Medication errors and patient safety: tools for system improvement

PHM 310: Health Systems II
September 16th, 2015
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.
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.

Latest News and Resources

- Caution: Not All Medicines Are Taken Every Day 2015-03-31
- Beware: Medicine Names May Sound Alike, but the Medicines May Be Very Different! 2015-03-18
- Same Brand Name, Different Ingredient 2015-02-12
- Confusion with a Baby's Dose of Medicine 2015-01-14
- Reminder: Pay Attention to the Appearance of Your Medicines 2014-12-02
- Health Canada Advisory - Unlicensed Home-Use HIV Test Kits via amazon.ca
- Health Canada Advisory - Health Canada reminds Canadians not to use unauthorized health products
- Know When Your Medicine Should Be Stopped! 2014-11-04
- SafeMedicationUse.ca's Jennifer Turple talks about medication safety and drug interactions on CBC (interview starts at the 22nd minute)
- One Simple Solution for Medication Safety – Doc Mike Evans Video now available!
Death Associated with Inadequate Reassessment of Venous Thromboembolism Prophylaxis at and after Hospital Discharge

For acute care facilities, incorporate a standard process for reassessment of all medications, including VTE prophylaxis, before discharge from the acute care setting.

For LTC facilities, primary care and home care practitioners: Conduct medication reconciliation with re-dispensing/re-administration in a timely manner. Reassess the risks and benefits of VTE prophylactic regimen at transfer points (e.g., acute care to long-term care and periodically thereafter).

Venous thromboembolism (VTE) prophylaxis, also known as thromboprophylaxis, reduces the risk of deep vein thrombosis, pulmonary embolism, and death, especially in high-risk patients. VTE prophylaxis is recommended for acutely ill, hospitalized medical patients at risk of thrombosis.1

Anticoagulants, the pharmacologic agents of choice to prevent VTE, are considered high-alert medications. By definition, therefore, anticoagulants have a heightened risk of causing significant patient harm when they are used in error.2 As part of ongoing collaboration with a provincial data management service, ISMP Canada analyzed a report of a final incident that involved continuation of VTE prophylaxis with enoxaparin for a patient discharged to a long-term care (LTC) facility from an acute care setting. The findings and recommendations from this case are shared to highlight the need to build routine reassessment of VTE prophylaxis into the process for discharging patients from the acute care setting and upon transfer to another facility or to primary care.

Medication Incident

An elderly woman with a history of falls was admitted to acute care from a retirement home for treatment of a urinary tract infection. This admission followed several hospital stays over the preceding months during which she received 40 mg aspirin subcutaneously daily as prescribed for VTE prophylaxis because of decreased mobility, and then appropriately discontinued when the patient was discharged from hospital. During the most recent hospital stay, enoxaparin at the same dose was again prescribed for VTE prophylaxis for approximately 3 weeks, the patient was discharged to an LTC facility. The enoxaparin was continued as a result of a miscommunication between the discharge medication list from the acute care facility.

Within the first few weeks at the LTC home, the patient experienced 3 unexplained falls. After the first fall, she sustained a bleeding scalp wound, which prompted transfer to the local emergency department for assessment. The wound was small, but blood composition was not performed. The patient was transferred back to the LTC facility. No recommendations were made to change her medications; in particular, the enoxaparin was continued. Over the next week, the patient became...
Sign up to receive bulletins

http://www.ismp-canada.org/subscription.htm
Sign up to receive bulletins (cont’d)
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
Alignment with CPSI

Patient Safety Competencies

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 chorpromazine

• 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 (2011-14)

• 92 incidents reported between Oct 1, 2011 and Dec 31, 2014
  • 20 - death
  • 72 – severe harm

• Most common incident types reported in 2014
  • “Other”
  • Wrong quantity
  • Wrong product
  • Extra dose

Medications most commonly involved in critical incidents in Ontario hospitals

Year 3: 2014 (n=27)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Frequency</th>
<th>Severe Harm</th>
<th>Death</th>
<th>Total</th>
<th>Percentage of total incidents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROMorphine</td>
<td></td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>18.5</td>
</tr>
<tr>
<td>methadone</td>
<td></td>
<td>2</td>
<td></td>
<td>2</td>
<td>7.4</td>
</tr>
<tr>
<td>ondansetron</td>
<td></td>
<td>2</td>
<td></td>
<td>2</td>
<td>7.4</td>
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<tr>
<td>alteplase</td>
<td></td>
<td>2</td>
<td></td>
<td>2</td>
<td>7.4</td>
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Year 2: 2013 (n=29)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Frequency</th>
<th>Severe Harm</th>
<th>Death</th>
<th>Total</th>
<th>Percentage %</th>
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</thead>
<tbody>
<tr>
<td>hydromorphone</td>
<td></td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>17.6</td>
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<tr>
<td>desmopressin</td>
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<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
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<tr>
<td>epinephrine</td>
<td></td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>heparin</td>
<td></td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>morphine</td>
<td></td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>5.9</td>
</tr>
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</table>
Medications most commonly involved in critical incidents in Ontario hospitals

