Introduction to Root Cause Analysis (RCA) and Failure Mode and Effects Analysis (FMEA) to Support Medication Safety Initiatives

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Disclosure

• No personal financial relationships with industry

• The Institute for Safety Medication Practices Canada (ISMP Canada) has strict guidelines on the types of activities that can be funded by the pharmaceutical industry in order to maintain our independence

• This presentation was made possible through grant funding from Health Canada
Presentation Outline

• Brief overview of ISMP Canada
• Overview of medical/medication error as a general problem in healthcare
• Review of system factors that contribute to errors
• Use of human factors engineering (HFE) principles in error analysis and solution development
• Prospective and retrospective approaches to error prevention with case examples
Learning Objectives

At the conclusion of this presentation, participants will understand:

- The importance of incident analysis in organizational safety efforts
- The impact of system factors on error potential in the medication use process
- How HFE principles are applied in error analysis and solution development
- When to use retrospective analysis (root cause analysis) and prospective analysis (failure mode and effects analysis)
About ISMP Canada

ISMP Canada is an independent not-for-profit organization dedicated to reducing preventable harm from medications.

Our aim is to heighten awareness of system vulnerabilities and facilitate system improvements.

www.ismp-canada.org
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)

Ontario MOHLTC Supported Initiatives

- Ontario Critical Incident Learning
- Hospital-Acquired Hyponatremia - Resources for Safety
- Safe Use of Insulin Interventions
- Safe Use of Insulin Pen e-Learning Module
- Safer Medication Use in Older Persons

Multi-Stakeholder Projects

- Opioid Stewardship
- Drug Shortage Safety
- Medication Reconciliation
- Canadian Incident Analysis Framework

Upcoming ISMP Canada Events

Workshops  Wednesday, June 10, 2015
June 11-12, 2015

Resolving Drug-Drug Interactions: A Guide for Community Pharmacies to Reduce Potential Hospitalizations - Toronto, ON - All Sessions are FULL

Medication Safety for Pharmacy Practice: Incident Analysis and Prospective Risk

ISMP Canada Activities for the CMIRPS:

- Reporting Systems for Medication Incidents
- A consumer medication safety reporting and learning program: SafeMedicationUse.ca
- Safety bulletins and alerts by ISMP Canada about medication incidents and prevention strategies
- Medication Safety Self-Assessment programs
- Root Cause Analysis workshops and frameworks
- Failure Mode and Effects Analysis workshops and frameworks
- Responding to queries on medication safety (email or telephone)
- Medication safety workshops and webinars

Purpose of the CMIRPS

- Evaluation of ISMP Canada Activities
- Bulletins
- PDF Downloads

- Labelling and Packaging: An Aggregate Analysis of Medication Incident Reports
- Evaluation of the Canadian Medication Incident Reporting and Prevention System Services provided by ISMP Canada
- Consultation Document: Working with Consumers to Prevent Medication Incidents - A Consumer Reporting and Learning Strategy for the Canadian Medication Incident Reporting and Prevention System
Help Prevent Harmful Medication Incidents

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!
ISMP Canada Safety Bulletin

Volume 14 - Issue 7 - July 30, 2014

Neuromuscular Blocking Agents: Sustaining Packaging Improvements over Time

Neuromuscular blocking agents, also known as paralyzing agents, are high-alert medications. They paralyze muscle function by blocking the conduction 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 immediately ventilated. Serious injuries and deaths have occurred with substitution errors involving these drugs.1,2 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 Bulletins.1,2 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 2005, 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.3

The pharmaceutical representatives agreed upon several ideal packaging and labelling features for neuromuscular blocking agents to help differentiate them from all other drugs.1

• red cap with white lettering: “Paralyzing Agent” or “Warning: Paralyzing Agent”
• red ferrule (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 prepared syringes, as set out by the Canadian Anesthesiologists’ Society (CAS; www.cas.ca) and the American Society of Anaesthesiologists (ASA; www.asahq.org)
• spacex on the product label for application of a bar code

Figure 1. Examples of closures on vials of neuromuscular blocking agents currently available in Canada. Although the colour may vary (see “Note about Colour” on next page), all neuromuscular blocking agents currently available in Canada have a warning on the cap and/or ferrule.

10-Fold Dose Errors

Many medicines are available in a variety of strengths. This allows the prescriber to personalize the dosage according to the patient’s condition. Unfortunately, mistakes can happen that involve taking the wrong dose. A dose that is too high may cause harm. A dose that is too low may not have the desired effect.

