Lessons Learned from Medication Incidents Reported by Community Pharmacies in Nova Scotia: A 7-Year Study

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Disclosures

• Nothing to disclose
Agenda

- **Background**: The Canadian Medication Incident Reporting and Prevention System (CMIRPS)
- **Introduction**: Continuous Quality Improvement (CQI) & SafetyNET-Rx in Nova Scotia
- **Methods**: Approaches to Medication Incident Analysis
- **Results**: Trends, Main Themes, Sample Incidents
- **Conclusion**: Lessons Learned and Shared
- **Key Messages**: Implications to Pharmacy Professionals
Learning Objectives

• To learn about the Canadian Medication Incident Reporting and Prevention System (CMIRPS)
• To be aware of current implementation of mandatory standardized CQI programs in Canadian jurisdictions
• To describe the benefits and challenges associated with quantitative and qualitative analyses of medication incidents
• To review the most common trends, main themes, and common medication incidents that occur in community pharmacy
• To share lessons learned from incident reporting and analysis
Background
Canadian Medication Incident Reporting and Prevention System (CMIRPS)

- A collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI)
- **Goal**: To reduce and prevent harmful medication incidents in Canada
- **Reporting, sharing, and learning** about medication incidents will help reduce their reoccurrence and help create a safer healthcare system
Analysis of Medication Incidents

• “Ultimately, it is the action we take in response to reporting – not reporting itself – that leads to change.”

ISMP Canada CMIRPS
Medication Incident Analysis and Learning Framework

Incident Reporting
- Practitioner reporting
- Consumer reporting
- Community pharmacy reporting
- Hospital-based reporting
  - Immediate electronic notification for critical incidents
  - Review of NSIR database

Incident Analysis
- Medication incident prioritization process
- Incident analysis (individual report review, aggregate review, and root cause analysis)

Solutions Development and Dissemination
- Short term strategies, such as:
  - Safety bulletins (including alerts), journal articles
  - Recommendations (including review of evidence, failure mode and effects analysis)
- Long term strategies, such as:
  - Evidence-based medication safety tools and programs
  - Standards and regulations

Knowledge Translation

Cumulative Enhancement of Patient Safety

From: Canadian Medication Incident Reporting and Prevention System (CMIRPS)
Medication Incident Analysis and Learning Framework © 2007
Institute for Safe Medication Practices Canada

September 2012
Two Complementary Approaches

• Quantitative Analysis ("numbers")
  - Summarize medication incident data
  - Descriptive statistics (e.g. frequency distribution tables)

• Qualitative Analysis ("narratives")
  - Analysis of narrative data ("the stories")
  - Qualitative research methods
  - Individual Incident Analysis & Multi-Incident Analysis
Quantitative Analysis

• Role: Addresses the “what” question
  - Overview of the data
  - Monitoring of trends
  - Quick identification of areas for improvement

• Limitations
  - Does not identify case specific contributing factors
  - Voluntary reporting does not ensure reliability of results
Qualitative Analysis

• Role: Addresses the “why” question
  - In-depth analysis of the narrative data
  - Identification of detailed, case-specific contributing factors

• Limitations:
  - Does not identify incident rates
  - Time-consuming (analysis prioritization may be required)
Summary of Medication Incident Analysis Strategies

Medication Incident Data

- Quantitative Analysis
- Qualitative Analysis
  - Individual Incident Analysis (Comprehensive/Root Cause Analysis & Concise)
  - Multi-Incident Analysis
Introduction
Continuous Quality Improvement (CQI)

1. **Reporting**
   Medication incidents, from near miss to causing patient harm, should be documented

2. **Analysis**
   Based on the harm and your unique settings, find commonalities between the incidents

3. **Solution Development**
   Work with your team and brainstorm solutions appropriate for your setting

4. **Implementation**
   Prioritize and implement solutions with high standards and effectiveness
Standardized CQI Program

Key Components & Tools

• **PROACTIVE**: Regular performance of a medication safety self-assessment, and monitoring the progress of action plans

