return Policy*) took effect on October 1, 2016. These regulations establish obligations on prescribers, dispensers and patients, and make it more difficult for patients to abuse or misuse fentanyl patches. The introduction of this mandatory program completes a process that began in October 2014, when a private member's bill was first introduced in the Ontario legislature. At that time, more than 40 communities across the province had already implemented voluntary fentanyl patch return programs.

In anticipation of the implementation of the regulation, the College collaborated with the College of Physicians and Surgeons of Ontario (CPSO) in developing a [fact sheet](#) for physicians and pharmacists. Prescribers and dispensers are required to fulfill specific obligations when prescribing and dispensing fentanyl patches. For example:

- Prescribers are to record the name and address of the pharmacy where a prescription will be filled, identify whether a prescription is a 'first prescription', and notify the pharmacy in advance.
- Pharmacists are to confirm the information recorded on the prescription, examine used patches to ensure they aren't fakes, and dispose of them appropriately.

Patients must return all used fentanyl patches to the pharmacy before being able to access a prescription refill.

The fentanyl patch return program is just one of several initiatives aimed at providing further safeguards relating to opioid use in Ontario.

THE NARCOTICS MONITORING SYSTEM

In 2012, the province established a [Narcotics Monitoring System](#) which collects dispensing data for all dispensed narcotics, controlled substances and other monitored drugs. The collected information is used for multiple purposes including educational, public health and reporting purposes. In the first 6 months following implementation of the system, there was a 12% reduction in potentially inappropriate opioid prescriptions.¹

NALOXONE

In June 2016 the province [approved](#) pharmacist dispensing of naloxone without a prescription and at no cost to eligible Ontarians. The purpose of the scheduling change was to make naloxone more accessible to those at risk of an opioid overdose. Naloxone is a synthetic drug that can reverse the effects of an overdose of opioids such as heroin, methadone, opium, codeine, or hydrocodone. Naloxone does not have an intoxicating effect, has no potential for abuse or dependency, and its only purpose is to reverse the effect of opioids. A person cannot develop a tolerance

to naloxone. Although data is not yet available, the expectation is that greater access to naloxone will result in a reduction of deaths due to opioid overdose.

HIGH DOSE OPIOIDS - DELISTED

Starting in January 2017, the Ontario public drug plan will stop paying for high doses of morphine and fentanyl. On that date, higher strengths of long-acting opioids will be de-listed from the [ODB Formulary](#), including Fentanyl 75 mcg/hr and 100 mcg/hr patches. The medications that are being delisted from the formulary will not be available through the Exceptional Access Program or Compassionate Review Policy. The announcement of this change was made six months in advance to provide patients and physicians time to make any required changes to prescribed drug therapy.

According to [data](#) associated with reimbursement under the Ontario Drug Benefit program, approximately 48% of Fentanyl patch prescriptions reimbursed are for high strength patches.

NEXT STEPS

The government is currently developing a provincial framework for pain management and prescription opioid use disorder. **PC**

¹Gomes, et al. "Impact of legislation and a prescription monitoring program on the prevalence of potentially inappropriate prescriptions for monitored drugs in Ontario: a time series analysis" CMAJ Open. 2014 Oct-Dec; 2(4): E256-E261.

PHARMACISTS CONTINUE TO PLAY AN IMPORTANT ROLE IN PROVIDING FLU SHOTS TO ONTARIANS

2016-2017 is the fifth season that pharmacies will be involved in the province's Universal Influenza Immunization Program (UIIP)

Influenza is the most common infectious disease cause of death in Canada, and it is estimated that 3,500 Canadians pass away in a given year from influenza and its complications.¹ Therefore, it is particularly important for high risk groups, including patients 65 or older, women who are pregnant and patients with chronic health conditions, to receive the flu vaccine.²


TO ADMINISTER THE FLU VACCINE TO PATIENTS FIVE YEARS AND OLDER, PHARMACISTS MUST:

- Be participating in Ontario's UIIP
- Have completed an OCP-approved injection training course and registered their training with the College
- Hold a valid certification in CPR and First Aid

Pharmacists participating in the UIIP are also authorized to provide the FluMist vaccine to patients age 5 to 17. Patients outside this age range can receive the publicly-funded FluMist vaccine from their family physician.

More information about the UIIP is available on the Ministry of Health and Long-Term Care's website at <http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/>.

COMMON QUESTIONS FROM PATIENTS ABOUT THE FLU SHOT

It's a good idea for pharmacists to familiarize themselves with the following commonly asked questions about influenza immunization. Patients who are hesitant or ambivalent about vaccination may be more comfortable with reassurance from their pharmacist. 

Question	Answer ³
Does the flu shot work?	The flu shot acts as a barrier, making the body more resistant to flu viruses. As influenza viruses are always changing, it's important to get vaccinated every year to protect oneself against whichever flu viruses are going around during that particular time.
Is the flu shot safe?	Absolutely. Flu vaccine ingredients have been tested to ensure they're safe, and the province regularly checks the safety of the flu vaccine. Hundreds of millions of people have already benefited from the flu shot.
What is in the flu shot?	Flu vaccines contain dead viruses and have small amounts of egg protein. Flu shots are safe for patients with egg allergies.
Is the flu shot painful?	Many patients don't experience any pain at all. The shot may pinch or sting, but only for three or four seconds. Those who relax their arm will help themselves avoid any pain. If patients are especially concerned with potential pain during the flu shot, they can use a cream or a patch that numbs the skin.

RESOURCES FOR PHARMACISTS ON ADMINISTERING INJECTIONS

The College's [Practice Tool](#) contains information on administering injections, including an FAQ and information on training and registration requirements.



With almost 9,000 pharmacists trained to provide immunizations and nearly 2,600 community pharmacies participating in the UIIP, patients will once again have broad access to publicly-funded flu shots.

REFERENCES

1. Influenza Immunization: Protecting your health and the health of your community.
Retrieved at http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/docs/hcw_factsheet_pro_staff_en.pdf
2. Flu Consult Toolkit. Retrieved at <http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/resources.aspx>
3. Get the facts about the flu shot.
Retrieved at http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/docs/flu_uiip_concerns_handout_2015-16_en.PDF

WE WANT TO HEAR FROM YOU!



Later this fall, OCP will be undertaking an online survey to help us understand the effectiveness, value and reach of our communications tools – the website, Pharmacy Connection, eConnect, Twitter, Facebook, YouTube and LinkedIn – to pharmacy professionals.

WE WANT TO HEAR FROM YOU:

How do you prefer to receive information?

How do you use the information you get from the College? How can we improve?

Please watch for your invitation to participate in this important initiative.

We encourage all pharmacists and pharmacy technicians to take a few moments to complete the survey.

Proposed Regulatory Amendments under the PHARMACY ACT

At its September meeting, Council approved a framework and approach to guide the development of proposed amendments to regulations under the Pharmacy Act that will affect two separate regulatory functions of the College: registration and quality assurance. The amendments will reflect an outcome-based approach to regulation and introduce important changes to registration requirements and quality assurance reviews. Council's approval of the framework is an important first step in the process to update and revise these regulations.

The outcome-based approach to revising these regulations will be similar to the approach used for recent amendments to the regulations under the *Drug and Pharmacies Regulation Act*. The value of this approach is that the expected outcomes will have the weight of legislation, while providing the College with the flexibility to update standards and expectations in policies and guidelines as needed to better reflect the current practice environment. Once the amendments to the regulations are drafted and Council has approved them for public consultation, members of the College will be provided an opportunity to review and comment on the proposed regulations.

REGISTRATION

Five years ago, pharmacy technicians in Ontario became a regulated profession; however, at the time the regulations were updated to incorporate this new class, the College did not create a graduated approach to licensing. At present there is no way for pharmacy technicians to register post-graduation but prior to completing all entry exams and practical assessment/training. Additionally, there is duplication in the requirements for the existing student and intern classes for pharmacists. To address these issues, the College is proposing a single provisional registration class that combines the current student and intern classes for pharmacists and adds a provisional class for pharmacy technicians.

The College is also proposing to require registrants to complete a police background check as part of the registration process. This requirement balances the current approach that requires a Declaration of Good Character from pharmacists and pharmacy technicians, supports the Code of Ethics, and aligns the College with many regulatory authorities in Canada and Ontario that require a police background check as part of the registration process.

QUALITY ASSURANCE

At present, the College maintains a two-part register for pharmacists: Part A for those engaged in patient care and Part B for those who wish to maintain registration but who might be

employed in an administrative or educational capacity. Through this approach, the public can easily identify practitioners who are actively engaged in patient care, and members must engage yearly to declare their participation. The College is therefore able to focus

to Quality Assurance requirements is a shift from hourly reporting of practice to a yearly confirmation of competence. In considering this area, it became clear that there was a lack of evidence that correlates minimum practice hours to competence, and that the better


The College is taking a new approach to its Quality Assurance reviews. Instead of applying a standardized competence assessment on-site at the College to evaluate performance (formerly known as Peer Review), the College will evaluate individual practitioners

outcome-based approach amendments REGULATORY CHANGES consultation quality assurance framework registration

resources on those practitioners whose practice most impacts patient health outcomes and safety. The proposed changes would implement a comparable two-part register for regulated pharmacy technicians.