SafeMedicationUse.ca has received a report about a consumer who was prescribed a 50 mg capsule of a triamterene capsule to be taken twice daily. This medicine is used after organ transplantation to prevent rejection. It is also used to treat hypertension. The consumer picked up the prescription for terazosin at the pharmacy, and took it for 4 weeks. Over time, the consumer began to feel the effects of the medication. The consumer noted that he was losing a lot of weight. The consumer contacted the pharmacy and discovered that the pharmacy had dispensed terazosin 50 mg capsules instead of the triamterene 50 mg capsules (see Figure 1). The consumer was taking 10 times the amount of medication that the doctor had prescribed.

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

Ontario CRITICAL Incident Learning

Sharing Insulin Pens is a High-Risk Practice

Insulin pens are injection devices that are designed to help patients administer their own insulin with greater ease, convenience, and accuracy relative to the traditional insulin vial, needle, and syringe.4 These advantages have led to a rise in the popularity of insulin pens in facilities, which has been paralleled by an increase in concerns about the high-risk practice of sharing insulin pens between different patients.5 Since insulin delivery devices and resources can be contaminated with blood and other body fluid material, transmission of blood-borne pathogens (e.g., HIV, hepatitis B, hepatitis C) is a risk.6

In 2009, with support from the Ontario Ministry of Health and Long-Term Care, a knowledge translation project to develop evidence-based interventions and tools for promoting the safe use of these devices. A key resource developed is the “Safe Use of Insulin Pens” e-Learning module. The module is intended to help healthcare providers recognize the advantages and disadvantages of insulin pens, understand the risks associated with the use of these devices, and develop best practice administration techniques while learning to use insulin pens safely.7

Call to Action for Hospitals

Make system-based changes to ensure insulin pens are used safely:

• Prohibit the sharing of insulin pens between patients.
• Dispense insulin pens with cartridges already inserted.
• Label insulin pens with pharmacy-generated, patient-specific labels, for single-patient use.
• Place patient-specific labels on the barrel of the insulin pens, not on the cap.
• Use insulin vials cartiledly only with an insulin pen. Do not use a needle and syringe to withdraw insulin from a cartridge.
• Use educational tools such as the ISMP Canada e-Learning module, along with hands-on training, to educate healthcare providers on the potential risks associated with using these devices, as well as on best practice techniques.
Definitions

Safety:

Freedom from accidental injuries.


Medication Safety:

Freedom from preventable harm with medication use.

ISMP Canada, 2007
Foundational Principles

• Errors/incidents occur at all levels of healthcare

• All staff, even the most experienced and dedicated professionals can be involved in preventable adverse events

• Incidents result from a sequence of events and tend to fall in recurrent patterns regardless of the personnel involved
Numerous high profile examples of medication errors causing harm
Case Example

9 month old baby brought to ED with fever and ear pain.

Baby receives hydromorphone 4 mg PO intended for an adult patient.

Treated with naloxone (opioid antidote) and charcoal.

Fortunately no adverse outcome...
How many patients do you think experience preventable adverse events in Canadian hospitals?

1. 1%
2. 2.5%
3. 5%
4. 7.5%
5. 10%
# International Comparison

## Table 1. Data on adverse events in health care from several countries

<table>
<thead>
<tr>
<th>Study</th>
<th>Study focus (date of admissions)</th>
<th>Number of hospital admissions</th>
<th>Number of adverse events</th>
<th>Adverse event rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA (New York State) (Harvard Medical Practice Study) (1,2)</td>
<td>Acute care hospitals (1984)</td>
<td>30,195</td>
<td>1,133</td>
<td>3.8</td>
</tr>
<tr>
<td>USA (Utah-Colorado Study (UTCOS)) (10)</td>
<td>Acute care hospitals (1992)</td>
<td>14,565</td>
<td>475</td>
<td>3.2</td>
</tr>
<tr>
<td>USA (UTCOS)³(10)</td>
<td>Acute care hospitals (1992)</td>
<td>14,565</td>
<td>787</td>
<td>5.4</td>
</tr>
<tr>
<td>Australia (Quality in Australian Health Care Study (QAHCS)) (3)</td>
<td>Acute care hospitals (1992)</td>
<td>14,179</td>
<td>2,353</td>
<td>16.6</td>
</tr>
<tr>
<td>Australia (QAHCS)² (10)</td>
<td>Acute care hospitals (1992)</td>
<td>14,179</td>
<td>1,499</td>
<td>10.6</td>
</tr>
<tr>
<td>UK (4)</td>
<td>Acute care hospitals (1999-2000)</td>
<td>1,014</td>
<td>119</td>
<td>11.7</td>
</tr>
<tr>
<td>Denmark (12)</td>
<td>Acute care hospitals (1998)</td>
<td>1,097</td>
<td>176</td>
<td>9.0</td>
</tr>
<tr>
<td>New Zealand (6,7)</td>
<td>Acute care (1998)</td>
<td>6,579</td>
<td>849</td>
<td>12.9</td>
</tr>
<tr>
<td>Canada (8)</td>
<td>Acute and community hospitals (2001)</td>
<td>3,720</td>
<td>279</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Of the adverse events that occur, how many do you think are related to medication use?