Year 1: Oct 2011-Dec 2012 (n=36)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Frequency</th>
<th></th>
<th></th>
<th>Percentage %</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Severe Harm</td>
<td>Death</td>
<td>Total</td>
<td></td>
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<tr>
<td>Hydromorphone</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>11.1</td>
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<td>Fentanyl</td>
<td>2</td>
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<td>Heparin</td>
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<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>
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<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>
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</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


International Context: US Joint Commission Sentinel Events

<table>
<thead>
<tr>
<th>Type of Sentinel Event</th>
<th>2004 - 2Q 2015 Total</th>
<th>2013</th>
<th>2014</th>
<th>2Q 2015</th>
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</thead>
<tbody>
<tr>
<td>Anesthesia-Related Event</td>
<td>109</td>
<td>8</td>
<td>6</td>
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<tr>
<td>Criminal Event</td>
<td>391</td>
<td>52</td>
<td>47</td>
<td>12</td>
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<tr>
<td>Delay In Treatment</td>
<td>1013</td>
<td>113</td>
<td>73</td>
<td>37</td>
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<tr>
<td>Dialysis-Related Event</td>
<td>12</td>
<td>1</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Elopement</td>
<td>95</td>
<td>9</td>
<td>6</td>
<td>1</td>
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<tr>
<td>Fall</td>
<td>750</td>
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<td>91</td>
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<tr>
<td>Fire</td>
<td>130</td>
<td>9</td>
<td>10</td>
<td>13</td>
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<tr>
<td>Infant Abduction</td>
<td>29</td>
<td>2</td>
<td>0</td>
<td>1</td>
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<td>Infant Discharge to Wrong Family</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Infection-Related Event</td>
<td>182</td>
<td>13</td>
<td>12</td>
<td>4</td>
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<td>Inpatient Drug Overdose</td>
<td>102</td>
<td>8</td>
<td>8</td>
<td>3</td>
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<td>Maternal Death</td>
<td>127</td>
<td>7</td>
<td>11</td>
<td>2</td>
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<tr>
<td>Med Equipment-Related</td>
<td>238</td>
<td>20</td>
<td>9</td>
<td>6</td>
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<tr>
<td>Medication Error</td>
<td>452</td>
<td>38</td>
<td>18</td>
<td>18</td>
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<tr>
<td>Op/Post-op Complication</td>
<td>884</td>
<td>77</td>
<td>52</td>
<td>36</td>
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<tr>
<td>Other Unanticipated Event***</td>
<td>613</td>
<td>81</td>
<td>73</td>
<td>34</td>
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<tr>
<td>Perinatal Death/Injury</td>
<td>327</td>
<td>35</td>
<td>32</td>
<td>21</td>
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<tr>
<td>Radiation Overdose*</td>
<td>39</td>
<td>4</td>
<td>4</td>
<td>1</td>
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<tr>
<td>Restraint Related Event</td>
<td>128</td>
<td>4</td>
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<td>5</td>
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<tr>
<td>Self-Inflicted Injury</td>
<td>77</td>
<td>9</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Severe Neonatal Hyperbilirubinemia*</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Suicide</td>
<td>905</td>
<td>90</td>
<td>82</td>
<td>48</td>
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<tr>
<td>Transfer-Related Event</td>
<td>28</td>
<td>2</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Transfusion Error</td>
<td>134</td>
<td>7</td>
<td>7</td>
<td>6</td>
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<tr>
<td>Unassigned</td>
<td>97</td>
<td>0</td>
<td>31</td>
<td>66</td>
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<tr>
<td>Unintended Retention of a Foreign Body*</td>
<td>1037</td>
<td>102</td>
<td>112</td>
<td>50</td>
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<tr>
<td>Utility System Failure</td>
<td>7</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>Ventilator Death</td>
<td>51</td>
<td>5</td>
<td>3</td>
<td>2</td>
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<tr>
<td>Wrong-patient, wrong-site, wrong-procedure</td>
<td>1162</td>
<td>109</td>
<td>67</td>
<td>58</td>
</tr>
<tr>
<td>Total Incidents Reviewed</td>
<td>9119</td>
<td>887</td>
<td>764</td>
<td>474</td>
</tr>
</tbody>
</table>

http://www.jointcommission.org/sentinel_event_statistics_quarterly/
Medication Error Events Reviewed by The Joint Commission

