Medication errors and patient safety: tools for system improvement

PHM 301
Julie Greenall
ISMP Canada
Advancing safe medication use

The Institute for Safe Medication Practices Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices. ISMP Canada’s mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Reporting and Prevention Systems

- **Medication Incident and Near Miss Reporting Programs for:**
  - Practitioners
  - General Public
  - SafeMedicationUse.ca

MOHLTC Supported Initiatives

- **Ontario Critical Incident Learning**
  - Safe Use of Insulin Interventions
  - Medication Safety Support Service (MESS)
  - Ontario Antimicrobial Stewardship Project
  - Operating Room Medication Safety Checklist®
  - FMEA Report - Reducing the Risk of Incorrect Injection of Concentrated Epinephrine Intended for Topical Use
  - Multiple IV Infusions Project | Webinar
  - Safe Medication Use in Older Persons

Multi-Stakeholder Projects

- **Canadian Pharmaceutical Bar Coding Project**
- **MyMedRec App: Keep track of your medicines and vaccines**
- **Canadian Incident Analysis Framework**
- **Consumers Can Help Prevent Harm from Optimal Use**

Upcoming ISMP Canada Events

<table>
<thead>
<tr>
<th>Webinars</th>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wednesday, October 2, 2013</td>
<td>The Risk of Look-Alike Arterial Blood Gas Syringes: A Blinded Experiment</td>
<td></td>
</tr>
<tr>
<td>Tuesday, October 8, 2013</td>
<td>Promoting the Safe Use of Insulin in Hospitals</td>
<td></td>
</tr>
<tr>
<td>Wednesday, September 18, 2013</td>
<td>This session is full. BPHM Training for Pharmacy Technicians - Toronto, ON</td>
<td></td>
</tr>
<tr>
<td>Wednesday, September 26, 2013</td>
<td>Request to be placed on the wait list of this session</td>
<td></td>
</tr>
<tr>
<td>Thursday, September 26, 2013</td>
<td>Root Cause Analysis (RCA) Workshop for Pharmacists - Toronto, ON</td>
<td></td>
</tr>
<tr>
<td>Friday, September 27, 2013</td>
<td>Incident Analysis Framework Trainer Workshop For PSEP-Canada Trainers - Toronto, ON</td>
<td></td>
</tr>
<tr>
<td>Friday, September 27, 2013</td>
<td>Proactive Risk Assessment in Pharmacy Practice using Failure Mode and Effects Analysis (FMEA) - Toronto, ON</td>
<td></td>
</tr>
<tr>
<td>Wednesday, October 9, 2013</td>
<td>Root Cause Analysis (RCA) Workshop for Nurses - Toronto, ON</td>
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</table>
Preventing harm from medication incidents is a responsibility of health professionals. Consumers like you can also play a vital role.

Reporting Medication Incidents benefits all Canadians.

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Neuromuscular blocking agents, also known as paralyzing agents, are high-risk medications. They paralyze muscle function by blocking the connection between nerves and muscles. Notably, the muscles that are essential for breathing become paralyzed in patients who receive these medications—these patients need to be intubated and ventilated. Serious injuries and deaths have occurred with substitution errors involving these drugs. Incidents involving inadvertent administration of neuromuscular blocking agents and recommendations for prevention of error have been highlighted in previous issues of the ISMP Canada Safety Bulletin. The purpose of the current bulletin is to affirm the progress that has been made in the packaging and labelling of these drugs, in an effort to sustain key safety improvements.

**Background**

In 2006, ISMP Canada convened a meeting of representatives of Canadian manufacturers of neuromuscular blocking agents. The intent was to collaborate in identifying opportunities to reduce the risk for accidental administration of a neuromuscular blocking agent because of a product mix-up.

The pharmacological representatives agreed upon several ideal packaging and labelling features for neuromuscular blocking agents to help differentiate them from other drugs:

- red cap with white lettering: “Paralyzing Agent” or “Warning: Paralyzing Agent”
- red female (metal seal) with white lettering: “Paralyzing Agent”
- red lettering on the product label: “Paralyzing Agent” or “Warning: Paralyzing Agent”
- peel-off label, using the colour scheme and content information recommended in standards for labels to be applied to proposed syringes, as set out by the Canadian Anaesthesiologists Society (CAS; www.cas.ca) and the American Society of Anaesthesiologists (ASA; www.asahq.org)
- space on the product label for application of a bar code

Although it is not known what caused this particular incident, 10-fold errors can be the result of calculation mistakes. They can also occur when different strengths of the same product look similar. Be aware that this type of error is possible.

**Conclusion**

The ISMP Canada Safety Bulletin offers recommendations for improving the safety of neuromuscular blocking agents. The bulletin emphasizes the importance of clear and consistent packaging and labelling, as well as the use of technologies like bar codes and electronic prescribing systems to reduce the risk of medication errors.

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**Sharing Insulin Pens is a High-Risk Practice**

Insulin pens are injection devices that are designed to help patients administer insulin accurately. However, they can be dangerous if shared among multiple users, as the risk of cross-contamination is high. This practice is particularly concerning in healthcare settings where insulin pens are commonly used. To mitigate this risk, healthcare providers should follow best-practice administration techniques while learning to use insulin pens safely.

