Presenter Disclosure

• I have no current or past relationships with commercial entities

• I have received no speaker’s fee for this learning activity
Agenda

• Background

• Regulatory Framework

• Update on Accreditation of Hospital Pharmacies and assessments

• Compounding

• Next Steps

• Questions
A case for change – learning from the Chemo Under-dosing incident

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 of recommendations begins
“The most detrimental error is failing to learn from an error.”

- James Reason
Thiessen Recommendations

- #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
Hospital Regulatory Framework

• Dec 2014 – Bill 21 *Safeguarding Healthcare Integrity Act 2014*

• June 2015 – Enabling DPRA regulations, following public consultation, approved by council and submitted to government

• Dec 2015 – Enabling bylaws regarding hospital accreditation fees, following public consultation, approved by council

• August 1, 2016 proclamation of new DPRA regulations
Accreditation of Hospital Pharmacies

Overriding Objectives:

• Assess pharmacy and practitioner adherence to operational and practice standards
• Prioritize focus based on patient and/or public risk
• Support and mentor facilities and individuals to develop necessary action plans and timelines to meet required standards
• Identify and share best practices amongst facilities and individuals – continuous quality improvement (CQI)
Accreditation of Hospital Pharmacies

Principle-Based Approach

1. Collaborative
   - In process development and inspection process

2. Flexible
   - Adaptable to various practice sites and activities

3. Continuous Quality Improvement (CQI)
   - Solid base already in place (system is not broken)
   - Supportive and educational (not punitive)

4. Mandate of Public Interest
   - Safe and effective delivery of pharmacy services
The Just Culture Approach

• Recognition that healthcare is high risk and all employees must be actively engaged in the creation of safety
• Organizations are accountable for systems and how they respond to staff behaviours
• Staff are accountable for quality of choices and for reporting both errors and system vulnerabilities
• Learning and accountability are emphasized over blame and punishment
• There is zero tolerance for reckless behaviour
Continuous Quality Improvement (CQI)

• An essential constituent of Patient/Medication Safety
• Regular systematic review, monitoring and improving workflow processes in medication management system
• Eliminate sources of inefficiencies, suboptimal quality of care and services and enhance overall system performance
• Lessons learned from incidents and near misses
Hospital Assessment Criteria

Overview:
A. Systems to Provide Safe, Effective and Appropriate Pharmacy Services
B. Order Processing, Verification, Dispensing and Distribution
C. Preparation, Packaging and Labelling of Medication
D. Pharmaceutical Compounding
E. Safe Medication Use Systems in Patient Care Areas
F. Medication Therapy Management
G. Documentation and Record Keeping
H. Evaluation of Pharmacy Services
Number of Accredited Hospitals in each LHIN

1. Erie St. Clair 8
2. South West 32
3. Waterloo Wellington 10
4. Hamilton Niagara Haldimand Brant 21
5. Central West 3
6. Mississauga Halton 6
7. Toronto Central 26
8. Central 10
9. Central East 16
10. South East 14
11. Champlain 24
12. North Simcoe Muskoka 8
13. North East 33
14. North West 16

Total # Active Hospitals in Ontario: 227
<table>
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<tr>
<th>LHIN</th>
<th>Total</th>
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<th>Private</th>
<th>Pharmacist provides oversight</th>
<th>High Risk (Chemo and/or Sterile Prep)</th>
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*Updated December 31, 2016*
61% of hospitals provide **Chemotherapy** and/or **Sterile Compounding** services

- Sites that provide Chemotherapy and/or Sterile Compounding services have been prioritized
- 138 sites
- Considered high risk
- Gap analysis and action plans

72% of hospitals have **OCP Member** providing oversight of pharmacy/medication management system
Hospital Assessments

60% of hospitals visited for 1st visit (after baseline) to date

2016:
- 59 Routine Assessments completed
- 4 Baseline/New Opening Assessments
- 1 Closing Assessments

2017:
- 77 Routine Assessments completed in first quarter
- 1 New Opening Assessments
- 0 Closing Assessments

- 100% of hospitals to be visited for 1st visit (after baseline) before the end of 2017
Themes of Findings

Operations (place):
- Policies and Procedures
- Traceability and Record Keeping
- Compounding (USP 795, 797 and 800)

Practice (people):
- Professional Responsibilities
  - Standards of Practice
- Intra-Professional and Inter-Professional Relationships
  - Pharmacists and Pharmacy Technicians
  - Pharmacy team with other healthcare professionals
System Gaps / Priority Setting

Themes of Findings:
• Understanding of requirements for a safe medication management system
• Scopes of practice
• Standards of Practice
• Security of Medications
  – Controlled Drugs and Substances
• Automated dispensing cabinets
• Traceability and auditability
System Gaps / Priority Setting

- Action plans required to achieve compounding standards (facilities, people & processes, quality monitoring and cleaning)
- Action plans to increase security for narcotics and other medications
- Action plans to achieve standards for chemotherapy preparation
- Processes in place that consistently ensure therapeutic checks for all orders
Themes of Recommendations:

1. Re-assess ability to safely and effectively provide specific services; explore alternative options such as centralizing, regionalizing and/or outsourcing.

