Canadian Pharmacists Conference 2015

Innovation and Collaboration

An Overview of Sterile Compounding

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Jointly presented by the Canadian Pharmacists Association (CPhA) and the Ontario Pharmacists Association (OPA)

Disclosure Statement

"I have no real or potential conflicts, biases or relevant financial relationships to disclose for this presentation"

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Learning Objectives

- Learn the background and rationale for the development of national standards for sterile and non-sterile compounding
- Understand the development process, current status and next steps relating to compounding standards and other Thiessen recommendations
- Appreciate the significance of the adherence to standards in the delivery of safe and effective healthcare

Agenda

- Background
- Compounding Standards – Update
- Alignment with College's strategic objective - "Moving the Mountain"
- Discussion

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Under-dosing of chemotherapy medication

March 2013

Incident discovered

April 2013

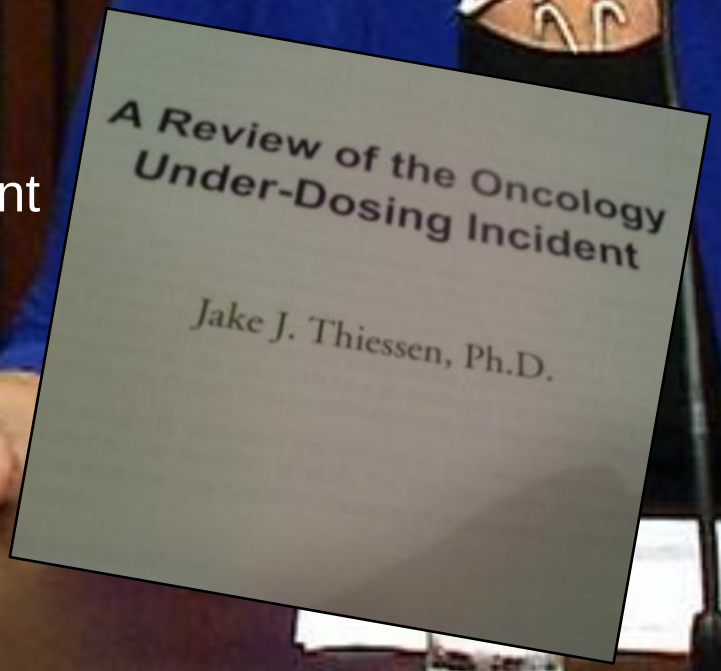
Thiessen named to lead independent study

August 2013

Thiessen Report and recommendations released to the public and accepted by government

September 2013

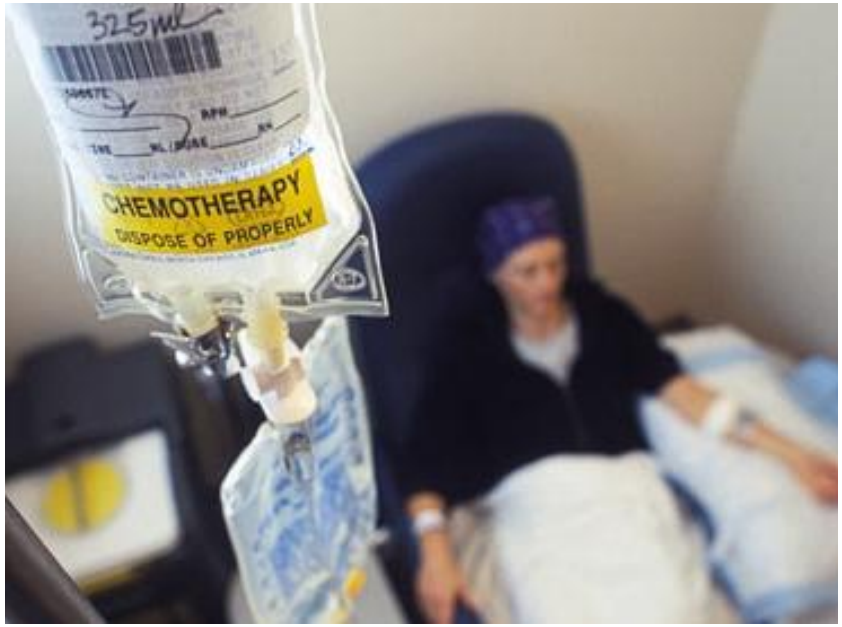
Implementation Task Force established



Thiessen Report

12 Recommendations to prevent future incidents and strengthen the drug supply:

- 5 directly call out OCP and/or NAPRA
- Recommendations #6, 7, 8, 9 & 12



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Thiessen Report

- #6 – Define best practices and contemporary **standards for non-sterile and sterile** product preparation
- #7 – Stipulate specialized **electronic material records and label requirements** for non-sterile and sterile product preparation
- #8 – **Inspection of Drug Preparation Premises** (DPPs) where pharmacists and pharmacy technicians work
- #9 – **Specified credentials** for personnel engaged in sterile and non-sterile compounding
- #12 – **License** all pharmacies operating within **Ontario's clinics or hospitals**