**Call to Action for Hospitals**

- Make system-based changes to ensure insulin pens are used safely.
  - Prohibit the sharing of insulin pens between patients.
  - Assign insulin pens with cartridges already inserted.
  - Use specific labels, for single-patient use only.
  - Place patient-specific labels on the barrel of the insulin pen, not on the cap.
  - Use insulin cartridges only with an insulin pen. Do not use a needle and syringe to withdraw insulin from the cartridge.

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**Additional Resources**

- ISMP Canada: www.ismp-canada.org
Learning Objectives

After attending this lecture and completing the assigned readings, students should be able to:

• Explain the need for risk management activities in pharmacy practice settings

• Be able to select and apply appropriate medication safety tools to support risk management activities:
  • Incident analysis (root cause analysis)
  • Prospective risk assessment
    • Failure mode and effects analysis
    • Medication safety self assessment program

...... Cont’d
Learning Objectives (cont’d)

• Explain the rationale for multidisciplinary participation in analysis teams; and

• Apply systems theory and human factors engineering principles at a basic level in the identification of contributing factors to incidents and the development of strategies to reduce the likelihood of medication incidents.
This lecture builds on concepts presented in earlier courses:

• Medical/medication error is a significant problem in healthcare

• A “systems” approach taking in account human factors engineering principles is key

• Human factors engineering principles impact error potential and solution development
1. Contribute to a culture of safety
2. Work in teams for patient safety
3. Communicate effectively for patient safety
4. Manage safety risks
5. Optimize human and environmental factors
6. Recognize, respond to and disclose adverse events
Required Reading

• Petrov E, Ho C. Medication Incidents Reported to and Reviewed by the ICRC: An Analysis by ISMP Canada. OCP Pharmacy Connection  2012; Summer; p. 36-38


OCP Multi-IIncident Analysis

• 2007-2008, n=78, 42.3% of errors resulted in harm

• Most frequent types of incidents included:
  • Incorrect dose/frequency/duration
  • Incorrect drug/dosage form
  • Incorrect strength/concentration

• Possible contributing factors:
  • Use of dangerous abbreviations, look-alike/sound-alike drug names, storage of look-alike packaging
  • Environmental factors, staffing or workflow problems, education, miscommunication

Petrov E, Ho C. Medication Incidents Reported to and Reviewed by the ICRC: An Analysis by ISMP Canada. OCP Pharmacy Connection Summer 2012; p. 36-38
OCP Analysis (cont’d)

• Common medications reported include:
  • Levothyroxine (8), amlodipine (5), clindamycin (3), warfarin (3)
  • Previous review (2008; n=229) identified warfarin, prednisone, atenolol and chlorpromazine

• Areas of concern:
  • Documented allergy
  • Keeping up to date with therapy changes in blister packs
  • Compounding errors

Petrov E, Ho C. Medication Incidents Reported to and Reviewed by the ICRC: An Analysis by ISMP Canada. OCP Pharmacy Connection Summer 2012; p. 36-38
Ontario Hospitals: Critical Incident Reporting (2011-13)

• 59 incidents reported between Oct 1, 2011 and Dec 31, 2013
  • 16 - death
  • 49 – severe harm

• Most common incident types
  • Wrong rate/ frequency
  • Wrong product
  • Wrong quantity

Medications most commonly involved in critical incidents in Ontario hospitals

Year 1: 2011-2012

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Severe Harm</th>
<th>Death</th>
<th>Total</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydromorphone</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>11.1</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6.7</td>
</tr>
<tr>
<td>Heparin</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Morphine sulphate</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>4.4</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>4.4</td>
</tr>
</tbody>
</table>

Year 2: 2013

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Severe Harm</th>
<th>Death</th>
<th>Total</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>hydromorphone</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>17.6</td>
</tr>
<tr>
<td>desmopressin</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>epinephrine</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>heparin</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>morphine</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
</tbody>
</table>
High-Alert Medications

Drugs that bear a heightened risk of causing significant patient harm when they are used in error.

e.g.; opioids, insulin, anticoagulants

Incident Analysis
(Root Cause Analysis)
Why is analysis important?

• Errors occur at all levels of healthcare.
• All staff, even the most experienced and dedicated professionals can be involved in preventable adverse events.
• Accidents result from a sequence of events and tend to fall in recurrent patterns regardless of the personnel involved.
Case Example

- Insulin dependent diabetic
- Rx for Novolin® ge 30/70 Penfill twice daily via insulin pen
Case Example (cont’d)

• Patient obtained insulin Rx refill
• Next morning, inserted new cartridge into pen
• A short time later, patient found:
  • Diaphoretic (perspiring profusely)
  • Pupils dilated
  • Decreased level of consciousness
  • Glucometer 2.5 mmol/L (normal 4-7 mmol/L)
How can we analyze this incident effectively?

• Designed to provide a standardized approach to analysis of critical incidents and near miss events in healthcare environments.
Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM

CLOSE THE LOOP
Share what was learned (internally and externally)

BEFORE THE INCIDENT
Ensure leadership support
Cultivate a safe and just culture
Develop a plan including resources

IMMEDIATE RESPONSE
Care for and support patient/family/providers/others
Report incident
Secure items
Begin disclosure process
Reduce risk of imminent recurrence

PREPARE FOR ANALYSIS
Preliminary investigation
Select an analysis method
Identify the team
Coordinate meetings
Plan for/conduct interviews

ANALYSIS PROCESS
Understand what happened
Determine how and why it happened
Develop and manage recommended actions

FOLLOW THROUGH
Implement recommended actions
Monitor and assess the effectiveness of actions

Canadian Incident Analysis Framework

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Preliminary Investigation

• An initial understanding is prepared based on the facts known at the time.
  • Effective ways to provide this information may be a flow chart or narrative timeline, or chronological description.