• **RETROSPECTIVE**: Anonymous reporting of medication incidents to an independent, objective third party organization for population of a national aggregate database

• **DOCUMENTATION**: Regular pharmacy staff CQI meetings to discuss & review aggregate incident data & medication safety self-assessment improvement initiatives
Jurisdictions with Mandatory Standardized CQI or Medication Safety Programs

• Nova Scotia – SafetyNET-Rx – mandatory standardized CQI program
  – As of Oct 2010

• Saskatchewan – COMPASS™ (Community Pharmacists Advancing Safety in Saskatchewan) – mandatory standardized CQI program
  – [https://scp.in1touch.org/site/compass/compass?nav=sidebar](https://scp.in1touch.org/site/compass/compass?nav=sidebar)
  – As of Dec 2017
Jurisdictions with Mandatory Standardized CQI or Medication Safety Programs

- New Brunswick – MMIR (Mandatory Medication Incident Reporting) Practice Directive
  - As of Jan 2019

- Ontario – AIMS (Assurance and Improvement in Medication Safety) – mandatory medication safety program
  - https://youtu.be/5-FvoLf mj5c
  - As of Mid 2019
Jurisdictions with Mandatory Standardized CQI or Medication Safety Programs

• Manitoba – **Safety IQ (Safety Improvement in Quality)** – mandatory standardized CQI program
  – [https://www.cphm.ca/site/safetyiq](https://www.cphm.ca/site/safetyiq)
  – As of Jan 2020
# Jurisdictions with Mandatory Standardized CQI or Medication Safety Programs

<table>
<thead>
<tr>
<th>CQI Components</th>
<th>NS</th>
<th>SK</th>
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<tbody>
<tr>
<td>Program</td>
<td>SafetyNET-Rx</td>
<td>COMPASS</td>
<td>MMIR</td>
<td>AIMS</td>
<td>Safety IQ</td>
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<td>Proactive</td>
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<td>Retrospective</td>
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<td>CPhIR</td>
<td>CMIRPS</td>
<td>Pharmapod</td>
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<tr>
<td>Documentation</td>
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“Quality-related events (QRE) reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis”

- Quantitative Analysis: [http://cmajopen.ca/content/6/4/E651.full](http://cmajopen.ca/content/6/4/E651.full)

“A Multi-Incident Analysis on Medication Incidents Associated with Patient Harm”

Methods
Methods

- **SafetyNET-Rx**: Community pharmacies in Nova Scotia are required to anonymously report medication incidents to an independent, objective third party organization for population of a national aggregate database.

- **Data**: All reported medication incidents (n = 98,097) from Nova Scotia community pharmacies occurring between October 1, 2010 and June 30, 2017.
Methods (Quantitative Analysis)

• Descriptive analysis was conducted with respect to:
  – Discoverer
  – Medication system stage
  – Type of incident
  – Medications
  – Outcome
Methods (Qualitative Analysis): A Multi-Incident Analysis on Harm Incidents

• 971 medication incidents involving harm from 2009 to 2017
• 62 incidents were excluded due to inadequate “incident description”
• 909 Incidents were analyzed for themes and subthemes
• Contributing factors were identified
• Recommendations were offered to improve work processes
Results
Results (Quantitative Analysis)

- A total of 98,097 medication incidents reported by 301 community pharmacies were included in the analysis.
- Pharmacists discovered the largest portion (75.2%), followed by pharmacy technicians/assistants (10.3%), and then patients (9.9%).
- Incidents occurred most frequently during order entry (58.7%) followed by prescription preparation/dispensing (29.3%) and then prescribing (9.0%).
Incidents Reported by Outcome

- Near Miss: 82.05%
- No Harm: 17.00%
- Mild Harm: 0.86%
- Moderate Harm: 0.08%
- Severe Harm: 0.01%
- Death: 0%
Type of Incident