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#12 Oversight of Hospitals

- Dec 2014 – Bill 21 *Safeguarding Healthcare Integrity Act 2014* passed by government
- Proclamation of College's hospital inspection authority requires development of *Regulations*
- Draft revisions to the DPRA currently underway – to June Council for approval
- Baseline Assessments of Hospital currently underway – target for accreditation January 2016

90 of 260 sites assessed to date

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DPRA Regulations

Background:

- **The DPRA legislation and its related regulations provide the framework for the College to regulate pharmacy practice sites in Ontario**
  - DPRA is about pharmacies (addition of hospitals) not pharmacy professionals (RHPA)
- **College introduced an outcomes based approach when drafting the regulation**
  - leaving specificity to supplemental documents (standards, policies, guidelines) that can be amended easily as public expectations and practice evolves

DPRA Regulations

- The College is developing the necessary support documents to address the specificity that has been removed
- The effect of the new DPRA regulation with the supplementary documents is that on proclamation of the new regulation there are **NO CHANGES** from the current expectations of pharmacy operations

DPRA Regulations

- When drafting new, or revising existing, standards, policies, guidelines or other documents that are intended to define expectations of practice the College will use a ***Consultation Framework*** to ensure that when appropriate stakeholder consultation is sought

DPRA Regulations

- **Public Consultation (60 days)**
  - Deadline was May 10, 2015
  - 45 responses (32 individuals, 13 organizations)
- **Consideration of feedback / proposed amendments**
- **Council approval of final draft regulation**
  - June 15, 2015
- **Submission of Council approved regulation to government**
- **Enactment of regulation by government**
  - Before end of 2015

#6 - Compounding Standards

- Identified need to develop Standards at a national level
- Accelerated work already begun by NAPRA
  - Working group established Spring 2013
- Objective to develop 3 Standards documents:
  - Sterile Compounding – Hazardous
  - Sterile Compounding – Non-Hazardous
  - Non-Sterile Compounding

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#6 - Compounding Standards

- Sterile – Hazardous & Non-Hazardous
  - Primary drivers – USP 797 (800) and Quebec Compounding Standards
  - Draft documents developed through consultative process:
    - Initial circulation to stakeholders – Summer 2014
    - Working Group revised documents and recirculated (to Regulatory Bodies) – Early 2015
    - Final revisions made (with USP 797 expert)
  - NAPRA **approved** content of document – April 2015

#6 - Compounding Standards

Next Steps / Timeline:

- Sterile – Hazardous & Non-Hazardous
  - Editing and formatting (including french translation)
  - Made available by NAPRA – late summer/early fall 2015
  - Each Regulatory Body in Canada will then need to consider; adopting or adapting – Fall 2015
    - Similar process to NAPRA's Model Standards of Practice for pharmacists and pharmacy technicians

Although there will be an implementation plan with respect to how and when new standards will take effect . . . you should be working towards compliance now.

#6 - Compounding Standards

- **Non-Sterile**
  - Primary drivers – USP 795 and Quebec Compounding Standards
  - NAPRA working group will develop through 2015
  - Consultation process through 2016
  - Final NAPRA approval anticipated before the end of 2016
    - Each Regulatory Body in Canada will then need to consider; adopting or adapting

#9 – Specified Credentials

- For Sterile Hazardous and Non-Hazardous
  - Identified need to develop competencies at a national level
  - Work already begun by NAPRA
- Objective to ensure educational curriculum will deliver necessary skills and knowledge to practice to Standards
- Regulatory Colleges will determine application
  - Example: Injection Training