• The team reviews the initial understanding to determine next steps and where the information gaps exist.
When are other processes appropriate?

• Was the event thought to be the result of:
  • a criminal act;
  • a purposefully unsafe act;
  • an act related to substance abuse by provider/staff;
  • or events involving suspected patient abuse of any kind (i.e. situations outside the scope of the risk management / quality improvement program)?

• If yes, refer to applicable administrative processes.

(Based on VA Triage Questions for RCA, 2000)
Interdisciplinary Team-Based Approach

• Provides important perspective
  • Practitioners with different clinical backgrounds will view situations with a different “lens”
  • Detailed examination often identifies information not known by all team members

• Invaluable to involve frontline staff
  • Staff understand and have direct knowledge of care processes
  • Participation creates greater visibility and acceptability for the recommendations
  • Will ultimately be responsible for implementing and sustaining process change(s)
Interview Process

• As soon as possible after the event
• One person at a time
• Interview all staff involved in event as well as patient/consent provider and family as appropriate.
• Cooperative approach is important
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Canadian Incident Analysis Framework
What Happened

- Gather Information
  - Review incident report/ initial understanding
  - Review additional information
    - Interviews, prescription, drug labelling and packaging, pharmacy physical environment
- Create a detailed timeline
- Review supporting information:
  - Policies, procedures, literature, environmental scan, previously reported incidents, consultations with colleagues or experts
What Happened

• When insulin supply was checked, found 4 boxes of Novolin® ge 30/70 (intermediate + short-acting insulin) and one box of NovoRapid® insulin (rapid-acting insulin)
Packaging and Labelling
What Happened

- Use a timeline to plot the event
  - Capture what actually happened, *not* what was supposed to happen
  - Often very different than the initial understanding as systems and underlying processes are uncovered
## Timeline

<table>
<thead>
<tr>
<th>Time</th>
<th>Information Item</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:30 pm, 3 days prior to event</td>
<td>Patient calls for refill of insulin prescription from community pharmacy – will pick up in evening.</td>
<td>Prescription record</td>
</tr>
<tr>
<td>5:00 pm</td>
<td>Technician processes refill in the computer and leaves the label in a basket for filling by the dispensary student</td>
<td>Technician interview</td>
</tr>
<tr>
<td>5:30 pm</td>
<td>Student obtains 5 boxes of insulin from fridge and scans the top box 5 times, labels the top box, and then tapes all 5 boxes together. The prescription is left in the basket for the pharmacist to check.</td>
<td>Technician and student interview</td>
</tr>
<tr>
<td>5:50 pm</td>
<td>Pharmacist checks DIN on top box against prescription hard copy and signs off. Insulin placed in refrigerator for pick-up; bag and receipt placed in pick-up bin with note “medication in fridge”.</td>
<td>Pharmacist interview</td>
</tr>
<tr>
<td>8:40 pm</td>
<td>Patient’s wife comes in to pick up insulin. Student retrieves from refrigerator, bags and gives to patient’s wife.</td>
<td>Student and patient/family interview</td>
</tr>
<tr>
<td>9:00 pm</td>
<td>Patient’s wife places in home refrigerator.</td>
<td>Patient/family interview</td>
</tr>
</tbody>
</table>
## Timeline

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Information Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 am</td>
<td>Patient reloads cartridge into insulin pen and administers as usual</td>
<td>Patient/family interview</td>
</tr>
<tr>
<td>day of event</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:45 am</td>
<td>Patient found with decreased level of consciousness, sweating and</td>
<td>Patient interview</td>
</tr>
<tr>
<td></td>
<td>with dilated pupils by family member</td>
<td></td>
</tr>
<tr>
<td>7:50 am</td>
<td>Patient given sugar, followed by food by family member</td>
<td>Patient interview</td>
</tr>
<tr>
<td>8:00 am</td>
<td>Glucometer reading 2.5 mmol/L</td>
<td>Patient interview</td>
</tr>
<tr>
<td>8:15 am</td>
<td>Patient’s wife calls Telehealth who recommends they go to the</td>
<td>Patient interview</td>
</tr>
<tr>
<td></td>
<td>Emergency Dept and advises patient’s wife to bring all medications</td>
<td></td>
</tr>
<tr>
<td>9:20 am</td>
<td>IV Dextrose administered; kept for observation x 4 hours</td>
<td>Patient interview</td>
</tr>
<tr>
<td>12:45 pm</td>
<td>Emergency physician reviews medications prior to discharge and</td>
<td>Patient interview</td>
</tr>
<tr>
<td></td>
<td>notices one insulin box is NovoRapid.</td>
<td></td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Patient’s wife contacts pharmacy to advise of dispensing error.</td>
<td>Patient interview</td>
</tr>
</tbody>
</table>
How and Why the Incident Happened

• Analyze information to identify contributing factors and the relationship(s) among them:
  • Use systems theory and human factors
  • Use diagramming
• Summarize findings
Systems Approach

Focus on improving the processes, systems, and environment in which people work rather than attempting only to improve individual skills and performance.

Human Factors Engineering

• The design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics.