2. Continuous improvement plans should be prioritized based on areas of highest risk and include education to all relevant staff on enhancements to processes and procedures.

3. Where gaps exist, develop policies and procedures to ensure accountability and consistency of services.
System Gaps / Priority Setting

Themes of Recommendations:

4. Identify opportunities to enhance professional responsibilities e.g. work to full scope
5. Opportunity to bring best practices across all practice sites
6. Review and understand standards
Compounding Standards

- Implementation of Model Standards for Pharmacy Compounding of non-hazardous Sterile Preparations and hazardous Sterile Preparations for all practice sites (hospital, community, DPP)

  Implementation date – January 1, 2019

- Time allows pharmacy professionals the opportunity to examine practice, conduct a gap analysis, against standards, create an action plan and implement
## Section D. Pharmaceutical Compounding

### Category D: PHARMACEUTICAL COMPOUNDING

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<th>D.2. Non-hazardous Sterile Preparations</th>
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<td>Compounded Sterile Product (CSP) Preparation</td>
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<th>D.3. Specialized Sterile Compounding</th>
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<td>Total Parenteral Nutrition (TPN)</td>
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<td>Facility Requirements - Non-Hazardous Sterile Compounding</td>
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<th>D.4. Hazardous Sterile Preparations</th>
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<td>Hazardous Sterile Compound Preparation</td>
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<tr>
<td>Facility Requirements - Hazardous Sterile Compounding</td>
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</table>
Pharmaceutical Compounding: Overview of Compliance

- Meet: 57%
- Partially Meet: 28%
- Do Not Meet: 15%

[Graph showing the distribution of compliance levels]
Collaboration

- Canadian Society of Hospital Pharmacists (CSHP)–Branch (OB) and National
- Ontario Pharmacists Association (OPA)
- Ministry of Health and Long Term Care (MOHLTC)-policy, hospital, capital funding
- Cancer Care Ontario (CCO)
- Ontario Hospital Association (OHA)
- National Association of Pharmacy Regulatory Associations (NAPRA) and provincial pharmacy regulatory bodies
- Health Canada
- Other provincial regulatory bodies (CNO, CPSO)
- Community Care Access Centre (CCAC)
- Hospitals and practitioners
Implementation Steps

- **Gap Analysis***
  - Evaluate knowledge, skills and judgement
  - Consider regionalizing, centralizing or outsourcing

- **Action Plans**
  - People and processes
    - Standardization
    - Training and testing
  - Beyond use dates (BUDs)
  - Facilities
    - Environmental testing
Implementation Strategies

- Knowledge, skills and judgement
  - Out-source
  - regionalize
- LHIN pharmacy group
  - gap analysis
  - Action plan
- Facilities
  - Ministry of Labour
- OCP communications
  - Tools and guidance
Next Steps 2017

- Complete second round of hospital assessments
- Feedback survey
- Mine data from assessments and survey
- Revise and update assessment criteria
  - Move toward electronic process for assessments
- Refine assessment process
- Other healthcare related sites
- Hospital Pharmacy technicians and pharmacists Workshops
- Posting on public register
- By-law changes
2017 and Beyond

- Standards of Operation
- Standards of Practice - Member assessments – pharmacy technicians and pharmacists
- Pharmacy Technician Strategy
- Quality Assurance and Registration Regulation
- Model for Evaluation of Scope of Practice (MESPO)
- Cannabis
- Opioid Misuse
- Bill 84 Medical Assistance in Dying Statue
- Bill 87 Proposed Amendments to RHPA
Continuous Quality Assurance Programme for Medication Safety

Go Public | Parents find son’s lifeless body after pharmacy switches sleep medication for toxic dose of another drug

Ontario mom wants mandatory prescription-error reporting across Canada after son, 8, dies

Grieving mother urges more oversight for pharmacies that make errors

Family of boy who died after prescription error told health minister is 'all in' for change
**CODE of ETHICS: A VISUAL OVERVIEW**

**Beneficence (to benefit)**
Our primary role and function as healthcare professionals is to benefit our patients. We need to remember that our patients seek our care and services because they believe and trust that we will apply our knowledge, skills and abilities to help make them better.

**Non Maleficence (do no harm)**
As we strive to benefit our patients, we must be diligent in our efforts to do no harm and, whenever possible, prevent harm from occurring.

**Respect for Persons/Justice**
All persons are worthy of our respect, compassion and consideration. We demonstrate this when we respect our patients' vulnerability, autonomy and right to be self-governing decision makers in their own healthcare. The principle of "Justice" requires that we fulfill our ethical obligation to treat all patients fairly and equitably.

**Accountability (Fidelity)**
We must ensure that we keep our promise to our patients and society to always and invariably act in their best interests and not our own. It is this principle that holds us accountable, not just for our own actions and behaviours, but for those of our colleagues as well.

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All pharmacy professionals, regardless of practice setting, must abide by the principles and standards in the Code.

*Read the College’s full Code of Ethics*
3rd Largest Cause of Death

If not now, then when?

- Inappropriate medications
- Contaminated medications
"If you can't fly, then run, if you can't run, then walk, if you can't walk, then crawl, But whatever you do, you have to 
KEEP MOVING FORWARD."

~ Martin Luther King Jr.