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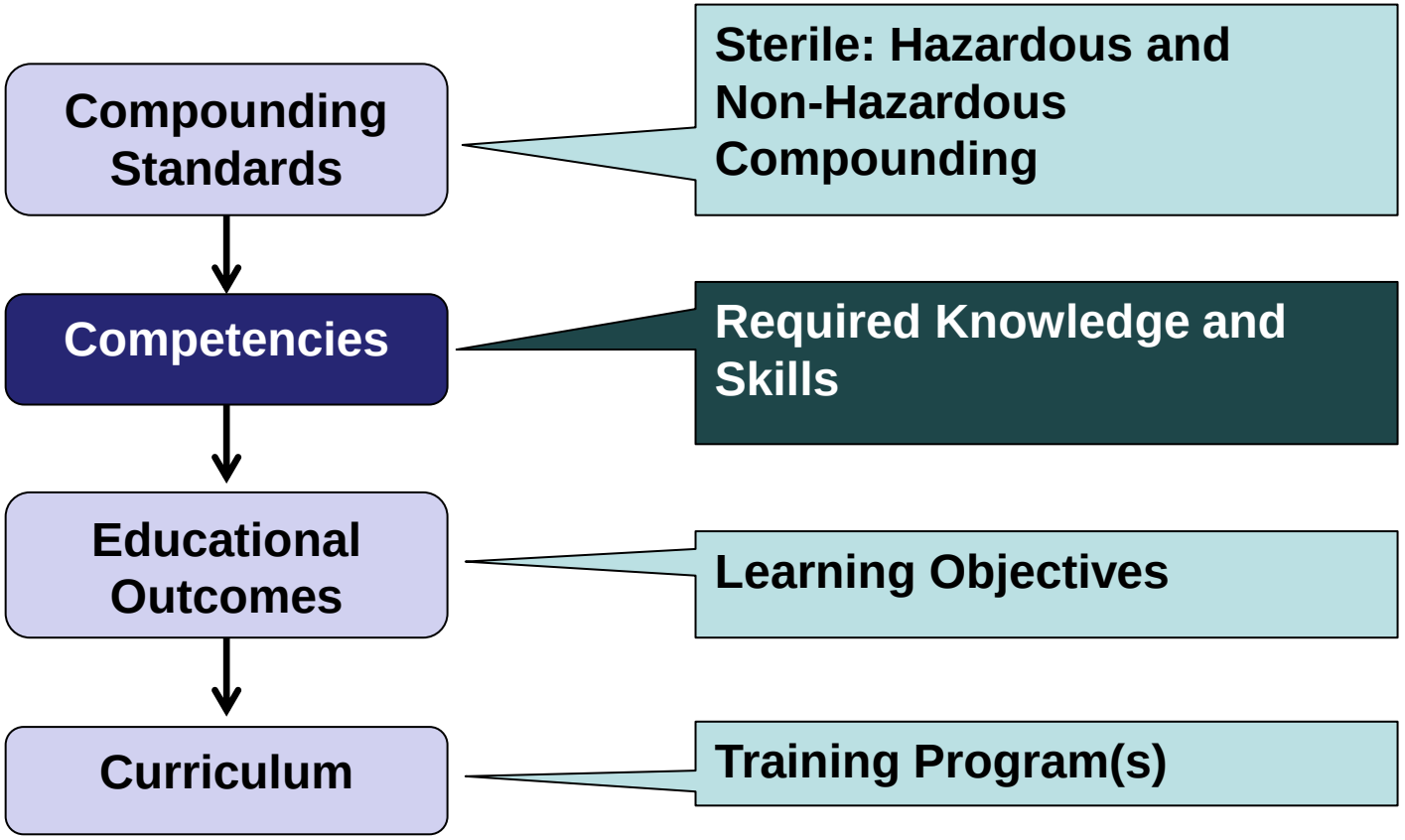
#9 – Specified Credentials



#7 - Traceability and Labeling

Stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation

- Supplement to NAPRA's *PPMS: Requirements to Support NAPRA's "Model Standards of Practice for Canadian Pharmacists"*
  - Requirement 36: Traceability and Record-Keeping for Preparations
  - Requirement 37: Traceability and Labeling
  - Requirement 38: Labelling and Automated Data Capture