• Human factors engineers work to make the environment function in a way that seems natural to people.
How and Why the Incident Happened

• Reasons for incidents are multi-factorial
• Need to consider
  • System/process design
  • Workflow
  • Individual accountability – e.g., workarounds
Key Determinants of Adverse Drug Events

Preventable Adverse Drug Events

Proximate (e.g., Human Factors)
- Prescribed High-Risk Medications (e.g., hypoglycemics, opioids, anticoagulants)
- Polypharmacy
- Medical and/or Psychiatric Comorbidities
- Multiple Providers
- Nonadherence or Misuse

Latent (e.g., Organizational and System Factors)
- Difficult to Use Materials
- Look-Alike Materials or Medications
- Policies Not in Place
- To Report and Investigate ADEs
- High Workload
- Unable to Counter Authority Gradient
- Organizational Culture
- Leadership Focus on Individual Rather Than Systems Improvement
- Formulas: Restrict Use of Certain Medications
- Fragmented Healthcare Delivery/Poor Care Coordination

Technical
- Limited Time in Patient-Provider Interaction for Counseling
- High Workload
- Unable to Counter Authority Gradient
- Organizational Culture
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Organizational
- Policies Not in Place
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Healthcare System
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- High Workload
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- Leadership Focus on Individual Rather Than Systems Improvement
- Formulas: Restrict Use of Certain Medications
- Fragmented Healthcare Delivery/Poor Care Coordination

Provider
- Provider Shift Change
- Medication Incorrectly Administered
- Order eligible
- Medication Incorrectly or Inappropriately Prescribed
- Prescribed High-Risk Medications (e.g., hypoglycemics, opioids, anticoagulants)

Patient
- Lack Access to Accurate Health Information
- Poor Health Literacy
- Polypharmacy
- Medical and/or Psychiatric Comorbidities
- Multiple Providers
- Nonadherence or Misuse

Reality of Health Care Environments

- Cognitive overload
- Workloads
- Multitasking
- Interruptions
- Difficult technology
- Look-alike packaging and labelling
- Sound-alike medication names
Workarounds - “At-Risk” Behaviours

• Natural tendency to take shortcuts to make completion of tasks easier or increase efficiency

• Workarounds occur when a procedure or action does not “fit” with the workflow
Workaround Research

• 84 percent of physicians and 62 percent of nurses/other clinical-care providers have seen co-workers taking shortcuts that could be dangerous to patients.

• Fewer than 10 percent of physicians, nurses and other clinical staff directly confront their colleagues about their concerns
  • 1 in 5 physicians said they have seen harm come to patients as a result.

American Association of Critical Care Nurses
How and Why the Incident Happened

• Diagramming can be a helpful tool to:
  • Visualize relationships
  • Move away from the “sharp end”
  • Avoid “hindsight bias”
Constellation Diagramming
Steps to Create a Constellation Diagram

Step 1: Describe the incident and outcome

2012. Canadian Incident Analysis Framework, page 93
Step 2: Identify potential contributing factors

First, list the contributing factor categories in a circle around the incident.
Step 2 (cont’d)

Next, begin to list possible influencing factors within each category

• Ask questions like “What caused this?”; “What was this influenced by?”

• “5 levels of Why”
Potential contributing factors

• For each potential contributing factor ask:
  • How and why did this happen?
  • What was this influenced by?
  • What else influenced the circumstances?

• Use this information to build “relational chains” of contributing factors

• Use the guiding questions to brainstorm contributing factors (CI AF 2012, p. 89)
Examples of Guiding Questions

Task (care/work process):

» Were there previous or predicted failures for this task or process?
» Were specialized skills required to perform the task?
» Was a fixed process or sequence of steps required (e.g. order sets, checklists)?
  Did it exist and was it followed?
» Was a protocol available, was it up-to-date, and was it followed in this case?
» Were there constraints or pressures (e.g. time, resources) when performing the task?
» Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)?
» Was there a risk assessment/audit/quality control program in place for the task/process?
» Other?
Step 3: Define relationships among potential contributing factors
Step 4: Identify the findings

Three categories of findings:

1. Preventive factors:
   - If corrected, would likely have prevented the incident or mitigated harm

2. Incidental factors:
   - If corrected, would likely not have prevented the incident or mitigated the harm but important for patient/staff safety

3. Mitigating factors:
   - Factors that didn’t allow the incident to have more serious consequences and represent solid safeguards that should be kept in place – mitigating factors.

CIAF 2012, p. 96-98
Step 5: Confirm the findings with the team
Summarize findings

• Statement of findings:
  • Focus on the contributing factors
  • Be as specific as possible

• Statement format:
  • “the contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur”

• Provides the backbone for development of recommended actions
Sample Statement

Unclear task and role definition increased *the likelihood that* a student would be responsible for selecting medications during dispensing, in turn *increasing the likelihood of* a medication selection error leading to a patient receiving and self administering an incorrect medication.
Develop and Manage Recommended Actions

- What can be done to reduce the risk of recurrence and make care safer:
  - Develop recommended actions
  - Suggest an order of priority
  - Prepare a summary report for endorsement by leadership as appropriate
  - Delegate recommended actions for implementation and empower implementation
Ideas for redesign???
Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM

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- Share what was learned (internally and externally)

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- Monitor and assess the effectiveness of actions

Canadian Incident Analysis Framework
How can we share learning with others??