The additional change contemplated for the College's approach

approach is to permit each individual practitioner to evaluate his or her own engagement in patient care activities and self-evaluate competence based on experience. The College will ask pharmacy professionals to declare that they have completed sufficient practice to maintain competence.

at their practice site, focusing on the areas of patient assessment, decision-making, documentation and communication/education. It is intended that these practice-based assessments will engage practitioners in a quality assurance context more frequently. 

How and When Will These Changes Take Effect?

More detailed information is available in the materials that were prepared for September Council, and can be accessed in the [Meetings and Reports section](#) of the College's website.

It will take some time to make these changes a reality. With Council's approval of the initial framework received, the next step is to draft the amended regulations. These will be brought forward to Council at a later meeting for approval for public consultation. Comments from all pharmacists and pharmacy technicians will be welcomed at that time. A final draft regulation, reflecting feedback received during the consultation process, is expected to be approved by Council, for submission to government, later in 2017.

Although these are the College's regulatory proposals, only the Ontario government has the authority to approve regulations. All regulations are filed with the Registrar of Regulations and come into force on the date on which they are filed, unless otherwise provided in the regulation or Act under which the regulation is made. More information on how Acts and Regulations Come into Force is available on the [Ontario Government website](#).

A MULTI-INCIDENT ANALYSIS ON QT-PROLONGATION IN THE COMMUNITY

Roshan Tahavori, HonBSc,
BScPhm, PharmD ¹

Kevin Li, PharmD Student ^{2,3}

Steven Lam, BSc, PharmD
Student ^{2,3}

Certina Ho, RPh, BScPhm, MSt,
MEd, PhD ^{2,3,4}

¹ Hospital for Sick Children

² Institute for Safe Medication
Practices Canada

³ School of Pharmacy,
University of Waterloo

⁴ Leslie Dan Faculty of Pharmacy,
University of Toronto

INTRODUCTION

The QT interval is the time measured from the initiation of the QRS complex to the termination of the T wave during an electrocardiogram (ECG).¹ This interval represents the time between ventricular depolarization until subsequent repolarization of the ventricles.¹ Long QT syndrome (LQTS) refers to a case in which the QT interval is abnormally long indicating an undesirable delay in cardiac repolarization. This syndrome can either be a result of genetic inheritance or is acquired.¹ The presence of a prolonged QT interval increases the risk of developing cardiac arrhythmias, most clearly torsades de pointes (TdP), a life threatening form of polymorphic ventricular tachycardia associated with rapid heart rates of 160 to 240 beats per minute.¹

TdP may present with symptoms of palpitations, dizziness, shortness of breath or syncope and in some cases this can be transient.^{1,2} However, in most other cases TdP will deteriorate into ventricular fibrillation that can result in sudden cardiac death.^{1,2}

Drug therapy is the most common cause of acquired LQTS; although some associated with greater risks than others, there are over 100 drugs available that have the potential to cause QT prolongation and many of these drugs are amongst the top 100 medications prescribed in Canada (Table 1).^{1,3,4}

*For a full list of QT-interval prolonging drugs see www.crediblemeds.org/



Table 1: Examples of Top 100 Prescribed Drugs Associated with Risk of TdP^{3,4}

Known TdP risk: Drugs that prolong the QT interval and are clearly associated with a known risk of TdP even when taken as recommended.		
<ul style="list-style-type: none"> • Azithromycin • Ciprofloxacin • Citalopram 	<ul style="list-style-type: none"> • Clarithromycin • Domperidone 	<ul style="list-style-type: none"> • Donepezil • Escitalopram
Possible TdP risk: Drugs that can cause QT prolongation but currently lack evidence for a risk of TdP when taken as recommended.		
<ul style="list-style-type: none"> • Venlafaxine • Risperidone 		
Conditional TdP risk: Drugs that are associated with TdP but only under certain circumstances of their use or by creating conditions that facilitate or induce TdP.		
<ul style="list-style-type: none"> • Trazodone • Sertraline • Amitriptyline 	<ul style="list-style-type: none"> • Paroxetine • Pantoprazole 	<ul style="list-style-type: none"> • Hydrochlorothiazide • Furosemide



The objective of this multi-incident analysis is to examine medication incidents involving QT prolongation interactions that are commonly encountered within the community setting. Common themes and potential contributing factors are identified and are presented along with suggested safety recommendations (Tables 2, 3, 4).

METHODS

A qualitative, multi-incident analysis was conducted using anonymous reports submitted to the Institute for Safe Medication Practices Canada (ISMP Canada) Community Pharmacy Incident Reporting (CPhIR) Program.⁵ Medication incidents reported with keywords “QT”, “TdP”, “Torsades de pointes”, “Prolong*”, and “QT-int*” were extracted from the CPhIR Program from April 2010 to June 2016. Ultimately, 92

incidents met the inclusion criteria and were included in this multi-incident analysis. At least two ISMP Canada analysts independently reviewed and analyzed the medication incidents.

LIMITATIONS

The results available for this analysis may be limited due to the voluntary reporting nature of the CPhIR Program. The quality of data available may be influenced by reporter bias and the paucity of most reported incident descriptions. Some assumptions had to be made based on the analyst’s knowledge and experience of community pharmacy practice. The “Incident Examples” provided in Tables 2, 3, and 4 were limited by what was inputted by pharmacy practitioners to the “Incident Description” field of the CPhIR program.

RESULTS

Table 2: Theme 1 - Prescriber Triggered Potential for QT Prolongation

Incident Examples	Commentary
<p>A patient was prescribed both ciprofloxacin and clarithromycin for a lung infection. The combination of these drugs increases the risk of QT prolongation. The physician was notified and decided to only use clarithromycin. The physician was not aware this combo could potentially have a negative effect.</p> <p>A patient was given a prescription for ciprofloxacin in the event a UTI develops. The patient has a history of tachycardia and MI and is currently on Sotalol and Elavil®. The pharmacy recognized the potential for QT prolongation given all the risk factors and drug interactions and [patient] was advised to return to prescriber for a different antibiotic.</p> <p>A patient was prescribed octreotide acetate omega and domperidone. These two medications have a drug interaction of increasing QT prolongation risk. The prescriber was notified and they decided to cancel the domperidone. The prescriber indicated they only ordered it based on a recommendation from the gastroenterologist.</p>	<p>The list of QT prolonging agents is vast and is frequently updated as new evidence arises. Prescribers may not be familiar with every single agent.</p> <p>Despite the wide implementation of electronic medical records (EMR) software in ambulatory care, a majority of prescribers do not fully utilize the advanced functions provided (e.g. review electronic alerts such as drug dose and interactions).⁶</p> <p>Episodic care (e.g. walk-in clinics) and transitions of care (e.g. specialists) may leave gaps of information transfer regarding patient's medical history and medication history thus leading to potential risk of prescribing errors.</p>

Table 3: Theme 2 - Potentially Inappropriate Pharmacist Interventions

Incident Examples	Commentary
<p>A patient on quetiapine was prescribed Zithromax®. Pharmacy contacted prescriber to change it to amoxicillin due to QT prolongation.</p> <p>A patient on citalopram was prescribed rabeprazole. Pharmacy noted they interact to increase QT interval. The prescriber was contacted and had rabeprazole changed to omeprazole.</p> <p>Pharmacist noticed a patient was on omeprazole 20 mg and citalopram 60 mg. The combination of PPI & high dose citalopram may increase QT prolongation risk. The prescriber was contacted and agreed to decrease the citalopram dose.</p>	<p>Although pharmacies have interaction checkers, the responsibility for evaluating the clinical significance of a detected interaction and making the most appropriate intervention when necessary is on the onus of pharmacists.</p> <p>Many pharmacists may rely heavily on technology for their clinical decision support capabilities. The interventions made may lack clinical significance due to the absence of a comprehensive patient assessment. (Note: Majority of the reporters had not indicated any apparent patient assessment prior to making an intervention. In reality, assessment may or may not have occurred.)</p> <p>Potential consequences of acting on interaction alerts without proper patient assessment may include: delayed treatments, switches to suboptimal therapies, and a waste of time and resources.</p>

Table 4: Theme 3 - Patient Potentiated Risk for Harm

Incident Example	Commentary
<p>A patient had their prescription faxed to the pharmacy. The prescription was for an antibiotic to treat a UTI. Upon checking with their regular pharmacy for a medication list, it was found this antibiotic has a QT prolongation interaction with the patient's regular medications. The prescriber was contacted and the antibiotic was changed.</p>	<p>When patients are consulting or seeking care from multiple prescribers (e.g. from the use of walk-in clinics or specialists clinics), they may fail to fully communicate all pertinent medical and medication information needed for the clinician to safely prescribe.</p> <p>Attending multiple pharmacies may potentiate harm by limiting pharmacists' access to a complete medication history of the patient.</p>

SAFETY RECOMMENDATIONS

FOR PRESCRIBERS

Ensure that computerized physician order entry systems have programming or the functionality to detect drug-drug and drug-disease interactions and are updated regularly.⁷

Use of a computer clinical decision support system (CDSS) incorporating identification of QT prolonging interactions will influence the prescribing of drugs with QT liability and reduce the risk of QT prolongation. The alerts will also act as a reminder to physicians to identify patients with TdP risk factors. Keep in mind that although some prescribers may already be using this software, ongoing evaluation of the alert frequency is essential to reduce alert fatigue.⁸

Ensure a patient's complete medication record is obtained.