Traceability Objective

Beginning

End

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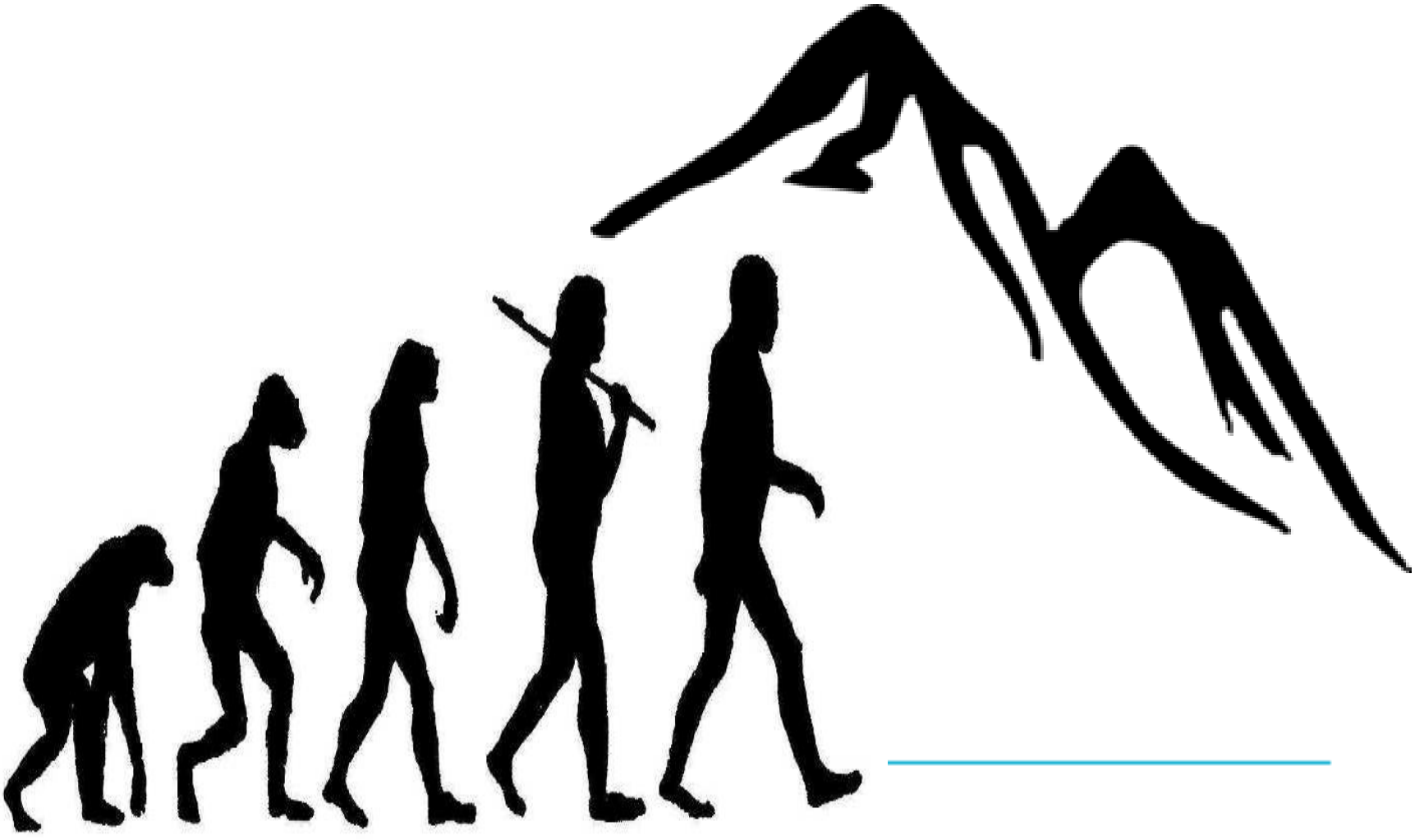
#7 - Traceability and Labeling

- Process - Complete
  - Draft additional requirements for PPMS document
  - Ontario-based stakeholder consultation
  - Revise draft document based on feedback
  - Revised document to CPRC / NAPRA April 2014 meeting for consideration
  - National stakeholder consultation of revised PPMS document (July 2015)
- Process – Next Steps
  - Approval by NAPRA


CHANGE
AHEAD

All healthcare professionals must practice to their full scope

Our evolving role . . .



ON THIS TEAM: Pharmacy professionals are the medication experts, relied on to use our knowledge, skills and abilities to make decisions that positively impact the health of our patients

Professional Judgment

Do I have enough knowledge about the condition and drug?

Do I have enough information about the patient and their health status?

Do I have a medication plan?

Empowered to use professional judgment to make decisions in the best interest of the patient

outcome?