A patient with insulin-dependent diabetes had a prescription for Novolin® 30/70 Penfill® and was self-administering the drug every morning and every evening by insulin pen (Novolin® Pen). The patient had recently obtained from the community pharmacy a refill of the cartridge prescription, receiving several boxes of 5 cartridges each. On the morning of the incident, the patient had inserted a new cartridge, taken from one of the new boxes, into the insulin pen. A short time after self-injecting the prescribed morning dose, the patient was found in a diaphoretic state, with pupils dilated and with a decreased level of consciousness. Fortunately, the symptoms were recognized as signs of hypoglycemia, and the patient was given sugar followed by additional food. Shortly thereafter, the patient’s blood glucose level, measured with a glucometer, was approximately 2.5 mmol/L. Because of the unexplained hypoglycemia, the insulin supply was checked. It was discovered that one box of NovoRapid® insulin had been given to the patient, along with several boxes of the correct Novolin® 30/70. A dose of Novolin® 30/70 consists of 30% short-acting insulin and 70% intermediate-acting insulin. In contrast, NovoRapid® is an ultrashort-acting insulin.

The following contributing factors were identified in this report:

- Novolin® 30/70 and NovoRapid® cartridges have similar packaging and labelling (Figures 1, 2, and 3).
- Although a barcode system was in use at the pharmacy, only one of the dispensed boxes had been scanned.

In addition to these factors, NovoRapid® and Novolin® 30/70 are likely to be stored in close proximity in a pharmacy; each is a form of insulin, both require refrigeration, and both brand names begin with “Novo”. As such, an incident like this one could easily occur in other pharmacies, as the underlying factors are likely to exist wherever these products are stocked (e.g., community pharmacies, hospitals).

The community pharmacy alerted its staff to the incident as a reminder of the standard procedure to check and scan every package during the dispensing process. ISMP Canada also offers the following recommendations for consideration:

- Segregate products. Consider storing insulin products according to their onset of action (e.g., rapid-acting, short-acting, intermediate-acting, long-acting) as well...
How do we prevent errors from occurring in the first place.....

.....prospective risk assessment
Examples of Prospective Analysis Processes used in Industry

- Errors of Omission (James Reason)
- Simulation
- Fault Tree Analysis
- Hazard Analysis
- Worst-case Analysis
- Hazard Analysis and Critical Control Point (HACCP)
- LEAN
- Failure Mode and Effects Analysis
Commonalities

- Multidisciplinary, team-based, and systematic approach
- Identification of process steps/ process mapping/ task analysis
Failure Mode and Effects Analysis

• FMEA focuses on how and when a system will fail, not if it will fail.

• Future, preventive, proactive
  • Opposite to incident analysis (root cause analysis) which is retrospective (after the event or close call occurs)
Gains Using FMEA

- Safety minded culture
- Proactive problem resolution
- Fault tolerant systems
- Lower waste and higher quality
- Engagement of front-line staff
- Improved team communication
## Conducting an FMEA: 8 Steps

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<thead>
<tr>
<th>Step</th>
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<td>Step 8</td>
<td>Implement and monitor the redesigned processes</td>
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High Risk Processes (Definition)

Those processes in which a failure of some type is most likely to jeopardize the safety of the individuals served by the health care organization. Such process failures may result in a sentinel event.
A Team-based Process

- Interdisciplinary
- Those with direct knowledge of care processes
- Those responsible for change
## Conducting an FMEA: 8 Steps

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</table>
2a: Diagram the Process

Diagrams from The Systems Approach to Quality Assurance: A Framework for Mitigating Risk (Alberta College of Pharmacists and ISMP Canada)
Available from: https://pharmacists.ab.ca/Content_Files/Files/FMEA_web.pdf
2b: Diagram the Sub-process

- **5a**: Patient requests medication at pick-up area
- **5b**: Pharmacy staff member verbally repeats patient name
- **5c**: Pharmacy staff member retrieves prescription from storage area
- **5d**: Pharmacy staff member requests second identifier (e.g., address, date of birth)
- **5e**: Pharmacy staff member confirms two identifiers against prescription receipt
- **5f**: Prescription is released to patient
Conducting an FMEA: 8 Steps

- **Step 1**: Select process and assemble the team
- **Step 2**: Diagram the process
- **Step 3**: Brainstorm potential failure modes
- **Step 4**: Identify the effects and causes of the potential failure modes
- **Step 5**: Prioritize failure modes
- **Step 6**: Redesign the processes to address the potential failure modes
- **Step 7**: Analyze and test the changes
- **Step 8**: Implement and monitor the redesigned processes
3: Brainstorm Potential Failure Modes

5a
Patient requests medication at pick-up area

5b
Pharmacy staff member verbally repeats patient name

5c
Pharmacy staff member retrieves prescription from storage area

5d
Pharmacy staff member requests second identifier (e.g., address, date of birth)

5e
Pharmacy staff member confirms two identifiers against prescription receipt

5f
Prescription is released to patient

5a1
Patient goes by more than one name (e.g., first name vs. nick name)

5b1
Pharmacy staff member does not verbally repeat patient name

5c1
Prescription not in storage area

5d1
Pharmacy staff member does not request a second identifier

5e1
Two identifiers not confirmed

5f1
Incorrect prescription released

5a2
Pharmacy staff member mishears patient name

5b2
Patient does not identify incorrect name used by pharmacy staff member

5d2
Second identifier is not unique (e.g., patients with similar names at same address)