- Incorrect dose / frequency: 26%
- Incorrect quantity: 20%
- Incorrect drug: 14%
- Incorrect strength / concentration: 11%
- Incorrect patient: 9%
- Incorrect durations of treatment: 6%
- Incorrect dosage form / formulation: 5%
- Incorrect duration of treatment: 3%
- Others: 6%
# Medications Associated with Harm

<table>
<thead>
<tr>
<th>Medication</th>
<th>Proportion of QREs with Harm (%)</th>
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<td></td>
<td>11 (3.51%)</td>
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<td></td>
<td>22 (2.95%)</td>
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<tr>
<td>Morphine</td>
<td>16 (2.82%)</td>
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<td>Atenolol</td>
<td>14 (2.57%)</td>
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<tr>
<td>Warfarin</td>
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Summary
(Qualitative Analysis)

- The majority of incidents were considered near misses or no harm incidents.
- Medications conveying a higher risk of harm include opioids, antipsychotics, and anticoagulants.
- Under reporting - 10% of pharmacies accounted for 42.7% of reported incidents.
Results (Qualitative Analysis):
Multi-Incident Analysis - Themes

- High Risk Processes in the Pharmacy
- Communication Gaps
- Preventable Adverse Drug Reaction
Themes and Subthemes

- High Risk Processes in the Pharmacy
  - Methadone Maintenance Therapy
  - Compliance Packs
  - Compounding

- Communication Gaps

- Preventable Adverse Drug Reaction
Methadone Maintenance Therapy

- **Incident Example:** A patient was given the wrong dose of methadone (110 mg), which was significantly higher than his normal dose (30 mg). The incident was discovered when the another patient arrived for his dose, but it could not be found. The two patients had similar names.

- **Contributing Factors** - Pre-pouring of daily methadone doses, similar names of patients.
Hierarchy of Effectiveness

- **High Leverage**
  - Most Effective
  - System-Based
  - Most Feasible
  - Examples: Forcing functions and constraints (e.g., removal of a product from use), automation or computerization (e.g., automated patient-specific dispensing)

- **Medium Leverage**
  - Moderately Effective
  - System-Based
  - Least Feasible
  - Examples: Simplification and standardization (e.g., standardized paper or electronic order sets)

- **Low Leverage**
  - Least Effective
  - Person-Based
  - Most Feasible
  - Examples: Rules and policies (e.g., policies to prohibit borrowing doses from other areas), reminders, checklists, double checks (e.g., independent double checks for high-alert medications), education and information (e.g., education sessions on high-alert medications)
## Recommendations for High Risk Processes

**Summary of Recommendations**  
Aim for high-leverage, effective, and system-based strategies

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Hierarchy of Effectiveness</th>
<th>More Effective / Less Feasible</th>
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<tbody>
<tr>
<td>Implement barcode scanning to ensure correct selection of medication.</td>
<td>Automation and Computerization</td>
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<tr>
<td>Develop standardized procedures and documentation for high-risk processes (e.g. USP 795).</td>
<td>Simplification and Standardization</td>
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<tr>
<td>Perform independent double checks throughout all steps of the medication-use process.</td>
<td>Reminder, Checklists, Double Checks</td>
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<tr>
<td>Ensure staff members are not interrupted when performing a high-risk task.</td>
<td>Rules and Policies</td>
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<tr>
<td>Ensure designated staff members are adequately trained and equipped.</td>
<td>Education and Information</td>
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Themes and Subthemes

High Risk Processes in the Pharmacy
- Methadone Maintenance Therapy
- Compliance Packs
- Compounding

Communication Gaps
- Patient-Provider Engagement
- Interprofessional Collaboration

Preventable Adverse Drug Reaction
Interprofessional Collaboration

• **Incident Example:** A nursing home contacted the pharmacy for a refill of a patient’s prescription for Arthrotec® (diclofenac/misoprostol). There was no record of Arthrotec® on the patient file, but there was a prescription for diclofenac. It was discovered that, in addition to receiving diclofenac, the patient was taking a sample of Arthrotec® that he received from the doctor.