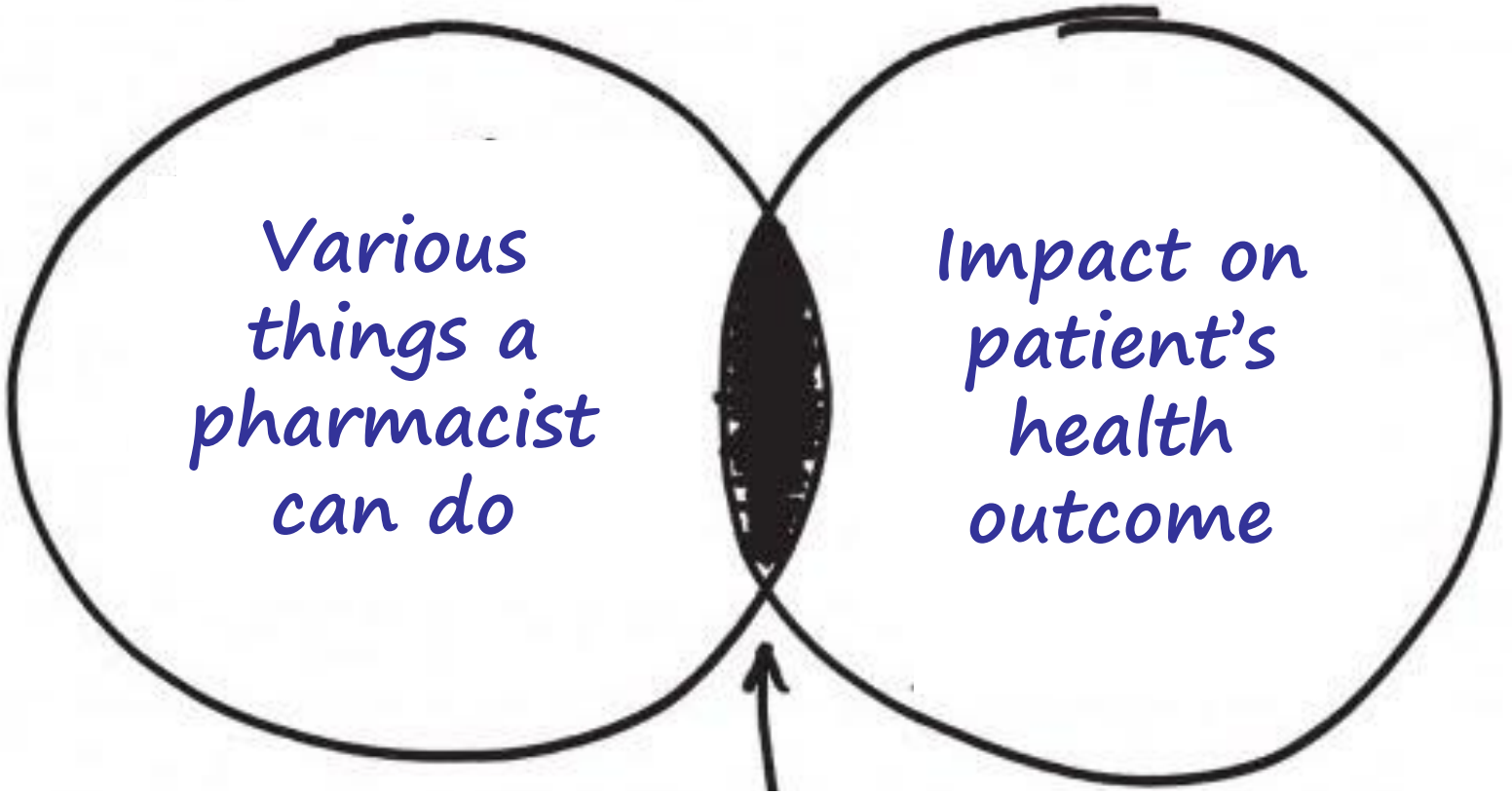
Does the patient agree?

Document my rationale

Notify appropriately

Bottom Line


Growing bucket of things to do.
AUTHORITY
With the authority to do them.



Are we focused on the right things?