5e2
Second identifier is not unique (e.g., patients with similar names at same address)
Cognitive Walkthrough

• Helps the FMEA team to better understand the process under review, from the perspective of the practitioner

• Its approach to identifying failure modes (potential risks) goes beyond, and can be complementary to brainstorming

• Physically walking through the process to examine the mental activities required at each step and the challenges experienced
### 4a. Identify Effects of Potential Failure Modes

<table>
<thead>
<tr>
<th>FMEA subject:</th>
<th>Process:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient identification in the dispensing process</td>
<td>#5: Prescription is released to patient</td>
</tr>
</tbody>
</table>

**Sub-process component:**
5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)

<table>
<thead>
<tr>
<th>Failure mode number</th>
<th>Potential failure modes</th>
<th>Effect(s) of failure</th>
<th>Cause(s) of failure</th>
<th>Severity (1-5)</th>
<th>Frequency (1-5)</th>
<th>Detectability (1-4)</th>
<th>Criticality score</th>
<th>Proceed? Yes or No</th>
<th>Actions to reduce risk and time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>5d1</td>
<td>Pharmacy staff member does not request second identifier</td>
<td>Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
<tr>
<td>5d2</td>
<td>Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building</td>
<td>Same as 5d1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes or No</td>
<td></td>
</tr>
</tbody>
</table>
### 4b. Identify Causes of Potential Failure Modes

**FMEA subject:** Patient identification in the dispensing process

**Sub-process component:**
5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)

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<tr>
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<tbody>
<tr>
<td>5d1</td>
<td>Pharmacy staff member does not request second identifier</td>
<td>Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed</td>
<td>Incomplete identification.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5d2</td>
<td>Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building</td>
<td>Same as 5d1</td>
<td>Second identifier is not unique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 5. Prioritize the failure modes

• Severity (1-5)
  • No effect (1), slight, moderate, major, severe/catastrophic (5)

• Frequency (1-5)
  • Yearly (1), monthly, weekly, daily, hourly (5)

• Detectability (1-4)
  • Always (1), likely, unlikely, never (4)
5. Prioritize

<table>
<thead>
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<tr>
<td>5d1</td>
<td>Pharmacy staff member does not request second identifier</td>
<td>Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed</td>
<td>Incomplete identification</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>24</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5d2</td>
<td>Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building</td>
<td>Same as 5d1</td>
<td>Second identifier is not unique</td>
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<td>24</td>
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Conducting an FMEA: 8 Steps

Step 1: Select process and assemble the team

Step 2: Diagram the process

Step 3: Brainstorm potential failure modes

Step 4: Identify the effects and causes of the potential failure modes

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Step 7: Analyze and test the changes

Step 8: Implement and monitor the redesigned processes
### 6: Redesign the Process

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<th>FMEA subject: Patient identification in the dispensing process</th>
<th>Process: #5: Prescription is released to patient</th>
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</thead>
<tbody>
<tr>
<td><strong>Sub-process component:</strong></td>
<td></td>
</tr>
<tr>
<td>5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)</td>
<td></td>
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<th>Frequency (1-5)</th>
<th>Detectability (1-4)</th>
<th>Criticality/score</th>
<th>Proceed? Yes or no</th>
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</table>
| 5d1                | Pharmacy staff member does not request second identifier | Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient receiving medication prescribed | Incomplete identification | 4              | 2              | 3                   | 24                  | Yes              | Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedures (1 month)  
Develop a standardized process requiring documentation of the second identifier used to verify the patient’s identity (1-3 months)  
Post information for patients explaining the identity verification process and the rationale; request their assistance in ensuring it takes place (1-3 months)  
Implement a photo identification process for selected high alert medications (e.g., methadone) (3-6 months)  
Assess opportunity for automation (e.g., barcoding) as a long-term goal (more than 12 months) |
### Summary of Recommendations and Timelines

<table>
<thead>
<tr>
<th>FMEA subject: Patient identification in the dispensing process</th>
<th>Process: #5: Prescription is released to patient</th>
<th>Sub-process step: #5c: Pharmacy staff member requests second identifier</th>
</tr>
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<tbody>
<tr>
<td><strong>Failure mode number</strong></td>
<td><strong>Recommended action</strong></td>
<td><strong>Strength of action</strong></td>
</tr>
<tr>
<td>5d1</td>
<td>Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedure</td>
<td>Low (policy development / education)</td>
</tr>
<tr>
<td>5d1</td>
<td>Develop a standardized process requiring documentation of the second identifier used to verify the patient’s identity</td>
<td>Medium (simplification / standardization)</td>
</tr>
<tr>
<td>5d1</td>
<td>Post information for patients explaining the identity verification process and the rationale and requesting their assistance in ensuring it takes place</td>
<td>Low (policy development / education)</td>
</tr>
<tr>
<td>5d1</td>
<td>Implement photo identification for selected high-alert medications (e.g., methadone)</td>
<td>Medium (reminders, checklists, double-checks)</td>
</tr>
<tr>
<td>5d1</td>
<td>Assess opportunity for automation (e.g., barcoding) as a long-term goal</td>
<td>High (automation / computerization)</td>
</tr>
<tr>
<td>5d2</td>
<td>Flag known patients with the same or similar names in the pharmacy computer system indicating requirement for data of birth identification for all prescriptions</td>
<td>Medium (reminders / checklists / double checks)</td>
</tr>
<tr>
<td>5d2</td>
<td>Ensure addresses for multi-unit dwellings include the specific unit</td>
<td>Low (policy development / education)</td>
</tr>
</tbody>
</table>

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Can you think of examples of processes that FMEA could help you to improve??