As shown in the multi-incident analysis, most incidents involved interactions with short-term agents (e.g. antibiotics) which were commonly prescribed in episodic care such as walk-in clinics and urgent care centres. It is pertinent for the prescriber to be aware of the patient's current medical and medication information in order to prescribe safely. Additionally, all encounters should be documented and communicated to the patient's primary care physician if possible.

FOR PHARMACISTS

Evaluate and update alerts in the clinical decision support system (CDSS).⁸

Use a reliable resource, such as Credible Meds (www.crediblemeds.org), to review the alerts that appear when an interaction is detected with

a drug associated with QT prolongation. Regularly review and try to reduce the frequency of warnings that are not clinically significant. Be aware that filtering drug interactions may prevent alert fatigue, but may also limit the CDSS's ability to detect interactions if its settings are overly restrictive.⁸ If modifications are made, inform all pharmacy staff of the alerts that have been added or removed.

Avoid over-reliance on technology.⁸

Do not base all clinical decisions solely on system alerts or notifications. Clinical decision support systems (CDSSs) are designed, as their name suggests, to provide support and should always be used in conjunction with the pharmacist's clinical assessment and professional judgement.

Over-reliance may lead to automation biases.⁹ An absence of an alert does not mean there is absolutely no concerns or issues with the prescription or medication order; this could be affected depending on the system alert settings and how up-to-date the CDSS may be. On the contrary, a generated alert does not always imply clinical significance.

Educate patients and caregivers. Monitor and provide regular follow-ups.⁸

Ensure that patients are informed of the clinical symptoms of QT prolongation that should prompt them to seek immediate medical attention (e.g. palpitations, syncope, light-headedness, or dizziness).

Recommend patients to carry an updated medication list when interacting with healthcare professionals. Patients should also be educated to communicate their comorbid conditions or any changes of their existing medical conditions

to clinicians of their circle of care.

Pharmacists can also play an integral part by routinely following up with patients and monitor their medication therapy management.

Perform a risk assessment and ensure a standardized communication system is in place to notify prescribers of recommendations and interventions with respect to patient care.⁷

Upon realization of a potential QT interval prolongation, perform a risk assessment (Appendix 1) to determine its clinical significance. To properly complete an assessment, an updated medication list and medical history should be obtained from the patient if not readily available. Interventions may or may not be required depending on the overall risk assessment.

A baseline ECG should be ordered prior to initiating therapy with a QT prolonging agent in an at-risk patient.^{10,11} Discuss with prescriber to request one, if necessary. This will aid in subsequent monitoring efforts for TdP.

FOR PATIENTS

Carry an up-to-date medication list to share with healthcare providers in the circle of care.

Ideally, patients should be aware of all the medications they are currently using so that an up-to-date medication list can be communicated to all healthcare providers in their circle of care. Realistically, carrying an accurate list of current medications that can be shared with healthcare providers would be the next best option. Consider the use of ISMP Canada's MyMedRec app (<http://www.knowledgeisthebestmedicine.org/index.php/en/app/>) for smartphones that can act as a portable health and medication record.¹²

CONCLUSIONS

This multi-incident analysis has identified common areas where QT prolongation incidents may occur in community pharmacy practice. Vulnerabilities are recognized in different stages of the medication-use process. Prescribers, pharmacists, and patients can collaborate to prevent these medication incidents from happening in the future.

SUGGESTED RESOURCES ON QT PROLONGATION


CredibleMeds – www.crediblemeds.org

Development and Validation of a Risk Score to Predict QT Interval Prolongation in Hospitalized Patients – <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3788679/pdf/nihms490533.pdf>

With the support of the Canadian Society of Hospital Pharmacists (CSHP) Foundation 2015 Education Grant, ISMP Canada is currently developing ToolQit, an evidence-based communication and decision-guiding

tool for pharmacists to evaluate the complexities of QT prolongation. We are currently seeking pharmacists to help test and evaluate our prototype. If you are interested, please email ISMP Canada at qt@ismp-canada.org. For further information regarding ToolQit, please refer to https://www.ismp-canada.org/ToolQit_QTprolongation/.

ACKNOWLEDGEMENTS

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

REFERENCES

1. Tisdale JE. Drug-induced QT interval prolongation and torsades de pointes: Role of the pharmacist in risk assessment, prevention and management. *Can Pharm J* 2016 May; 149(3):139–52.
2. Schwartz PJ, Woosley RL. Predicting the unpredictable: Drug-induced QT prolongation and torsades de pointes. *J Am Coll Cardiol* 2016 Apr; 67(13):1639–50.
3. Paquette A. Special Report: Top Drugs of 2015. *Pharmacy Practice Plus* 2016 [cited 2016 Jul 15]. Available from: <http://www.canadianhealthcarenetwork.ca/pharmacists/magazines/pharmacy-practice-plus/julyaugust-2016/special-report-top-drugs-of-2015-36905>
4. CredibleMeds. Risk categories for drugs that prolong QT & induce torsades de pointes (TdP) Arizona: Azcert; 2016 [cited 2016 Jun 14]. Available from: <https://crediblemeds.org/new-drug-list/>
5. Ho C, Hung P, Lee G, Kadija M. Community pharmacy incident reporting: A new tool for communicating pharmacies in Canada. *Healthcare Quarterly* 2010; 13: 16–24.
6. PwC. The emerging benefits of EMR use in ambulatory care in Canada: Benefits evaluation study. *Canada Health Infoway* 2016 [cited 2016 Jun 16]. Available from: <https://www.infoway-inforoute.ca/en/component/edocman/3025-the-emerging-benefits-of-emr-use-in-ambulatory-care-in-canada-full-report/view-document?Itemid=101>
7. ISMP Canada. Preventable death highlights the need for improved management of known drug interactions. *ISMP Canada Safety Bulletin* 2014; 14(5):1–7.
8. ISMP. The absence of a drug-disease interaction alert leads to a child's death. *Acute Care ISMP Medication Safety Alert* 2015; May 21. Available from: <https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=109>
9. Goddard K, Roudsari A, Wyatt JC. Automation bias: A systematic review of frequency, effect mediators, and mitigators. *J Am Med Inform Assoc* 2012 Jan-Feb; 19(1): 121–127.
10. Berul CI, Seslar SP, Zimetbaum PJ, Josephson ME. Acquired long QT syndrome. *UpToDate* 2016 [updated 2015 May 5; cited 2016 Jun 14]. Available from: <http://www.uptodate.com/contents/acquired-long-qt-syndrome>
11. Downey S, Jensen B, Regier L. QT prolongation and torsades de pointes: Drugs and sudden death. *RxFiles* 2015 Dec. Available from: <http://www.rxfiles.ca/rxfiles/>
12. Knowledge is the best medicine. *ISMP Canada* 2016 [cited 2016 Jun 17]. Available from: <http://www.knowledgeisthebestmedicine.org/index.php/en/app>

APPENDIX 1: QT-PROLONGATION RISK FACTORS CHECK-LIST^{1,2,3,4,5}

The following list is based on evidence from literature, which indicates that about 90% of drug interaction-induced TdP occurred in patients with at least one other risk factor, and 74% of cases have two or more risk factors.¹ Modifiable risk-factors should be reversed prior to administration if the drug-interaction cannot be avoided.¹



DISCLAIMER: The following check-list is intended to facilitate the practitioner's assessment, and is not intended as substitution for the practitioner's professional judgement. Pharmacist is highly encouraged to communicate his/her assessment with the prescriber, even if he/she does not believe an intervention is necessary, to facilitate continuity of care.