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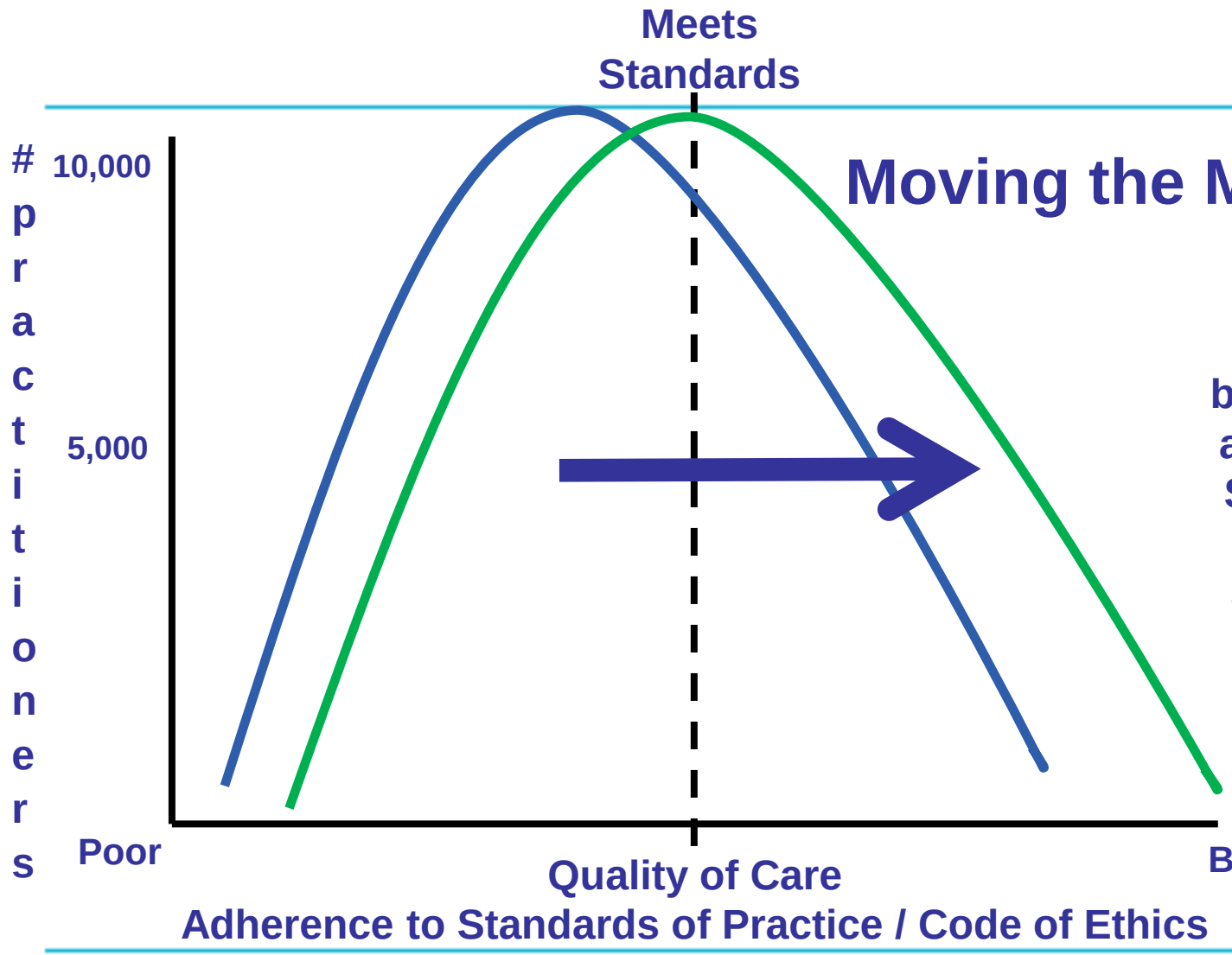
Focus on process and procedures in place to meet practice standards



Moving the Mountain

Enhance patient outcomes by increasing adherence to Standards of Practice and Code Of Ethics