1. 10%
2. 25%
3. 50%
4. 75%
Where do you think medication incidents occur most often?

1. Prescribing?
2. Order processing?
3. Dispensing?
4. Administration?
5. Monitoring?
Sources of Harm

Prescribing
(39% of errors; 28% cause harm)

Transcribing
(12% of errors; 11% cause harm)

Dispensing
(11% of errors; 10% cause harm)

Monitoring
n/a

Administering
(38% of errors; 51% cause harm)

Data from Leape et al. JAMA 1995
Prescribing and monitoring are most common

Only 2% intercepted!

48% intercepted
33% intercepted
34% intercepted

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What is “Root Cause Analysis”

Definition:

An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

Goals of Analysis

• What happened?
• How and why did it happen?
• What can be done to reduce the likelihood of recurrence and make care safer?

AND

• What was learned and how can the learning be shared?
Why do incidents happen?

• Reasons for incidents are multi-factorial
• Need to consider
  • System/process design
  • Workflow
  • Individual accountability – e.g., “at-risk” behaviours, workarounds
Why do incidents happen?

Physicians, nurses, and pharmacists are expected to function perfectly 100% of the time ....

But.... we work in an imperfect system
Reality of Health Care Environments

- Cognitive overload
- Workloads
- Multitasking
- Interruptions
- Difficult technology
Human Factors Engineering Principles

• 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
**SYSTEM-Based**

- **Low Leverage**
  - Rules and policies (e.g., policies to prohibit borrowing doses from other areas)
  - Education and information (e.g., education sessions on high-alert medications)

- **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)

**HIERARCHY OF EFFECTIVENESS**

Constraints and Forcing Functions
Using Technology to Re-engineer Medication Management

- Physician Order Entry/Pharmacist Clinical Order Screening
- Electronic MAR and To Do List
- Just-In-Time Inventory
- Smart Drawer Opens
- Or, automated med/supply depot door or drawer opens
- Scan Medication
- Scan Patient’s Wristband
Simplification and Standardization

Range 2:43 - 3:58 min, Avg 3:07 min

Range: 55-1:25 min, Avg 1:08 min

McLaughlin R. Redesigning the crash cart. AJN 2003; 103(4): 64A-E.
Infant receives hydromorphone 4 mg orally intended for an adult patient

Contributing factors:

- Order written on the wrong chart
- Patients had similar last names
- When the nurse requested confirmation of the order from the doctor, neither used patient identifiers
- Lack of familiarity and understanding about potency of hydromorphone due to infrequent use in the ED
- Availability of hydromorphone in the ED, despite infrequent use
# Examples of Recommended Actions

<table>
<thead>
<tr>
<th>Actions</th>
<th>Leverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use 2 patient identifiers at each stage of the medication use process</td>
<td>Medium – Reminders/Checklists/Double Checks</td>
</tr>
<tr>
<td>Include identifiers in all communications</td>
<td>Low – Rules and Policies</td>
</tr>
<tr>
<td>Include the calculated dose (mg/kg) in all pediatric medication orders</td>
<td>Low – Rules and Policies</td>
</tr>
<tr>
<td>Require documentation of medical assessment process prior to medication administration (exception: emergency situations)</td>
<td>Low – Rules and Policies</td>
</tr>
<tr>
<td>Use distinctly different charts for adult and paediatric patients</td>
<td>High – Constraints</td>
</tr>
</tbody>
</table>
How does ISMP Canada analyze incidents?