- pharmacy setting?
- other workplace?
- outside work/ school?
Another Type of Prospective Assessment: MSSA

Medication Safety Self-Assessment® (MSSA)

- Designed to help practitioners assess the safety of their own practice sites

- Web-based program allows comparison to aggregate data as well as monitor individual progress over time
Benefits of MSSA

- Assists with identification of areas of risk in an individual practice site
- Provides focus for quality improvement projects
- Generates local interest in system and culture change
- Provides a record of improvement over time
- Development of provincial / national database for comparative purposes
Internal and External Comparisons

- Web-based program allows comparison to:
  - Previous in-house surveys
  - Total aggregate
- Select fields:
  - Pharmacy size and type
  - Ownership
  - Prescriptions dispensed per week
  - FTEs
  - Services offered
  - Province
Demographics as of 10Sept2014 (n = 778)
Medication Safety Self-Assessment

Aggregate and User Scores by Key Elements

Scores as % Max. Weighted Scores

Key Elements

User Scores  Total Score  Std Dev  Average Aggregate Data (n=306)
Three Ways to Improve Safety

3 goals that guide safety efforts:

1. Mitigate or minimize harm from errors
   • ↓ Severity

2. Reduce or eliminate risks that cause error
   • ↓ Frequency

3. Make the error visible
   • ↑ Detectability
**SYSTEM-Based**

**Low Leverage**
- Rules and policies (e.g., policies to prohibit borrowing doses from other areas)

**Medium Leverage**
- Simplification and standardization (e.g., standardized paper or electronic order sets)

**High Leverage**
- Forcing functions and constraints (e.g., removal of a product from use)
- Automation or computerization (e.g., automated patient-specific dispensing)

**PERSON-Based**

**Low Leverage**
- Reminders, checklists, double checks (e.g., independent double checks for high-alert medications)

**Medium Leverage**
- Education and information (e.g., education sessions on high-alert medications)

**Hierarchy of Effectiveness**
Incident Reporting

• Why report incidents?

• How can you report incidents?
CPhIR Demo Site:

Login at http://www.cphir.ca/training

Username: testuser
Password: testuser

ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program

The Institute for Safe Medication Practices Canada (ISMP Canada) Community Pharmacy Incident Reporting (CPhIR) Program supports submission of medication incident reports to ISMP Canada using a secure transfer protocol. The reporter will be provided with a login ID and password that also allow for viewing individual pharmacy data and aggregate data from the CPhIR incident database. The data transmission is encrypted and strict confidentiality guidelines are enforced. ISMP Canada asks institutions or pharmacies submitting incident reports to ensure that all identifying information is removed before submission. ISMP Canada has completed a privacy impact assessment (PIA). Incident data are used by ISMP Canada only for the purposes of analysis, shared learning, and incident prevention strategy formulation.

ISMP Canada would like to acknowledge the support from the Ontario Ministry of Health and Long-Term Care for the development of the CPhIR Program. The feedback from community pharmacists who participated in the SafetyNET pilot project in Nova Scotia in 2008-2009 has also been extremely helpful and is very much appreciated.

Frequently Asked Questions
Contact ISMP Canada
Analysis of Medication Incidents in Community Pharmacy

Cerina Ho, Neil J. MacPherson, Todd A. Boyle, Tom Mathay, Bev Zwicker, Heidi Deal, Andrea Scoble, Sean Higgins, Roger Cheng, Patricia Hung, Gary Lee

Objectives

The Community Pharmacy Incident Reporting (CPHRI) program has been designed by ISMP Canada to improve medication safety in community pharmacies. This program assists community pharmacies in identifying and preventing medication errors. The project involved 18 community pharmacies in Nova Scotia, Canada.

Methodology

From August 2008 to January 2010, 1544 incidents were voluntarily reported by 18 community pharmacies participating in the SafetyNETRx® Pilot project. These 12 duplicates or test entries were excluded, leaving 1322 incidents to be analyzed. A focus was placed on the severity of outcome of the incidents to determine the underlying causes of medication errors.

Results

Severity of Outcome

- 160 (10.44%) incidents were near misses (Figure 1).
- 90 (5.87%) incidents resulted in no harm, which is acceptable (Figure 1).
- Only 1 (0.07%) incident resulted in temporary patient harm, which required the intervention of the pharmacist to correct the medication error (Figure 1).

Medication-Use Areas

- The majority of incidents occurred during the Order Entry/Transcription and the Dispensing/Dispensing stages – the two most common stages in community pharmacies (Figure 2).
- The most common types of incidents reported were incorrect dose, incorrect duration of treatment, incorrect strength/concentration, incorrect drug, and incorrect medication.
- More than one medication can be reported for a single incident. There were 1799 medications reported. The top five medications were pregabalin, celecoxib, ramipril, and metformin.

Possible causes of medication incidents (Figure 3):

- Medication errors due to a lack of knowledge or training.
- Medication errors due to a lack of communication.
- Medication errors due to a lack of technology or software.

Conclusion

This analysis of medication incidents serves as an initial attempt to study factors that may contribute to medication incidents in community pharmacies. It is important to identify the frequency of specific incidents to guide future research. Though, the analysis suggests that there is a potential to significantly reduce preventable patient harm by focusing on several specific high-risk medication-use areas.