Patient-related	Drug-related
<input type="checkbox"/> Female sex <input type="checkbox"/> > 60 year old <input type="checkbox"/> Structural heart disease – eg. HF, LVH <input type="checkbox"/> Renal impairment (drug clearance) <input type="checkbox"/> Hepatic impairment (drug metabolism) <input type="checkbox"/> Borderline or prolonged baseline QTc interval (>450ms) <input type="checkbox"/> Bradycardia (HR < 60 bpm) <input type="checkbox"/> Genetic susceptibility (mutations in the KCNH2, KCNQ1, KCNE2 gene) <input type="checkbox"/> Hypokalemia (< 3.5 mmol/L) <input type="checkbox"/> *Low-normal baseline potassium (3.5–4 mmol/L) <input type="checkbox"/> Hypomagnesemia (< 0.7 mmol/L)	<input type="checkbox"/> Already on ≥ 2 QTc-liability drugs <input type="checkbox"/> Antiarrhythmic: <input type="checkbox"/> Antidepressant: <input type="checkbox"/> Antipsychotic: <input type="checkbox"/> Other: _____ <input type="checkbox"/> On a Class I or **III antiarrhythmic: *** Relative risk amongst §macrolides: Clarithromycin ≈ Erythromycin > Azithromycin *** Relative risk amongst ¥fluoroquinolones: Moxifloxacin ≥ Levofloxacin > Ciprofloxacin *** Relative risk amongst antidepressants: TCA > SSRI (Citalopram > Escitalopram ≥ sertraline ≈ fluoxetine ≈ fluvoxamine ≈ paroxetine)
<p>* Investigate for drug-causes (eg. loop and thiazide diuretics); may also present in patients with eating disorders, predisposing them to electrolyte disturbances</p> <p>** Highly potent IKr channel blockers which exhibit concentration-independent QTc-prolongation</p> <p>*** Based on retrospective studies and reports, in conjunction with pharmacodynamic and pharmacokinetic characteristics of the drug. Note: With the exception of Class III antiarrhythmics, drug-induced QTc-prolongation is a dose-dependent phenomenon.</p> <p>§ Dual-risk mechanism: intrinsic IKr channel blockers and potent inhibitors of CYP3A4 (with exception of azithromycin) which is involved in metabolism of many QTc-prolonging agents</p> <p>¥ Not predominantly metabolized by CYP450</p>	

©2016 Institute for Safe Medication Practices Canada.

REFERENCES

1. Abo-Salem E, Fowler JC, et al. Antibiotic-induced Cardiac Arrhythmias. Cardiovascular Therapeutics 2014;32:19–25.
2. Beach SR, Kostis WJ, et al. Meta-analysis of selective serotonin reuptake inhibitor-associated QTc prolongation. Journal of Clinical Psychiatry 2014;75(5):441–9.
3. Funk KA and Bostwick JR. A Comparison of the Risk of QT Prolongation Among SSRIs. Annals of Pharmacotherapy 2013;47(10):1330–1341.
4. Gupta A, Lawrence AT, et al. Current concepts in the mechanisms and management of drug-induced QT prolongation and torsade de pointes. American Heart Journal 2007;153:891–9.
5. Owens RC and Nolin TD. Antimicrobial-Associated QT Interval Prolongation: Pointes of Interest. Clinical Infectious Diseases 2006;43:1603–11.

THE PHARMACIST'S ROLE AND RESPONSIBILITIES DURING TRANSITIONS OF CARE

Report from the Coroner



CASE SUMMARY

A 54-year old man being treated for a diabetic foot infection died due to an intracerebral hemorrhage secondary to thrombocytopenia complicating vancomycin therapy. The patient was initially treated in Hospital A and after discharge was treated as an outpatient for approximately four days. Upon readmission to Hospital A the patient's condition deteriorated and he was transferred to Hospital B where he subsequently died.

CASE HISTORY

The patient had a history of type II diabetes mellitus x 20 years, hypertension, hypothyroidism, erectile dysfunction and recent cataract surgery. It was also noted that he was allergic, from childhood, to penicillin (described as causing a rash). The patient was urgently admitted from the Skin and Soft Tissue Clinic at Hospital A. The Infectious Disease Service was consulted and recommended ciprofloxacin and clindamycin prior to admission.

COURSE OF TREATMENT

On admission the patient was prescribed vancomycin, ciprofloxacin and metronidazole (all IV) based on the results of cultures and sensitivities from the day of admission.

While in hospital, the patient received IV ciprofloxacin and metronidazole. In addition he received vancomycin 1g IV q12h (serum creatinine = 117 $\mu\text{mol/L}$) on day 1 and 2. This dose was increased over the next few days based on trough vancomycin and serum creatinine levels (see summary dosing chart). On day 7 the dose was reduced to 1.25g IV q8h and continued until discharged from hospital on day 9. On the

day of discharge a level drawn before administering the third dose of 1.25g, was 20 mg/L (serum creatinine = 85).

PATIENT DISCHARGE

The patient was discharged on the following medications: vancomycin 1.25 g IV q8h x 10 days, ciprofloxacin 750mg po bid x 10 days, metronidazole 500mg po bid x 10 days and Fluconazole 100mg po bid x 30 days. Home medications to be continued on discharge included: hydromorphone 2-4mg po q4-6h prn, novomix 30 new dose, levothyroxine 0.75mg po daily, metformin 500mg po daily, ramipril/hydrochlorothiazide

5/12.5mg po daily, rosuvastatin 20 po daily, testosterone 80mg po bid.

Home care was arranged for the patient through the local Community Care Access Centre (CCAC).

On his first day home following discharge, the patient indicated to the CCAC care provider that he was feeling unwell and was no longer able to walk with his cane and now needed a walker. Two days after discharge he contacted the care provider about swelling of his feet and asked about water pills. Four days after discharge he developed a rash and returned to the ER at Hospital A where he was re-admitted.

Summary Dosing Chart (Vancomycin dosing, trough levels and serum creatinine)			
Day	Vancomycin dose	Vancomycin level (mg/L)	Serum Creatinine ($\mu\text{mol/L}$)
Day 1	1g IV q12h		117
Day 2	1g IV q12h	7.0	97
Day 3	1.25g IV q8h		
Day 4	1.25g IV q8h	12.6	97
Day 5	1.5g IV q8h		
Day 6	1.5g IV q8h		
Day 7	1.25g IV q8h	19.4	103
Day 8	1.25g IV q8h		
Day 9 - Discharged from Hospital A	1.25g IV q8h	20 (early- pre 3rd dose)	85
Day 10	1.25g IV q8h		
Day 11	1.25g IV q8h		
Day 12	1.25g IV q8h		
Day 13 - Re-admitted to Hospital A	1.25g IV q8h	77 (random)	551
Day 14	discontinued		537
Day 15	discontinued		0315 = 553 0905 = 580
Day 16 - transferred to Hospital B			

PATIENT RE-ADMISSION

Upon re-admission the patient was suffering from acute renal failure and thrombocytopenia. His serum creatinine was 551 µmol/L and vancomycin level was 77 mg/L. Over the next 3 days in hospital his condition continued to worsen and he had increased epistaxis and hypertension. On the fourth day, he was found unresponsive in his hospital bed. A CT scan of his head showed extensive left-sided subarachnoid hemorrhage with midline shift and cerebral edema. He was transferred to the intensive care unit (ICU) at Hospital A and later that day transferred to Hospital B, where he was assessed by neurosurgery. At this time it was determined that he was not a surgical candidate. He was put on life support and treated with a platelet transfusion, IV steroids and started on dialysis. The day after admission to Hospital B his neurological condition continued to deteriorate and life support was withdrawn. He died later that evening.

LESSONS LEARNED

This is a complex case involving issues related to transitions of care from hospital to home. The patient suffered adverse complications from extremely high levels of vancomycin and elevated serum creatinine due to inappropriate management of vancomycin therapy. This case highlights the importance of coordinated care transitions that must include a detailed patient care plan at discharge, such as assigning responsibility for patient monitoring and follow-up in the community. Key contributing factors identified in this incident include:

- the absence of a medication review prior to discharge to determine if a less complicated treatment plan was possible;
- lack of clarity with respect to detailed follow-up requirements including the roles and responsibility of post-discharge care providers for laboratory monitoring (serum creatinine) and drug levels (vancomycin levels); and
- the need to ensure community care practitioners have the contact information needed to reach the discharging physician, hospital pharmacist, etc. should questions arise.

THE PHARMACIST'S ROLE AND RESPONSIBILITIES DURING TRANSITIONS OF CARE

Transitions of care, or "care transitions" refers to the transfer of patients between healthcare practitioners and settings as their condition and care needs change

during the course of a chronic or acute illness¹. This may include moving between areas within a hospital (i.e. between patient care units, from an inpatient unit to the ICU, from surgery to the patient care unit), moving to another institution (i.e. from hospital to a rehab centre, nursing home or continuing care centre), or returning home and receiving community care (e.g. home care from a visiting healthcare professional, monitoring by the family physician or community pharmacist).

At a time when more acutely ill and complex patients are being discharged for monitoring in the community setting, coordinated care transitions are critical to ensure optimal care and to prevent avoidable errors and readmissions. Evidence demonstrates that when patients move between care settings (within and between institutions, and from hospital to home) they are at high risk of adverse drug events (ADEs), particularly when communication and care coordination are suboptimal.²



*Canadian acute care studies have shown that **40% of patients** at discharge transitions of care experience unintentional medication discrepancies or potential errors.³*

The case presented here emphasizes the responsibility of the pharmacist, as part of the interdisciplinary healthcare team, in preventing adverse events during hospital discharge.

Hospital pharmacists are in a unique position to review and assess a patient's medication regimen prior to discharge, particularly when a patient is to be discharged on a medication that requires ongoing monitoring and follow-up for dosage adjustments. Reviewing the indication and appropriateness of new medications initiated in hospital on discharge creates further opportunities to collaborate with the most responsible physician (MRP) to determine if more suitable alternative treatments are required.

