

Medication errors and patient safety: tools for system improvement

PHM 310: Health Systems II September 16th, 2015 Julie Greenall, ISMP Canada



Home

Incident

News

Safety Bulletins

Report a Medication

Education Events

Current Projects

Related Links

Definitions

About Us

Contact Us

Publications

CMIRPS

Products & Services

>

>

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A Key Partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS)

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

REPORT
a Medication incident

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

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

June 11-12, 2015

SafeMedicationUse.ca

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A component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

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Reporting Medication Incidents benefits all Canadians.



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Latest News and Resources





- 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

Recent ISMP Canada Safety Bulletins



Institute for Safe Medication Practices Canada REPORT MEDICATION INCIDENTS Online: www.ismp-canada.org/err_Index.htm Phone: 1-866-544-7672 A KEY PARTNER IN

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ISMP Canada Safety Bulletin

Volume 15 - Issue 6 - July 22, 2015

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 each admission/ readmission in a timely manner. Reassess the risks and benefits of VTE prophylactic regimens 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 associated complications, including death, in high-risk patients. VTE prophylaxis is recommended for acutely ill, hospitalized medical patients at risk of thrombosis.

Anticoagulants, the pharmacologic agents of choice to prevent VTE, are considered high-alert medications. By definition, therefore, anticoagulants bear a heightened risk of causing significant patient harm when they are used in error. As part of ongoing collaboration with a provincial death investigation service, ISMP Canada received a report of a fatal 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 enoxaparin 40 mg subcutaneously daily had been 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. After approximately 3 weeks, the patient was discharged to an LTC facility. The enoxaparin was continued as a result of its inclusion on the discharge medication list from the acute care facility.

Within the first few weeks at the LTC home, the patient experienced 2 unwitnessed falls. After the first fall, she suffered a bleeding scalp wound, which prompted transfer to the local emergency department for assessment. The wound was glued, but head computed tomography (CT) was not performed. The patient was transferred back to the LTC facility without any recommendations to change her medications; in particular, the enoxaparin was continued. Over the next week, the patient became

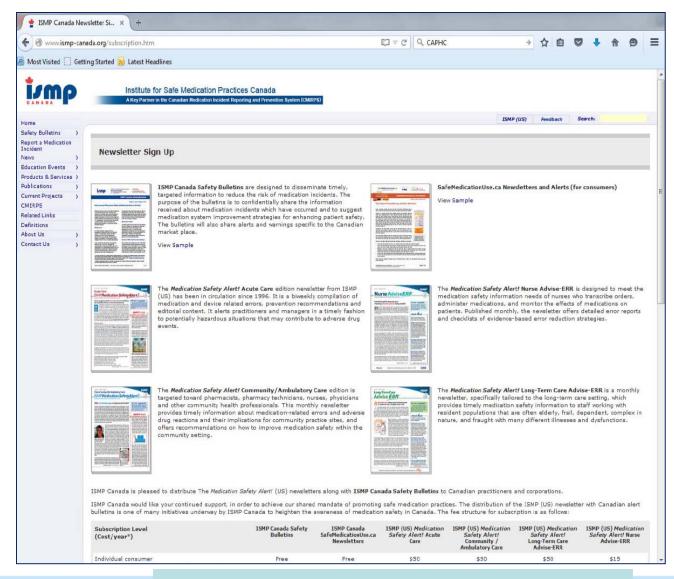
ISMP Canada Safety Bulletin - www.ismp-canada.org/ISMPCSafetyBulletins.htm