Creating a culture of patient safety within the support of a non-punitive reporting system is essential to improving medication safety in the community pharmacy. As the ISMP Canada CPHRI program continues to accumulate data over time, trends and changes in medication incident patterns can be identified. CPHRI will continue to contribute to CEMPS and help identify new areas of focus to enhance medication safety.
Continuous Quality Assurance Pilot Project in Saskatchewan Community Pharmacies

Certina Ho, RPh, BScPhm, MSc, Med; Jim Hanwen Kong, BSc, Pharm D Candidate; Carol Lee, C.H.M.

Objectives
- Continuous quality assurance (CQA) is necessary for advancing safe medication practices in community pharmacies.
- COMPASS™ (Community Pharmacists Advancing Safety in Saskatchewan) (https://compass.cpsa.sk.ca) is a CQA pilot project for community pharmacies in Saskatchewan, Canada.
- A component of this pilot project is to determine the underlying system-based contributing factors to medication incidents in community pharmacies voluntarily reported to the ISMP Canada Community Pharmacy Incident Reporting (CPIR) Program (www.ismpca.ca) and focus on the need for learning from incident reporting.

Methods
- From September 2013 to April 2014, 436 incidents were voluntarily reported by 9 community pharmacies participating in the COMPASS™ CPIR pilot project.
- The medication incidents were analyzed, with a focus on the severity of outcome of the incidents and medication-use associated with these incidents in community pharmacy.

Results
- Of the 436 incidents, 89% (392 of 456) were near misses, 16% (42 of 269) resulted in no harm, i.e., medication was dispensed, but no symptoms were detected and no treatment was required in patients. 5% (2 of 45) resulted in mild harm to patients, i.e., symptoms were mild, temporary and short-term, no treatment or minor treatment was required (Figure 1).
- The majority of incidents occurred during the Prescription Order Entry and the Prescription Dispensing stages.
- The most common type of incident reported was incorrect quantity (28%), incorrect dose frequency (18%), and incorrect prescription (13%) (Figure 2).
- Possible contributing factors to these near misses and medication incidents include illegible prescription orders, dangerous abbreviations, looks alike/ sound alike drug names, and interruptions in workflow.

Discussion
- Learning from medication incidents is a fundamental step to medication system improvement.
- Through the analysis of incidents and sharing of findings, practitioners can learn from reported incidents and implement safeguards.
- Creating a culture of patient safety with the support of a non-punitive reporting system needs to be encouraged within all areas of pharmacy practice.
- As the ISMP Canada CPIRR Program continues to accumulate data over time, trends and changes in medication incidents patterns can be identified. CPIRR will continue contributing to the Canadian Medication Incident Reporting and Prevention System (CMIIRS) (www.cmirs.ca) and help identify new areas of focus to enhance medication safety.

The authors would like to acknowledge the support from the Ontario Ministry of Health and Long-Term Care for the development of the CPIRR program. CPIRR contributes to the Canadian Medication Incident Reporting and Prevention System (CMIIRS).

The authors would like to acknowledge the Saskatchewan College of Pharmacists for its support and facilitation of this CQA pilot project. The incidents are anonymously reported by community pharmacy practitioners in Saskatchewan to CPIRR were extremely helpful in the preparation of this paper.
Shared Accountability: “Just Culture”

“...it is about creating a reporting environment where staff can raise their hand when they have seen a risk or made a mistake....where risks are openly discussed between managers and staff.”

“...while we as humans are fallible, we do generally have control of our behavioural choices.”

“...good system design and good behavioural choices of staff together produce good results. It has to be both.”

What can you do?

Think about your practice setting:

• Where/ how could errors occur?
  • Are there gaps in the medication use process?
• Consider human performance limitations
  • Try to avoid being placed in an unsafe situation
• Review published reports of errors and take steps to address system deficiencies at your practice site
  • Consider the hierarchy of effectiveness
What can you do?

• Report incidents
• Participate in incident reviews (RCAs) and prospective assessments
• Support your colleagues when errors occur
• Support sharing of learning from errors
What can you do?

Educate others!!

• Practitioners
  • E.g., high-alert medications and effective safety strategies
  • Vulnerable populations; e.g., children, cognitively impaired

• Patients
  • How can your patients help to protect themselves?
    • Awareness of medications they are taking and uses
    • Processes to ensure correct identification
    • Awareness of high-alert medications and risk for harm
    • Look-alike sound-alike problems (e.g., Celebrex, Cerebyx, Celexa…)

Top Ten U.S. Medications, 2000 Survey

1. Little blue pill
2. Small pink round pill
3. White one shaped like a "V"
4. The one you break in half
5. Don't you have my chart
6. The one I need more of
7. You know, the one that makes me pee
8. I just took it for five days
9. Name a few - I'll know it if I hear it
10. (Tie) The one that starts with an "S"
10. (Tie) A heart pill

If you were counselling a patient about a high-alert drug tomorrow, is there something different you would tell them about?
“The healthcare industry has not sufficiently developed a healthy preoccupation with system failures....”

“Each organization needs to .... acknowledge that the absence of .... errors is not necessarily evidence of success.”

ISMP Medication Safety Alert! 2007; 12(24)
Sign up to receive bulletins
Contact information:
Julie Greenall
jgreenall@ismp-canada.org

www.ismp-canada.org