- Canadian Incident Analysis Framework (2012)
  - CPSI, ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada, Paula Beard, Carolyn Hoffman, Micheline Ste Marie

- Systematic approach to incident analysis
- Applicable to all incident analyses
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
Case Example

- Insulin dependent diabetic unexpectedly experiences severe drop in blood sugar
- Rx for Novolin® ge 30/70 Penfill twice daily via insulin pen
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)
How and Why it Happened

• Diagramming can be a helpful tool to:
  • Visualize relationships
  • Move away from the “sharp end”
  • Avoid “hindsight bias”
Incident: incorrect insulin selected
Outcome: Hypoglycemia requiring intervention

Policies and procedures, staff training for bar code scanning did not focus on need to scan all packaging

Organization

Task

Incorrect product selected
Ineffective check process
Reliance on previous automated check
Bar code scanned on one package only

Equipment

Manual final check of top box only

Work Environment

Shift change
Peak Rx volume time

Look-alike packaging
Manufacturer's branding

Care Team

Unclear task/role definition re medication selection
Skill level – PhT vs. student
Limited understanding of complexity of work
Informal shift-to-shift handoff process

Other

Ineffective check process

Patient

Refill Rx for chronic condition assumed to be correct
? Eyesight less acute due to diabetes

? Sufficient staffing/appropriate skill mix

Insulin Incident
“Just telling doctors and nurses to be more careful won’t do much. We need to change the systems that allow errors to happen.”

James Bagian, Director, VA Center for Patient Safety Anesthesiologist and Astronaut
The Systems Approach

Recognizes that:

- Humans are incapable of perfect performance
- Accidents are caused by flaws in the working environment (system) and human errors that are an expected part of any working environment
- Accidents can be prevented by building a system that is resilient to expected human errors
Key Determinants of Adverse Drug Events

Provider
- Provider Shift Change
- Miscommunication between Providers or With Patient
- Staff Inexperience or New Work Setting
- Provider Knowledge Deficit

Patient
- Failure to Follow Policy (i.e., Use of a Workaround)
- Lack of Access to Accurate Health Information
- Inappropriate Monitoring
- Order Illegible
- Incorrect Transfer Procedure
- Medication Incorrectly Dispensed
- Reduced Hepatic and/or Renal Metabolism
- Cognitive Decline
- Physical Frailty
- Polypharmacy
- Medical and/or Psychiatric Comorbidities
- Nonadherence or Misuse

Proximate (e.g., Human Factors)
- Prescribed High-Risk Medications (e.g., hypoglycemics, opioids, anticoagulants)
- Multiple Providers

Preventable Adverse Drug Events
- Fragmented Healthcare Delivery/Poor Care Coordination
- Limited Time in Patient-Provider Interaction for Counseling
- Formularies Restrict Use of Certain Medications
- Leadership Focus on Individual Rather than Systems Improvement
- Organizational Culture
- Policies Not in Place
- To Report and Investigate ADEs
- Look-Alike Materials or Medications

Latent (e.g., Organizational and System Factors)
- High Workload
- Unable to Counter Authority Gradient
- Policies Not in Place
- For Safe Medication Use

Healthcare System
- Organizational
- Technical

High Alert Medications

“High-alert medications are drugs that bear a heightened risk of causing significant harm when they are used in error.”

From the ISMP Medication Safety Alert!, October 16, 2003. Survey on high-alert medications - Differences between nursing and pharmacy perspectives revealed
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)
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
What is FMEA?

Definition:
FMEA is a technique used to identify process and product problems before they occur.
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)
# Conducting an FMEA: 8 Steps

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Select process and assemble the team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Diagram the process</td>
</tr>
<tr>
<td>Step 3</td>
<td>Brainstorm potential failure modes</td>
</tr>
<tr>
<td>Step 4</td>
<td>Identify the effects and causes of the potential failure modes</td>
</tr>
<tr>
<td>Step 5</td>
<td>Prioritize failure modes</td>
</tr>
<tr>
<td>Step 6</td>
<td>Redesign the processes to address the potential failure modes</td>
</tr>
<tr>
<td>Step 7</td>
<td>Analyze and test the changes</td>
</tr>
<tr>
<td>Step 8</td>
<td>Implement and monitor the redesigned processes</td>
</tr>
</tbody>
</table>
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.
Example – Everyday FMEA

1. Wake up
2. Make coffee
3. Get dressed
4. Make and eat breakfast
5. Walk dog
6. Make lunch
7. Prepare to leave for work
8. Catch the bus to work
Everyday FMEA (cont’d)

Morning routine:
1. Wake up
2. Make coffee
3. Get dressed
4. Make and eat breakfast
5. Walk dog
6. Make lunch
7. Prepare to leave for work
8. Catch the bus to work
2a
Open basket