The College's [Code of Ethics](#) (the Code) outlines the ethical principles and standards which guide the practice of pharmacists and pharmacy technicians and outlines the responsibilities that pharmacy professionals have to both protect patients from harm (non-maleficence)

and actively benefit patients (beneficence). In practical terms this means taking steps to ensure that the patient's medication at discharge is the most appropriate to maximize benefit while minimizing harm. In this case if a discharge medication review, and discussion with the MRP (and/or the infectious disease service) about appropriate alternatives, had occurred, it could have resulted in an adjustment to a less complicated medication regimen.

Pharmacists can also assist with care transitions by providing a complete list of medications to the patient and the pharmacy where the patient will be receiving their prescriptions, whether it is a community pharmacy or another pharmacy service provider. In some cases patients will require further monitoring such as bloodwork and/or drug levels once they go home. Providing relevant patient information to other healthcare providers or facilities when involved with a patient's transition of care – to ensure that the transition is safe and effective – is critical and therefore included as a standard within the Code.

The hospital pharmacist in this case could have ensured that appropriate monitoring in the community would occur by collaborating with the patient's community pharmacy. By contacting the community pharmacy directly, both the pharmacist in the community and the hospital pharmacist can ensure there is a clear understanding of monitoring requirements and the plan for follow-up. The pharmacist providing the medications in the community also had a responsibility to reconcile discharge medications with medications on the patient record and confirm that necessary drug monitoring and follow-up was in place. Inter-professional collaboration creates an opportunity for both hospital and community pharmacists to clarify information to ensure they are confident that individual roles and responsibilities are clear.

Upon discharge from the hospital, patients receive a lot of information in a short period of time, usually on the day they are going home. It can be confusing and sometimes even overwhelming. During a hospital stay new medications can

be started, including those that will only be continued for a limited period of time after discharge, and medications used prior to admission can be stopped or undergo dosage adjustments. When both the community and hospital pharmacist review the discharge medications with the patient, it acts to clarify and reinforce the information provided and ensure the patient understands his or her new medication regimen.

With more patients going home from the hospital on complicated medication regimens, some requiring monitoring and dose adjustments, the need for all pharmacists involved in the patient's transition to recognize their professional responsibilities is crucial to support positive patient outcomes. Practitioners need to be diligent in identifying and responding to red flag situations that present in practice and ensure that when an issue is identified collaboration and communication are used to resolve the problem and optimize patient care. **Pc**

SUPPORT RESOURCES FOR TRANSITIONS OF CARE

There are many tools and programs available to pharmacists that support safe processes around transitions of care including:

- Ontario's MedsCheck Follow-up Program⁴ recognizes the pharmacist's role in helping patients manage their medications after being discharged from hospital.
- The Pharmaceutical Opinion supports the pharmacist's role in documenting and making recommendations in consultation with the prescriber when a drug therapy problem has been identified.
- ISMP's checklist [Hospital to Home – Facilitating Medication Safety at Transitions](#) designed to increase patient safety by decreasing medication errors and incidents that can occur when a patient goes home from the hospital⁵.

REFERENCES:

1. www.caretransitions.org accessed Aug 14, 2016
2. American College of Clinical Pharmacy. ACCP White Papers; Improving Care Transitions: Current Practice and Future Opportunities for Pharmacist. Pharmacotherapy 2012;32(11):e335.
3. Optimizing Medication Safety at Care Transitions – Creating a National Challenge. National Invitational Summit. ISMP Feb 10 2011, Toronto.
4. Ministry of Health and Long-Term Care. Professional Pharmacy Services Guidebook 3.0. July 2016 p.32, 65.
5. <https://www.ismp-canada.org/transitions/> accessed August 12, 2016. Hospital to Home – A Medication Safety Checklist for Transitions (free download)

COLLABORATION, GROWTH AND INSPIRATION: ONE STUDENT'S EXPERIENCE WORKING AT OCP

Each year the College participates in a co-op rotation with either a University of Toronto or a University of Waterloo student. This past summer, the College welcomed Sara Tawadrous, a third year student at the University of Toronto. Sara worked with the College from May until August. Before her return to school, Sara sat down with Pharmacy Connection to reflect on her experience.

Pharmacy Connection: What interested you about coming to work for the College?

Sara: I was first introduced to the possibility of doing an internship at the Ontario College of Pharmacists (OCP) at the end of my second year of the Doctor of Pharmacy program at the University of Toronto. Since high school, and throughout my undergraduate career, I have enrolled in courses and activities that engaged me in the art of political science. I am genuinely interested in legislation and its implications in the political landscape. Moreover, I was thrilled at the thought of engaging in the initiatives at the College and renewing my interests in government and the dialogue surrounding interactions with the law.

When I first walked into the College, I was driven with the goal of producing work that would assist and propel the initiatives of the College. What I quickly learned, however, was that I would first need to immerse myself in the affairs of the College to understand and contribute through collaboration. The College has granted me an unbelievable amount of experience to witness the degree of complexity behind self-regulation.

PC: In what ways did you work with College staff and committees?

Sara: Being provided with the opportunity to work alongside six different College departments was a unique and valuable experience for me. I learned how to negotiate potential avenues for collaboration between the departments, while recognizing each department's unique yet complementary role. For example while working on a project examining the implementation of background checks, I worked with the Investigations and Resolutions department for statistical data to support the report. The collaborative power of individual departments was exemplified in their service towards protecting the public.

Sitting in on an Inquiry, Complaints and Reports Committee (ICRC) meeting allowed me to actively contribute to the deliberation of allegations with the understanding that the preservation of justice was the ultimate impetus. The Investigations and Resolutions department involved me in very timely and exciting projects. I was provided with the opportunity to draft a guidance document for the retention of expert witnesses. The purpose of the guide is to assist the

ICRC panel in their disposition of a case and deliberation as to when to obtain an expert witness. In addition, I drafted a report summarizing the current investigative procedures surrounding allegations of sexual abuse, which served as a resource to direct future investigations towards "best practice". Sitting in on a discipline hearing allowed me to recognize that the primary purpose of disciplinary proceedings is not to reprimand, nor is it to punish, it is the upholding of the profession's high standards through deterrence, while appreciating that self-regulation is a privilege not a right.

PC: Can you describe one of the unique experiences you were given?

Sara: I was given the opportunity to participate in the College's new practice assessments under the mentorship of a practice advisor in order to develop a feedback survey that aims to evaluate changes in pharmacy practice. It was an enriching and inspiring experience – the pharmacy personnel were keenly motivated to meet the standards of practice as they took notes and asked for guidance and feedback. One of the goals of these assessments is to bring about progressive practice changes through coaching, focusing less on

inspections, and ultimately moving the profession towards positive growth and empowering members to practice to their full scope.

PC: What aspects of your work did you find most interesting?

Sara: I was interested in learning how decisions at the College are made: what considerations are used to deliver change and what factors influence the direction of change. While sitting in on the Quality Assurance committee, I took part in discussions on the legitimacy of the Single versus Two-part Register and how competence ought to be assessed to ensure that public safety, long after the pharmacist has met the registration requirements, is continuously protected. This illustrated that there is a tremendous amount of work and dialogue done prior to the delivery of legislative changes.

Additionally, working alongside the Registration Committee allowed me to learn about the process required to bring about fair procedures in light of requirements for licensure and the accurate details that must be considered prior to drafting a policy regarding language proficiency. The current project evaluated what steps could be implemented in the consideration of language proficiency outside of standardized tests. Prior to introducing new measures for practice, there is a substantial breadth of multidirectional research that has to be collected to support the establishment of guidance documents, which will govern high stakes decision-making.

PC: Are there things that you learned that you will apply as a student or practitioner?


Sara: The Policy and Communications department offered me

the opportunity to participate in the creation of articles for Pharmacy Connection. I engaged in conversation on what information is relevant to members and what resources are of most aid, in light of the current platform, audience and context. Language used to communicate ideas is critical for application, and it was worthwhile for me to reflect upon this as a professional student and future practitioner.

PC: Overall, what did you learn from your experience at the College?

Sara: I was able to understand the responsibility that the College undertakes to uphold its mandate to serve and protect the public interest. Changes all over the country, from real estate boards to medicine, can have a ripple effect on self-regulating bodies such as the College. The College must promptly and effectively respond to such triggers, while maintaining its fundamental duty to the public.

PC: How do you think this experience will influence your professional growth?

Sara: I owe so much to the experience I've gained while working with the College. It has provided me with the ability to see what can be accomplished and how it can be accomplished. My experience has inspired me to pursue further studies after obtaining my Doctor of Pharmacy degree, in order to be able to contribute towards positive change in the profession's regulations and policies. I look forward to sharing my experience and learning with my peers in order to lead and empower them to also be passionate about the profession's growth. 



Sterile Compounding Standards:

WHAT WE HEARD DURING CONSULTATION

As reported in the September 2016 Council Report (page 5), following consideration of the feedback received through public consultation, Council adopted the *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* (NAPRA, 2016) and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* (NAPRA, 2016) with an implementation deadline of January 2019.