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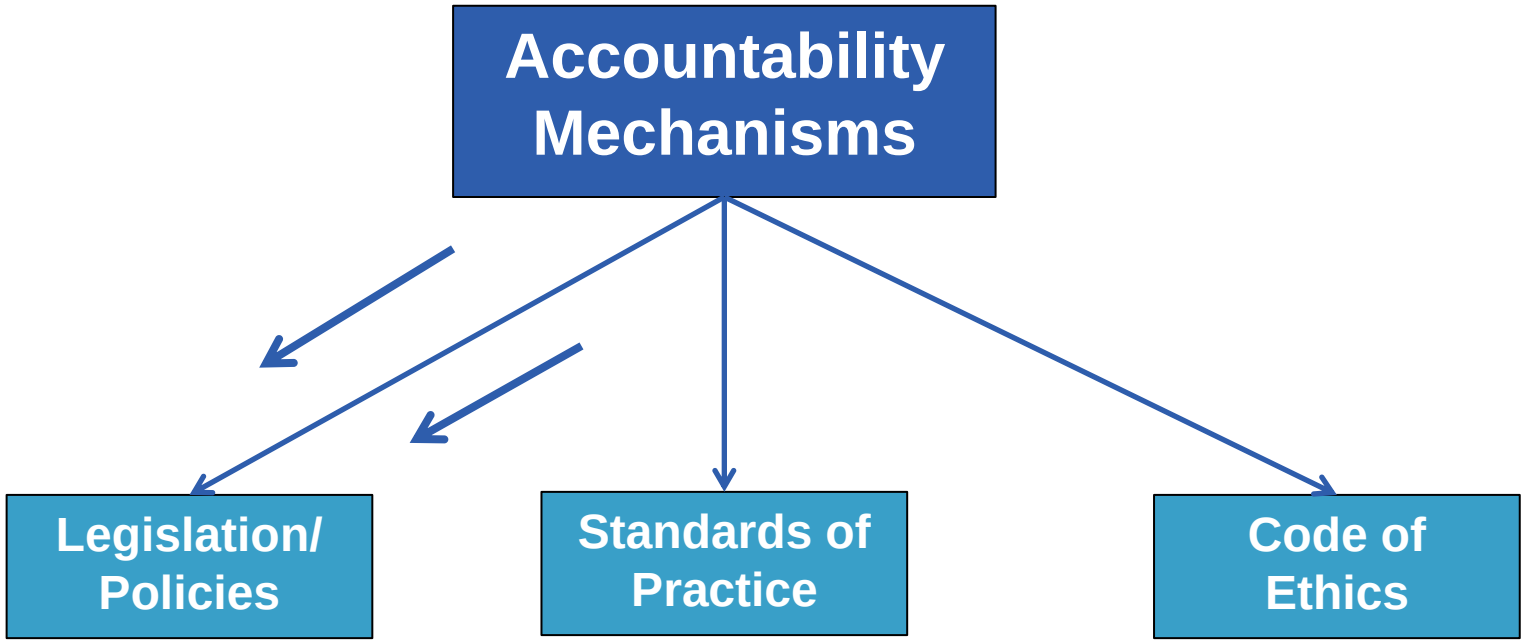
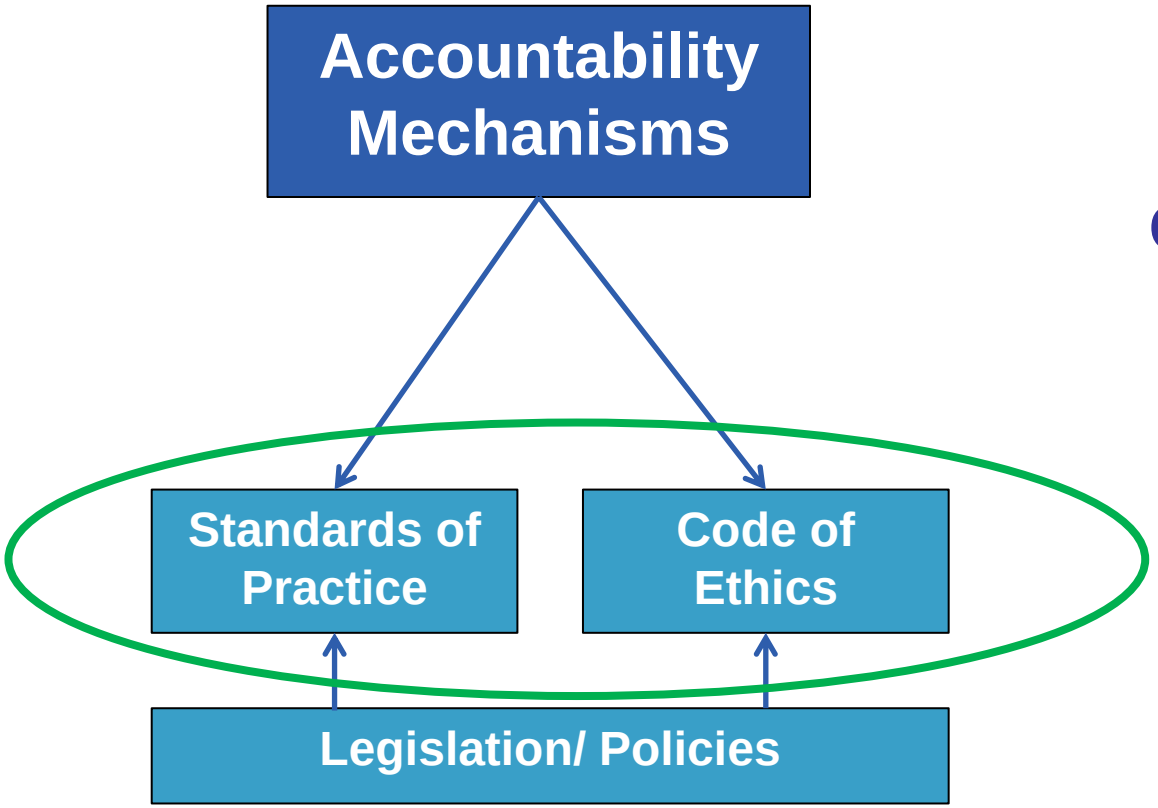
Current Focus