2b
Remove old filter/grounds

2c
Compost old filter/grounds

2d
Rinse basket

2e
Get new coffee filter

2f
Place filter in basket

2g
Get ground coffee from cupboard

2h
Measure coffee

2i
Put coffee in filter/basket

2j
Put basket in coffee maker

2k
Remove carafe

2l
Rinse carafe

2m
Fill carafe with water

2n
Open reservoir lid

2o
Pour water into reservoir

2p
Close reservoir lid

2q
Replace carafe in coffee maker

2r
Turn on coffee maker

2s
Wait for coffee to brew

2t
Get coffee mug

2u
Remove carafe from coffee maker

2v
Pour coffee into mug

2w
Add cream and/or sugar

2x
Enjoy!
Potential Failure Modes

2a. Open basket
   - 2a1. Stuck shut

2b. Remove old filter/grounds
   - 2b1. Basket won’t open
   - 2b2. Filter rips

2c. Compost old filter/grounds
   - 2c1. Compost bucket is full
   - 2c2. Drop filter or grounds on floor

2d. Rinse basket
   - 2d1. Basket stuck

2e. Get new coffee filter
   - 2e1. Filter box is empty

2f. Place filter in basket
   - 2f1. Filter won’t fit
## Prioritization and Action Planning

**FMEA subject:** Morning routine

**Sub-process component:**
2b – Remove old filter/grounds

<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>2b1</td>
<td>Basket won’t open</td>
<td>Cannot add new coffee</td>
<td>Latch broken</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>No</td>
<td>Not predictable; no action required—would likely require new coffee maker if occurred</td>
</tr>
<tr>
<td>2b2</td>
<td>Filter rips</td>
<td>Old coffee grounds spill, causing delay</td>
<td>Poor quality paper; mishandling</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>24</td>
<td>Yes</td>
<td>Purchase reusable filter (1 month)</td>
</tr>
</tbody>
</table>
Shared Learning from FMEA

A Collaborative Failure Mode and Effects Analysis Project with an Ontario Hospital:
Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use

Volume 12, Number 11
ISMP Canada Safety Bulletin
November 20, 2012

Usability Testing in Proactive Risk Assessments

The Institute for Safe Medication Practices (ISMP) has long supported usability testing as an essential component of proactive risk assessment and risk management. This approach involves evaluating the user experience of healthcare professionals with the medications, medical devices, and processes they use. By identifying usability issues and potential hazards, healthcare organizations can proactively address these risks before harm occurs.

One of the goals of medication safety is to identify and mitigate the factors that contribute to medication errors. Usability testing can help organizations understand how their processes and systems are perceived and used by healthcare professionals. This information can then be used to improve patient safety and reduce the risk of medication errors.

Incorporating usability testing into proactive risk assessment can help organizations:
- Identify potential usability hazards that could lead to errors or adverse events.
- Develop effective communication strategies to enhance usability and reduce errors.
- Implement design changes to improve the usability of medications and medical devices.
- Enhance training programs to ensure healthcare professionals are adequately prepared to use the products safely.

Usability testing should be an integral part of the proactive risk assessment process. By addressing usability issues early, healthcare organizations can prevent harm to patients and reduce the risk of medication errors.

Institute for Safe Medication Practices Canada 2015
Goal is harm reduction

• High alert medications
• Vulnerable populations
• Gaps in medication use processes
Importance of Incident Reporting
Healthcare thinking is evolving

Who did it?  What allowed it?

Punishment  Thank you for reporting?

Errors are rare  Errors are everywhere

Add more layers  Simplify/ standardize
International Efforts in Medication Safety

The International Medication Safety Network (IMSN) is an international network of established safe medication practice centres, operating medication error reporting programmes and producing guidance to minimise preventable harms from medicine use in practice. IMSN promotes safer medication practice to improve patient safety internationally. About IMSN

10th IMSN annual meeting

Thanks to the ACQFH Colombian Society of Hospital Pharmacists, the 10th annual meeting of the International Medication Safety Network will be held in Cartagena, Colombia on September 30th to October 1st 2015; and will be preceded by the LatinoAmerican Medication Safety Network meeting scheduled on Tuesday 29th September 2015.
We encourage you to report medication incidents!

Contact information:

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www.ismp-canada.org

Practitioner reporting:
http://www.ismp-canada.org/err_ipr.htm

Consumer reporting:
http://www.safemedicationuse.ca/report/