The consultation, which focused specifically on a proposed implementation timeline of two years (September 2018), was posted on the website for 45 days and closed on June 30, 2016. Over [50 comments](#) were received from individual pharmacists, pharmacy technicians and organizations. As anticipated the comments reflected the various challenges that would be faced by pharmacies and hospitals in order to appropriately conduct a gap-analysis against the new standards, and create and implement an action plan to be compliant with the standards, within the proposed timeline. Below is a summary of the key comments received.

SUMMARY OF KEY COMMENTS HEARD DURING PUBLIC CONSULTATION

1. The hospital budgetary cycle does not align to this timeline

Two years is not enough time for hospitals to implement these

changes and become compliant with the NAPRA standards. Many hospitals will require significant renovations involving capital investment, bid tenders and approval at multiple levels. They must secure funding for capital and operating costs, complete RFP processes, undertake physical renovations, and then recruit staff to develop, implement and maintain the standards, a process even more challenging for small and rural hospitals.

2. NAPRA guidelines and USP requirements are different

Although the College does not directly reference USP<800>, the basis of the document entitled *Pharmacy Compounding of Hazardous Sterile Preparations* has identical requirements to USP <800>. USP <797> and USP <800> are different requirements with different associated cost implications to the pharmacy. It is not acceptable for the College to adopt both requirements at the same time.

3. Two years is a sufficient period to implement the changes

Pharmacies that cannot comply with the implementation should not perform sterile compounding. For the safety of patients, changes must be implemented. It has always been expected that a pharmacist undertaking to make non-hazardous preparations does

so in compliance with existing standards/guidelines for sterile preparations.

4. Balance will be required

The preparation of medications (pharmacy compounding) has always been an integral part of the practice of pharmacy, and current pharmacy practice for the preparation of sterile products in Canada already incorporates many of the patient safety and quality assurance requirements of these new standards. While many standards may be implemented within this time frame, there are individual standards that will require thoughtful consideration of the financial impact and physical constraints on a facility in order to balance safety with access to care closer to home. The time period to implementation permits pharmacy professionals the opportunity to examine practice, conduct a gap analysis against standards, create an action plan, and implement the standards.

NEXT STEPS

Community and hospital practice advisers will work together to align expectations of compounding practice sites and their approach to implementation, as well as work with individual pharmacies on the development of their action plans. The College will also collaborate with other pharmacy regulators in meeting these standards nationally.

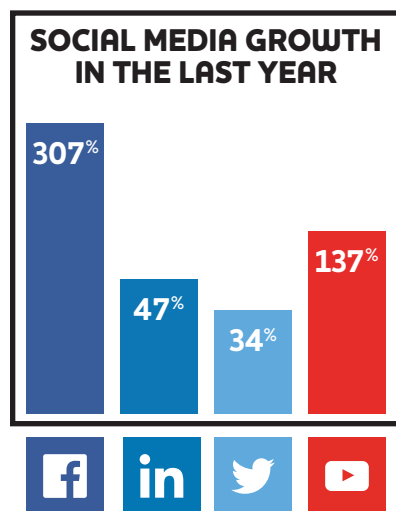
PC



CONNECT WITH US ON SOCIAL MEDIA

AND BE AMONG THE FIRST TO KNOW

Are you on social media? If so, connect with us on Facebook, LinkedIn, and Twitter to get the latest news and updates relating to your profession, helpful practice resources, and much more!



The College launched its official Facebook and LinkedIn pages in 2015 and its Twitter and YouTube accounts in 2009. Over the last year, many pharmacists and pharmacy technicians have connected with us on these channels to benefit from the content we publish.

Some of our most popular social media posts, as measured by link clicks and engagement, include:

- information about Ontario's new Patch 4 Patch program;
- a notice from Health Canada informing practitioners that pre-authorization is no longer required for the destruction of narcotics and controlled drugs;

- tips to minimize the loss of controlled substances within pharmacies;
- a video on how to integrate pharmacy technicians into community practice; and
- advice about using the narcotics monitoring system.

On Twitter, we're proud of the fact that OCP has surpassed all of the other health regulatory bodies in Canada in terms of follower count. The College is also on its way to surpassing other health regulatory bodies on Facebook, LinkedIn and YouTube. This demonstrates that members are engaged and interested in ensuring their patients continue to enjoy a high standard of care. **PC**

Tip:

Once you "Like" our Facebook page, simply hover your mouse over the "Liked" button at the bottom right of our cover photo and select "See First." This will ensure we'll continue to stay connected and you'll get all of the important news and updates we share on Facebook (Facebook doesn't automatically show you all of our updates unless you do this).

Connect With Us
on Social Media





“Close-Up on Complaints” presents errors that occur when providing patient care so that practitioners can use them as learning opportunities. Ideally, pharmacists and pharmacy technicians will be able to identify areas of potential concern within their own practice, and plan and implement measures to help avoid similar incidents from occurring in the future.

PHARMACY TECHNICIANS – PROFESSIONAL RESPONSIBILITIES AND STANDARDS OF PRACTICE

SUMMARY OF THE INCIDENTS

This Close Up on Complaints will outline two incidents related to a pharmacy technician’s professional responsibilities and Standards of Practice.

These incidents were similar in nature with the patients’ compliance aids being dispensed with an incorrect medication, incorrect dosing frequency of a medication, or a missing medication. In both cases, the pharmacy technician was responsible for completing and signing off on the technical check of the compliance aid and ensuring that the medications were not released to the patient prior to the pharmacist completing a therapeutic check.

In the first incident, a patient had been prescribed a pain medication that was not included in the compliance aid batch after the first month’s fill. The patient’s stool softener was also dispensed with the wrong dosing frequency. The patient discovered the error during a trip to the emergency department after feeling extremely sick. The patient then had to return

to her physician for a follow up assessment prior to restarting her pain medication.

In the second incident, the patient was dispensed another patient’s compliance aid and, prior to being alerted to the mistake by the pharmacy, she ingested medications not prescribed for her including diuretics, antidepressants and warfarin. The patient required follow-up with her family physician to monitor for adverse outcomes due to the mistake.

WHY DID THIS HAPPEN?

The incidents described above occurred because each of the pharmacy technicians were not clear regarding their professional responsibilities related to their scope of practice and did not meet the Standards of Practice

for dispensing medications, collaboration, safety and quality, and professionalism.

For all prescriptions they process, the pharmacy technician is required to reconcile that the technical aspects of a prescription match the medication dispensed to the patient, communicate any problems out of their scope or beyond their personal competence to the pharmacist, appropriately document on the patient record, and confirm that the pharmacist has completed a therapeutic review prior to releasing the medication to the patient.

COMPLAINT OUTCOME

The College’s Inquiries, Complaints & Reports Committee (ICRC) oversees investigations of each complaint the College receives. The Committee considers a practitioner’s conduct,

Have a Complaint?

Anyone who is not satisfied with the care of services provided by a pharmacy, pharmacist, pharmacy technician, student or intern can file a formal complaint with the College. Complaints must be received in writing and include as much detail as possible. The College investigates all written complaints.



competence and capacity by assessing the facts of each case, reviewing submissions from both the complainant and the practitioner, and evaluating the available records and documents related to the case.

In both of these cases, the Committee found that the pharmacy technician was professionally responsible for the incident. The Committee noted that practitioners must be very aware of their scope of practice and these pharmacy technicians should have more closely followed the Standards of Practice, such as ensuring that the prescription was technically accurate and that the pharmacist completed a therapeutic check prior to releasing the medication to the patient.

The Committee issued advice and recommendations to assist the technicians in meeting their responsibilities and provided them with insights and opportunities to improve practice and mitigate the risk of similar occurrences in the future.

LEARNING FOR PRACTITIONERS

As regulated healthcare professionals, pharmacy technicians are accountable and responsible for the technical aspects of both new and refill prescriptions, such as the correct patient, medication, dosage form, route of administration, strength, physician etc. When a pharmacy technician assesses a prescription for technical accuracy, he or she is accountable, and liable, for the technical accurateness of the medication released to the patient. In such cases, the pharmacist would also be required and accountable to review the prescription but would only review for the therapeutic appropriateness of the prescribed medication for that specific patient.

For example, if a pharmacy technician, while filling a prescription, dispensed the wrong dose, this would be a technical error and the pharmacy technician would be accountable for it. If, however, the dose was filled accurately by the technician but the dose was therapeutically inappropriate for the patient, it should have been discovered during the therapeutic check, which is the pharmacist's responsibility.

Each completed prescription must contain the signature, or some other identifying mechanism, of both the technician (for the technical functions) and the pharmacist (for the therapeutic functions). Pharmacy technicians must be aware that the pharmacist can complete a therapeutic check at any time during the process and, where a pharmacy technician has completed a technical check, is not required to review the physical medication or prescription in order to appropriately conduct this check. Therefore, although




[Integrating Pharmacy Technicians into Community Practice](#) explores ways to integrate these highly trained professionals, working to their full scope of practice, into the workflow of a community pharmacy.

an independent double technical check is best practice, a pharmacy technician cannot rely on the pharmacist to catch technical errors after an initial technical check has been completed.