(Resulting in death or permanent loss of function)

Sentinel Event Alerts
#11: "High-alert meds" November 1999
#16: "Mix-up leads to a Med Error" February 2001
#19: "Look-alike/sound-alike" May 2001
#23: "Abbreviations" September 2001
#35: "Medication reconciliation" January 2006
#39: "Pediatric med Errors" April 2008
#41: "Anticoagulants" September 2008

The reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.

http://www.jointcommission.org/se_data_event_type_by_year/
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:
  • Perspiring profusely
  • Pupils dilated
  • Decreased level of consciousness
  • Glucometer 2.5 mmol/L (normal 4-7 mmol/L)
What do you think happened?
Are there tools to help us analyze this incident?

• 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

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

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

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

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

Canadian Incident Analysis Framework

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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

• Practitioners with different clinical backgrounds will view situations with a different “lens”
  • Often identifies information not known by all team members

• 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)
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Canadian Incident Analysis Framework

©2013 Institute for Safe Medication Practices Canada (ISMP Canada)
Determine and document what happened

1. Gather information
   - Incident report
   - Interviews
     - Pharmacy staff
     - Other providers
     - Patient and/or family caregivers
   - Physical assessment
     - Medications
     - Environment

2. Create timeline
   - Document what actually happened, not what was supposed to happen
Supporting Information

- Review:
  - Policies/procedures
  - Standards of practice
- Consider:
  - Literature search, ISMP Canada Safety Bulletins, CPSI Global Patient Safety Alerts
  - Environmental scan, including consultation with colleagues or other experts
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.
Key Determinants of Adverse Drug Events

## Root Cause Information for Medication Error Events Reviewed by The Joint Commission

(Resulting in death or permanent loss of function)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Use</td>
<td>393</td>
</tr>
<tr>
<td>Leadership</td>
<td>346</td>
</tr>
<tr>
<td>Human Factors</td>
<td>339</td>
</tr>
<tr>
<td>Communication</td>
<td>328</td>
</tr>
<tr>
<td>Assessment</td>
<td>198</td>
</tr>
<tr>
<td>Information Management</td>
<td>170</td>
</tr>
<tr>
<td>Physical Environment</td>
<td>75</td>
</tr>
<tr>
<td>Care Planning</td>
<td>46</td>
</tr>
<tr>
<td>Continuum of Care</td>
<td>42</td>
</tr>
<tr>
<td>Health Information Technology-related</td>
<td>27</td>
</tr>
</tbody>
</table>

The majority of events have multiple root causes.

The reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these root cause data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of root causes or trends in root causes over time.

http://www.jointcommission.org/Sentinel_Event_Statistics/
How and Why the Incident Happened

• Reasons for incidents are multi-factorial

• Need to consider
  • System/process design
  • Workflow
  • Individual accountability – e.g., workarounds
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

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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.

CI AF 2012, p. 96-98
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???
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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

©2013 Institute for Safe Medication Practices Canada (ISMP Canada)
How can we share learning with others??
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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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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2a: Diagram the Process

![Diagram of the dispensing process](https://pharmacists.ab.ca/Content_Files/Files/FMEA_web.pdf)

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>
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<tbody>
<tr>
<td>Patient Identification in the dispensing process</td>
<td>#5: Prescription is released to patient</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Sub-process component:</th>
</tr>
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<tbody>
<tr>
<td>5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)</td>
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<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 receiving medication prescribed</td>
<td>Same as 5d1</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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4b. Identify Causes of Potential Failure Modes

<table>
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<th>Process: #5: Prescription is released to patient</th>
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</table>
| **Sub-process component:**
| 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | |

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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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<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>
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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

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<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>
<td>4</td>
<td>2</td>
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<td>Yes</td>
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## Conducting an FMEA: 8 Steps

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6: Redesign the Process

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<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>
</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>
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<tr>
<th>FMEA subject:</th>
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<th>Sub-process step: #5c: Pharmacy staff member requests second identifier</th>
</tr>
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<tbody>
<tr>
<td>Failure mode number</td>
<td>Recommended action</td>
<td>Strength of action</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>
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<tr>
<td>5d2</td>
<td>Ensure addresses for multi-unit dwellings include the specific unit</td>
<td>Low (policy development / education)</td>
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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
New MSSAs in 2015

Home and Community Care
Personal Support Worker Organizations
Medication Safety Self-Assessment©

Home Care Organizations
Medication Safety Self-Assessment©

Epidural Label Safety Checklist
Other MSSAs Available
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 28Aug2015 (n = 1068)
Medication Safety Self Assessment
User Scores by Key Elements (User = A00***)

Scores as % Max. Weighted Scores

Key Elements
- 2006-07-05
- 2006-07-12
- 2006-08-21
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
Incident Reporting

• Why report incidents?