Shift Focus



Standards of Practice and Code Of Ethics articulate minimum expectations of practice

Shift Focus - Practitioners

Practitioners focus on:

- the patient / health outcomes
- doing the things that add the most value to the patient
- being recognized by patients and the healthcare team for the value that they bring

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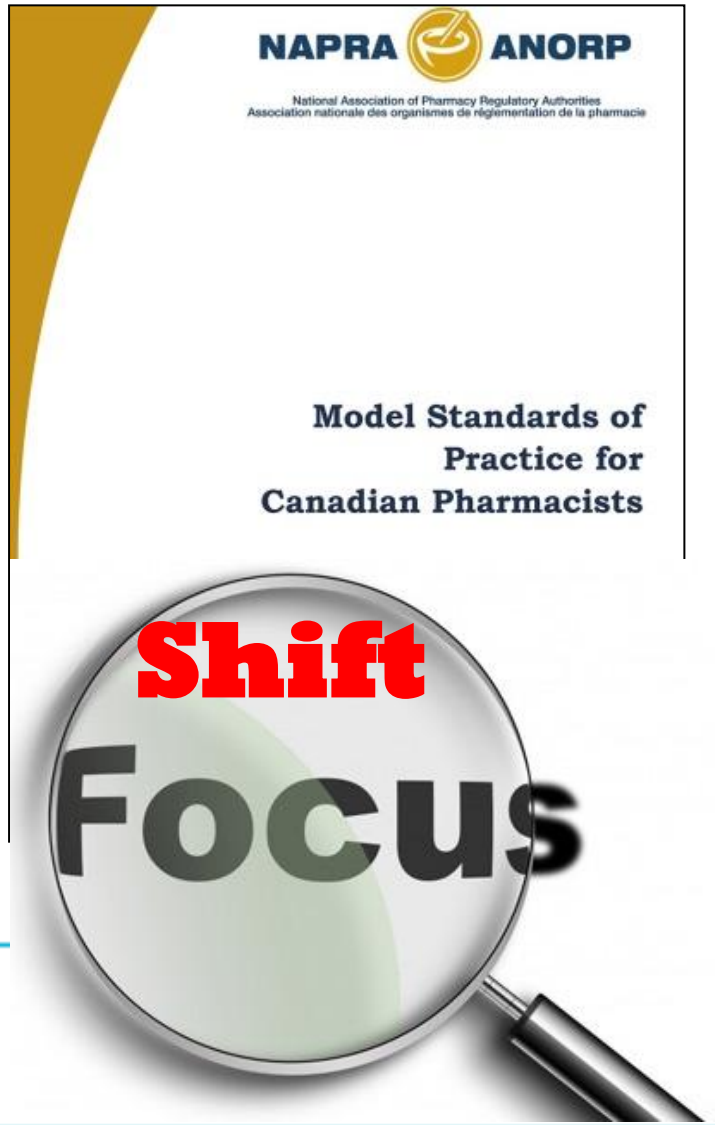
Shift Focus - College

College focus on:

- The Standards of Practice
- The Code of Ethics and Professional Responsibility Principles
- The things that have the most impact on patient and public safety



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Patient-Centred Care

We need to remember . . .

Our Professional Responsibility

Discussion

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