Prior to releasing a new or refill medication to a patient, it is the responsibility of the pharmacy technician to ensure that the prescription has been reviewed for therapeutic appropriateness by a pharmacist. This requires that pharmacy technicians collaborate and notify the pharmacist where issues arise using applicable policies and procedures and effective communication.

As a professional, a pharmacy technician must accept responsibility for their actions and decisions. Where an error or issue occurs, it is the responsibility of a pharmacy technician to respond to the safety risk by collaborating in documentation and review of the error in order to develop policies and procedures to minimize future events and promote patient safety.

Integrating a registered pharmacy technician into practice offers a viable solution to improve pharmacy workflow and patient care, particularly when maximizing the technician's scope. In order to do this, however, pharmacy professionals must clearly understand what a pharmacy technician can do under their own authority as a regulated healthcare professional and the expectations placed on pharmacy technicians in practice. 

ADVICE/RECOMMENDATION

Advice/recommendations allow an opportunity for practitioners to improve conduct or care.

Advice/Recommendation is issued as a remedial measure for matters which are not serious in nature and are considered to pose low risk of harm to the public.

DISCIPLINE DECISIONS



44

Member: Ashraf Bebawey (OCP #213897)

At a hearing on June 27, 2016, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Bebawey in that he:

- billed one or more third-parties for drugs that he did not actually dispense with respect to certain incidents relating to patient [Patient 1]
- created pharmacy records indicating the dispensing of drugs to patient [Patient 1] without actually dispensing the drugs with respect to certain incidents
- signed prescription hardcopies without verifying the drugs in question with respect to certain incidents relating to patient [Patient 1]
- billed one or more third-parties for drugs whose dispensing had not been authorized by a prescriber, with respect to certain incidents relating to patient [Patient 1]
- created pharmacy records indicating the dispensing of drugs to patient [Patient 1] without having authorization from a prescriber with respect to certain incidents
- signed a prescription hardcopy relating to prescriptions that were not authorized by a prescriber, with respect to certain incidents relating to patient [Patient 1]
- put “as needed” drugs on a weekly dispensing schedule for patient [Patient 1]
- signed reprinted hardcopies as though they were original hardcopies and/or sought to pass reprinted hardcopies off as original with respect to certain incidents
- dispensed weekly compliance packs to patients [Patient 1] and [Patient 2], and charged a dispensing fee on each such occasion, despite being aware that patients [Patient 1] and [Patient 2] picked up their medication monthly, not weekly, with respect to certain identified incidents

In particular, the Panel found that he

- falsified a record relating to his practice
- signed or issued, in his professional capacity, a document that he knew contained a false or misleading statement
- submitted an account or charge for services that he knew was false or misleading
- contravened the Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, section 155 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4
- contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular, section C.01.041 of the Food and Drug Regulations, C.R.C., c.870, as amended, under the Food and Drugs Act, R.S.C. 1985, c. F-27, as amended
- engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional

The Panel imposed an Order which included as follows:

1. A reprimand
2. Directing the Registrar to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:
 - a. that the Member complete successfully, at his own expense, within 18 months of the date of this Order, the Medication System Safety Review for a Community Pharmacist On-Site Assessment course offered by the Institute of Safe Medication Practices;
 - b. that the Member's practice shall be monitored by the College by means of inspection(s) by a representative or representatives of the College in such number and at such time or times as the College may determine, for a period of 18 months from the date of this order. The Member shall cooperate with the College during the inspections and, further, shall pay to the College in respect of the cost of monitoring, the amount of \$600.00 per inspection to a maximum of 2 inspections, such amount to be paid immediately after completion of each of the inspections.
 - c. that the Member shall be prohibited from acting as a Designated Manager in any pharmacy until the later of 12 months from the date of this Order and the date the College is notified that the

Member has successfully completed the course set out in paragraph 2(a) above;

3. Directing the Registrar to suspend the Member's Certificate of Registration for a period of 10 months, with 2 months of the suspension to be remitted on condition that the Member complete the remedial training as specified in subparagraph 2(a) above.

4. Costs to the College in the amount of \$5,000.

In its reprimand, the Panel noted that this was the Member's second appearance before a panel of the Discipline Committee, though on separate and unrelated allegations. The Panel pointed out that integrity, trust, and professional conduct are at the core of the practise of pharmacy, and that in return, pharmacists are held in high regard by the people of Ontario. The Panel observed that pharmacy is a self-regulated profession and a privilege, which carries obligations to the public, the profession, and oneself. The Panel noted that the Member took responsibility for his actions and admitted that his conduct was disgraceful, dishonourable, and unprofessional. The Panel agreed that the Member's conduct was unacceptable to both his fellow pharmacists and the public. The Panel expressed its hope that the Member will not appear again before another panel of the Discipline Committee.

Member: Sammy Agudoawu (OCP #206184)

This individual applied to the Discipline Committee for reinstatement of his certificate of registration. The application was heard on April 14, 2016, and was granted pursuant to a decision dated June 30, 2016.

Member: Kallol Mukjerhee (OCP #217345)

At a hearing on June 16 and 17, 2016, a Panel of the Discipline Committee made findings of professional misconduct against Mr. Mukherjee with respect to the following incidents, while he was engaged in the practice of pharmacy as dispensing pharmacist at Progressive Drug Mart in London:

- On or about September 17, 2013, while working as the sole pharmacist on duty, he left the Pharmacy without ensuring that another pharmacist was physically present in the Pharmacy;
 - On or about September 17, 2013, while working as the sole pharmacist on duty at the Pharmacy, he left the Pharmacy without taking reasonable and/or necessary steps to protect and/or ensure the security of narcotics and controlled or targeted substances on the premises;
 - On or about September 17, 2013, he engaged in inappropriate conduct at the Pharmacy in relation to [Employee], a pharmacy assistant employed there, consisting of inappropriate comments, physical contact and/or unwelcome advances;
- In particular, the Panel found that he
- Failed to maintain a standard of practice of the profession
 - Contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular:
 - o sections 6 and 7 of the Benzodiazepines and Other Targeted Substances Regulations, SOR/2000-217 under the Controlled Drugs and Substances Act, S.C. 1996. c. 19; section 43 of the Narcotic Control Regulations, C.R.C., c. 1041 under the Controlled Drugs and Substances Act
 - Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional
- Following submissions heard on July 12, 2016, the Panel imposed an Order against the Member which included as follows:
1. A reprimand to occur within 12 months of the date of this Order, failing which it shall occur within 12 months of the date on which the Member successfully applies for registration with the College.
 2. The Registrar shall impose the following specified terms, conditions or limitations ("Conditions") on the Member's Certificate of Registration, effective on the date on which he successfully applies for registration with the College:
 - (a) That the Member must complete successfully with an unconditional pass, at his own expense and within 12 months of obtaining a Certificate of Registration, the ProBE Program on Ethics for

Healthcare Professionals;

- (b) That the Member must complete successfully, within 12 months of the date that he successfully completes the ProBE course identified above in paragraph 2(a), a course with Gail E. Siskind Consulting Services, or another professional ethics consultant acceptable to the College, to be designed by the consultant, with the purpose of addressing the professional misconduct issues raised in this case; the following terms shall apply to the course:

- (i) the number of sessions shall be at the discretion of the consultant, but shall be a minimum of 3;
- (ii) the manner of attendance at the session(s) (e.g. in person, via Skype, etc.) is a matter to be discussed in advance between the Member and the consultant, but shall ultimately be at the discretion of the consultant;
- (iii) the Member shall provide to the consultant his evaluation from the ProBE course, and any essay he completed as part of that course, and discuss with the consultant the issues arising from that course;
- (iv) the Member shall be responsible for the cost of the course;
- (v) the consultant shall agree to confirm to the College once the Member has completed the course to the satisfaction of the consultant;

- (c) That the Member shall be prohibited for a period of three (3) years from the date the Member returns to active practice as a pharmacist in Ontario, from acting as a designated manager at any pharmacy;
- (d) That for a period of twelve (12) months from the date the Member returns to active practice as a pharmacist in Ontario:
- (i) he shall notify the College in writing of any employment in a pharmacy, which notification shall include the name and address of the employer and the date on which he began or is to begin employment, within seven (7) days of commencing such employment, and
 - (ii) he shall only work for an employer in a pharmacy who provides confirmation in

writing from the Designated Manager of the pharmacy to the College, within seven (7) days of him commencing employment at the pharmacy, that the Designated Manager received and reviewed a copy of the panel's decision and reasons in this matter before the Member commenced employment.

3. The Registrar shall suspend the Member's Certificate of Registration for a period of five (5) months, with two (2) months of the suspension to be remitted on condition that the Member complete the remedial training as specified in paragraphs 2(a) and 2(b), above. The suspension shall commence immediately on the date that the Member successfully applies for registration with the College and shall run without interruption for three (3) months. If the Member is required to serve the two (2) month remitted portion of the suspension because he fails to complete the remedial training as specified in paragraphs 2(a) and 2(b), the suspension shall continue for two months from the date the College is notified that the Member has not complete the remedial training specified in paragraphs 2(a) and 2(b).