• How can you report incidents?
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.

Username: testuser
Password: testuser

CPhIR Demo Site:
Login at http://www.cphir.ca/training

Frequently Asked Questions
Contact ISMP Canada

Powered by

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Analysis of Medication Incidents in Community Pharmacy

Certina Ho, Neil J. MacIntyre, Todd A. Boyie, Tom Maftei, Bev Zwicker, Heidi Deal, Andrea Scoble, Sean Higgins, Roger Chong, Patricia Hung, Gary Lee

Objectives

The Community Pharmacy Incident Reporting (CPIR) program has been designed by the Institute for Safe Medication Practices Canada (ISMP Canada) with support from the Ontario Ministry of Health and Long-Term Care, Canada. CPIR contributes to the Canadian Medication Incident Reporting and Prevention System (CIMP-PS).

SafetyNetRx is a continuous quality improvement (CQI) program for community pharmacies in Nova Scotia, Canada.

A component of this pilot project is to determine the underlying system-based contributing factors to medication incidents in community pharmacies and focus on the need for learning from incident reporting.

Methodology

From August 2008 to January 2010, 1544 incidents were voluntarily reported by 13 community pharmacies participating in the SafetyNetRx/Phased pilot project. There were 13 duplicates or near misses, so 1532 incidents were analyzed, with a focus on the severity of outcome of the incident and medication-use areas associated with these incidents in community pharmacy.

Results

Severity of Outcome

- 64% (1281 of 1532) of the incidents were near misses (Figure 1).
- 10% (259 of 1532) of the incidents resulted in no harm, of which 24% (58 of 259) involved patients who actually received the medication (Figure 1).
- Only 0.07% (1 of 1532) resulted in temporary patient harm which required the patient to discontinue the medication immediately (Figure 1).

Medication-Use Areas

- The majority of incidents occurred during the Order Entry/Transcription and the Dispensing/Delivery stages (Figure 2).
- The most common types of incidents reported were incorrect dose, incorrect duration of treatment, incorrect strength/concentration, incorrect drug, and incorrect patient.
- More than one medication can be reported for a single incident. There were 1799 medications reported. The top five medications reported were aspirin, salicylic acid, ibuprofen, and mefenamic acid. (Note: It is possible that the likelihood of a medication to be involved in an incident is correlated with the frequency the medication is dispensed in community pharmacy)
- Possible causes of medication incidents (Figure 3).

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 infer the probability of specific incidents based on voluntary reporting, but this analysis suggests that there is a potential for significantly reducing preventable patient harm by focusing on several specific high-risk medication-use areas.

Through the analysis of incidents and sharing of findings, practitioners can learn from reported incidents and implement changes.

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 CPIM Canada CPIM Program continues to accumulate data over time, trends and changes in medication incident patterns can be identified. CPIM will continue to contribute to CIMP-PS and help identify new areas of focus to enhance medication safety.

References:
Continuous Quality Assurance Pilot Project in Saskatchewan Community Pharmacies

Certina Ho, RPh, BScPhm, MIS, 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 (http://ismpcanada.ca/compass) 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 (CPIRR) Program (www.cpirr.com) and focus on the need for learning from incident reporting.

Methods
- From September 2013 to April 2014, 435 incidents were voluntarily reported by 9 community pharmacies participating in the COMPASS CQA 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 435 incidents, 89% (389 of 435) were near misses, 16% (42 of 435) resulted in harm, i.e., medication was administered, but no symptoms were detected and no treatment was required in patients, and 1% (6 of 435) 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 types of incidents reported were in incorrect quantity (28%), incorrect dose frequency (18%), and incorrect prescription (12%) (Figure 2).
- Possible contributing factors to these near misses and medication incidents include illegible prescription orders, dangerous abbreviations, unclear/ambiguous 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 incident patterns can be identified. CPIRR will continue contributing to the Canadian Medication Incident Reporting and Prevention System (CMIIPS) (www.cmiips.ca) and help identify new areas of focus to enhance medication safety.

The authors would like to acknowledge the support from the Saskatchewan College of Pharmacists for its support and facilitation of this CQA pilot project. The authors are especially grateful to community pharmacy practitioners in Saskatchewan to CPIRR were extremely helpful in the preparation of this poster.

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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...)

If you were counselling a patient about a high-alert drug tomorrow, is there something different you would tell them about?
Contact information:
Julie Greenall
jgreenall@ismp-canada.org
www.ismp-canada.org