• **Contributing Factors** - Limited sharing of medical information, lack of medication review.
Recommendations

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<td>Automation and Computerization</td>
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<tr>
<td>• Implement Electronic Health Records and E-prescribing in pharmacy practice.</td>
<td>Simplification and Standardization</td>
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<tr>
<td>• Have standardized documentation for follow-up of problematic orders and hand off between healthcare professionals.</td>
<td>Reminder, Checklists, Double Checks</td>
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<tr>
<td>• Use “show and tell” and “teach back” technique to ensure understanding.</td>
<td>Rules and Policies</td>
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<tr>
<td>• Conduct regular medication reviews or best possible medication history to identify real and potential drug therapy problems.</td>
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<tr>
<td>• Encourage patients to carry an updated medication list when interacting with health care professionals.</td>
<td>Education and Information</td>
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Themes and Subthemes

High Risk Processes in the Pharmacy
- Methadone Maintenance Therapy
- Compliance Packs
- Compounding

Communication Gaps
- Patient-Provider Engagement
- Inter-Professional Collaboration

Preventable Adverse Drug Reaction
- Drug-Drug Interaction
- Documented Drug Allergy
Documented Drug Allergy

• **Incident Example:** A patient complained of tight throat over several days. He/she went to emergency and was diagnosed with an allergic reaction to moxifloxacin. The pharmacist had missed the allergy caution when dispensing.

• **Contributing Factors** – Inadequate alerts, alert fatigue.
## Recommendations

### Summary of Recommendations

**Aim for high-leverage, effective, and system-based strategies**

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<td>• Clinical decision support systems (CDSS) for prescribers and pharmacists should have the functionality to detect drug-drug interactions/drug allergies and be updated regularly to prevent missing alerts and alert fatigue.</td>
<td>Automation and Computerization</td>
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<tr>
<td>• Develop standardized procedures with documentation when a drug interaction or drug allergy is identified.</td>
<td>Simplification and Standardization</td>
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<tr>
<td>• Double check allergy status at order entry and pick-up.</td>
<td>Reminder, Checklists, Double Checks</td>
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<tr>
<td>• Require documentation when a drug interaction or allergy override occurs and audit documentation regularly.</td>
<td>Rules and Policies</td>
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<tr>
<td>• Subscribe to a drug information service and post information on known dangerous drug interactions.</td>
<td>Education and Information</td>
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Summary
(Qualitative Analysis)

• High risk processes, communication gaps, and preventable adverse drug reactions are associated with patient harm.

• Healthcare practitioners should:
  – Be aware of high risk processes in the medication use system
  – Deliver clear communication within the circle of care
  – Consider technology as a potential clinical decision support system

• Potential recommendations include independent double checks, medication reviews, and technology aids in practice.
Conclusion
Lessons Learned & Shared

• Different types of medication incident analysis
  – Complementary nature

• Quantitative analysis provides a broad picture of the incidents, but qualitative analysis is necessary to understand the contributing factors

• Incident reporting allows for analysis and shared learning

• Quality of incident analysis greatly depends on not only the quantity, but also the quality of incidents reported
  – Reports rich in details ➔ High-quality solutions
Key Messages
Implications to Pharmacy Professionals

3 WAYS OF REPORTING ONLINE

- Serious Adverse Drug Reactions
- Medical Device Incidents
- Medication Incidents

CANADIANS

Stronger Knowledge leads to Safer Products

RESULTS
- Feedback
- Learning
- Improvements

REPORTING

Vanessa’s Law

Today’s Focus
Continuous Quality Improvement (CQI)

1. Reporting
   Medication incidents, from near miss to causing patient harm, should be documented

2. Analysis
   Based on the harm and your unique settings, find commonalities between the incidents

3. Solution Development
   Work with your team and brainstorm solutions appropriate for your setting

4. Implementation
   Prioritize and implement solutions with high standards and effectiveness
References