4. Costs to the College in the amount of \$10,000

The reprimand in this matter is awaiting scheduling.

Member: Shamik Patel (OCP #106291)

At a hearing on July 15, 2016 a Panel of the Discipline Committee made findings of professional misconduct against Mr. Patel with respect to the following incidents:

- That he sold and/or dispensed prescription drugs, controlled drugs and or narcotics to [DC 1] and/or [DC 2] from on or about November 24, 2014 to on or about January 8, 2015;
- That he sold and/or dispensed prescription drugs, controlled drugs and/or narcotics without a prescription and/or proper authorization to [DC 1] and or [DC 2] on or about December 31, 2014, January 3, 2015 and January 8, 2015 with respect to 40mg Oxyneo pills;
- That he failed to keep accurate records that are consistent with applicable legislation, regulations, policies and standards from on or about January 1, 2013 until on or about January 8, 2015 for certain prescription drugs, controlled drugs and/or narcotics.

In particular, the Panel found that Mr. Patel:

- Failed to maintain a standard of practice of the profession
- Sold or dispensed drugs for an improper purpose
- Contravened the Pharmacy Act, 1991, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991 or the regulations under those Acts, and in particular:
 - o sections 153, 155 and 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4
- Contravened a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular:
 - o section 5(1) of the Controlled Drugs and Substances Act, S.C., 1996, c. 19
- Knowingly permitted the premises to be used for unlawful purposes
- Permitted, consented to or approved, either expressly or by implication, the commission of an offence against any Act relating to the practice of pharmacy or to the sale of drugs by a corporation of which he was a director
- Engaged in conduct or performed an act or acts relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional

The Panel imposed an Order which included as follows:

- A reprimand
- Directing the Registrar to revoke the Member's certificate of registration; and
- Costs to the College in the amount of \$1,500.00

In its reprimand, the Panel observed that Mr. Patel betrayed the profession of pharmacy and undercut the public's confidence in the profession. The Panel pointed out that Mr. Patel's misconduct, trafficking, preys upon vulnerabilities in the community and places the public at risk; the Panel noted that this is the antithesis of the role of the pharmacist. The Panel expressed its view that Mr. Patel's conduct was

disgraceful, dishonourable, and unprofessional, and was deserving of revocation.

Member: Mona Yacoub (OCP #210496)

At a hearing on July 26, 2016, a Panel of the Discipline Committee made findings of professional misconduct against Ms. Yacoub, with respect to the following incidents that occurred while she was engaged in the practice of pharmacy as director, shareholder, and/or dispensing pharmacist at Total Care Pharmacy in Toronto:

- That she contravened the Pharmacy Act, the Drug and Pharmacies Regulation Act, the Regulated Health Professions Act, 1991, or the regulations under those Acts, and in particular, sections 155 and 156 of the Drug and Pharmacies Regulation Act, R.S.O. 1990, c. H-4, as amended
- That she contravened, while engaged in the practice of pharmacy, a federal or provincial law or municipal by-law with respect to the distribution, sale or dispensing of any drug or mixture of drugs, and in particular, sections 5, and 15(1) of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10, as amended
- Engaged in conduct or performed an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members of the profession as disgraceful, dishonourable or unprofessional, in connection with identified claims made for drugs and or other products between February 12, 2010 and October 4, 2011.

The Panel imposed an Order which included as follows:

1. A reprimand
2. That the Registrar is directed to impose specified terms, conditions or limitations on the Member's Certificate of Registration, and in particular:
 - a. That the Member complete successfully with an unconditional pass, at her own expense, within 12 months of the date of this Order, the ProBE Program on professional/problem-based ethics for health care professionals;
 - b. That the Member's practice at each pharmacy of which she is an owner or Director will be monitored by the College for a maximum period of three years from the date the Order is imposed

by means of inspections (practice assessments) by a Community Practice Advisor ("CPA") as the College may determine. These practice assessments may be in addition to any of the routine practice assessments conducted by the College pursuant to the authority of section 148 of the Drug and Pharmacies Regulation Act. The Member shall cooperate fully with the College during the practice assessments, and, further, shall pay to the College the amount of \$1,000 per practice assessment, such amount to be paid immediately after each practice assessment. At each of the Member's pharmacies, if the initial practice assessment conducted under the authority of this Order reveals no cause for concern in the opinion of the CPA, there will be no further practice assessments conducted under the authority of this Order at the pharmacy in question. If the initial practice assessment does reveal cause for concern in the opinion of the College CPA, the practice assessments may continue until the issues are resolved in the opinion of the College CPA or until three years have elapsed, whichever is sooner, with the total number of inspections not to exceed four in any 12 month period. The Member will be liable to pay for no more than six practice assessments overall.

3. That the Registrar suspend the Member's Certificate of Registration for a period of six months, with one month of the suspension to be suspended on condition that the Member complete the remedial

training specified in subparagraph 2(a) above.

4. Costs to the College in the amount of \$6,500.

In its reprimand, the Panel noted that the right to practice pharmacy is a privilege that should not be lightly regarded. The Panel pointed out that the public expects that members will maintain high standards of practice, including all aspects of legislation. The Panel related that the Member's lack of attention to detail in this matter was a cause for concern, and that the Member admitted that she did not meet the level of due diligence required of a member of the profession. The Panel noted that it was disturbed that the Member allowed inappropriate billing to go on under her watch, as the owner is responsible for the actions of his or her employees. The Panel observed that the Member's conduct was unprofessional as it failed to live up to the expected standards of the profession. **PC**

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.

PRACTICE TIP!

GET A NEW PRACTICE TIP EVERY WEEK ON TWITTER

As you may be aware, the College has an official [Twitter account](#). On a daily basis, we tweet out helpful regulatory news and updates, new practice tools, important member reminders, and much more. Recently, we launched an initiative where every week we give you a new practice tip (followed by the hashtag #OCPPracticeTip).

Tips are developed from actual observations and encounters in practice and include: record keeping and documentation, methadone dispensing, narcotics reconciliation, clinical decision making, patient counselling, and much more.

Be sure to follow [OCP on Twitter](#) so you can see each new tip once it is published!



FOCUS ON ERROR PREVENTION

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

PEDIATRIC PATIENTS ARE EXPOSED TO GREATER RISK OF MEDICATION ERROR OCCURRENCE WITH INCREASED POTENTIAL FOR HARM.

Factors placing pediatric patients at increased risk include:

1. Need for calculation of individualized doses based on the child's age, weight and indication for use of the medication.
2. Need for precise dosage measurements, especially in neonates.
3. Lack of available dosage forms and concentrations appropriate for administration to infants and children.
4. Dosage formulations are often extemporaneously compounded and lack stability, compatibility or bioavailability data.
5. Incomplete development of infants body organs and their defense systems.

Extra care must therefore be taken to ensure that all aspects of the drug being dispensed are appropriate for the pediatric patient.

CASE:

Rx: Amoxicillin
Dose: 500mg
Route/Frequency: by mouth three times daily
Dispense: 10 days

The above computer generated prescription was given to the parent of a six month old patient. The child's mother took the prescription to her local community pharmacy for processing.

The pharmacy assistant failed to note the age and weight of the patient. She therefore entered into the computer, amoxicillin 500mg capsules to be taken three times daily for ten days. The 500mg capsules were prepared and labelled appropriately for checking by the pharmacist.



Upon checking the prescription, the pharmacist identified the inappropriate dosage form for a six month old patient. He also obtained the child's weight from the parent and determined that a daily dose of 1500mg amoxicillin would be inappropriate for the six month old child.

The prescriber was contacted to clarify/confirm the dose and indication for use. The physician explained that he intended to prescribe 500mg as the total daily dose and not each individual dose. The prescription was therefore changed to 167mg three times daily.


POSSIBLE CONTRIBUTING FACTORS:

- The computer generated prescription provided the dose in an ambiguous manner. The system software provided the total daily dose. However, the printed prescription indicated "dose" and not "total daily dose".
- The total daily dose of 500mg is commonly prescribed as a single dose. Hence, the pharmacy assistant did not readily identify the computer entry error.

- The pharmacy assistant failed to notice the child's age and failed to collect and record the child's weight when the prescription was presented by the parent.

RECOMMENDATIONS:

- Though computer generated prescriptions can minimize medication errors due to illegible handwriting, be aware that new types of errors may be introduced.
- Always contact the prescriber to clarify ambiguous prescriptions.
- Educate all staff on the benefit of using the patient's age to determine the appropriateness of the drug therapy.
- Always double check pediatric dosages for appropriateness. The child's weight should be collected and used to confirm the appropriateness of the prescribed dose on a mg/kg basis.
- Whenever possible, obtain the indication for use to determine the most appropriate dosage regimen.
- Educate the prescriber regarding the potential for error. Suggest the software vendor be contacted to change the prescription format.

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

CONTINUING EDUCATION

CHECK OUT OUR ONLINE TOOL FOR A LIST OF CE ACTIVITIES

<http://www.ocpinfo.com/practice-education/continuing-education/>