1 of 6

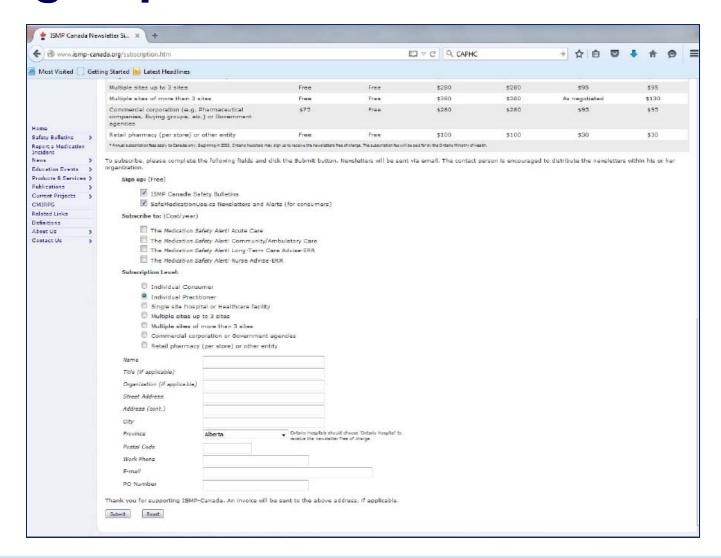




Sign up to receive bulletins



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
 - Baker GR, Norton PG, Flintoft V et al. The Canadian Adverse Events Study: the incidence of adverse drug events among hospital patients in Canada._CMAJ. 2004 May 25;170(11):1678-86.
- A "systems" approach taking in account human factors engineering principles is key
 - Reason J. Human error: models and management. BMJ 2000; 320:768-770.
- 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
- 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
- Incident Analysis Collaborating Parties. *Canadian Incident Analysis Framework*. Edmonton, AB: Canadian Patient Safety Institute; 2012. p. 39-45.
- Greenall J, Walsh D, Wichman K. Failure mode and effects analysis: a tool for identifying risk in community pharmacies. *Can Pharm J* 2007; 140(3): 191-193.
- Wichman K, Greenall J. Take a proactive approach with the Medication Safety Self Assessment. Can Pharm J 2006; 139(5): 25-27

OCP Multi-Incident 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

Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Reports, 2013, 2014, 2015. Available from: http://www.ismp-canada.org/ocil/ under "Analysis Reports"

Medications most commonly involved in critical incidents in Ontario hospitals

Year 3: 2014 (n=27)

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage of
				total incidents (%)
HYDROmorphone	4	1	5	18.5
methadone	2		2	7.4
ondansetron	2		2	7.4
alteplase	2		2	7.4

Year 2: 2013 (n=29)

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage %
hydromorphone	3	3	6	17.6
desmopressin	2	0	2	5.9
epinephrine	2	0	2	5.9
heparin	2	0	2	5.9
morphine	2	0	2	5.9

Medications most commonly involved in critical incidents in Ontario hospitals

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

Frequency			
Severe Harm	Death	Total	Percentage %
3	2	5	11.1
2	1	3	6.7
2	0	2	4.4
2	0	2	4.4
0	2	2	4.4
2	0	2	4.4
2	0	2	4.4

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

ISMP List of High-Alert Medications in Acute Care Settings. Available from: www.ismp.org/Tools/highalertmedications.pdf.

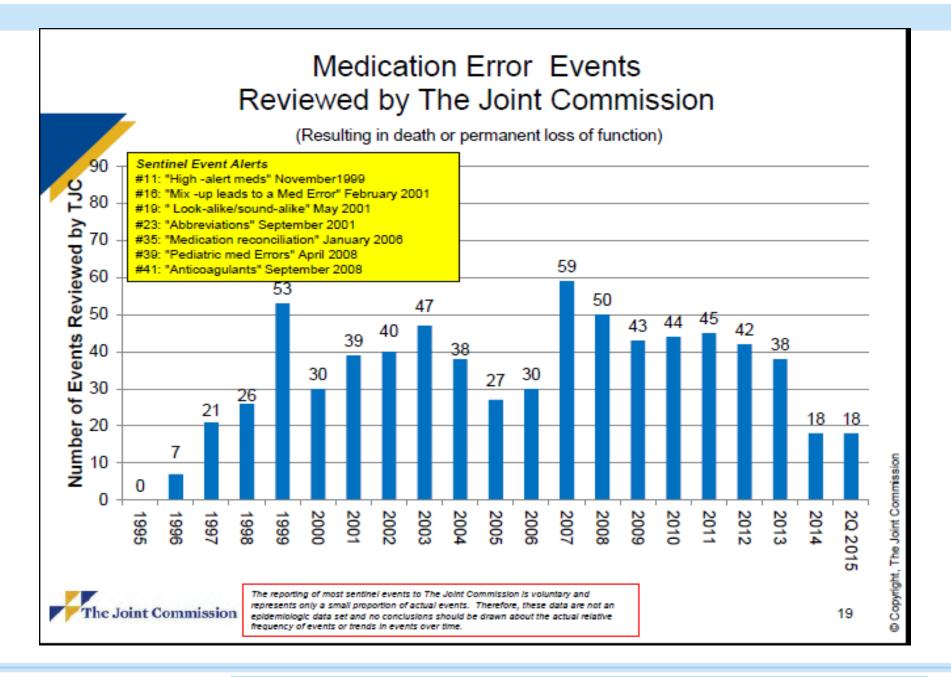
ISMP List of High-Alert Medications in Community/Ambulatory Healthcare. Available from:

http://www.ismp.org/communityRx/tools/ambulatoryhighalert.asp

International Context: US Joint Commission Sentinel Events

Type of Sentinel Event	2004 - 2Q 2015 Total	2013	2014	2Q 2015
Anesthesia-Related Event	109	8	6	1
Criminal Event	391	52	47	12
Delay In Treatment	1013	113	73	37
Dialysis-Related Event	12	1	2	0
Elopement	95	9	6	1
Fall	750	82	91	39
Fire	130	9	10	13
Infant Abduction	29	2	0	1
Infant Discharge to Wrong Family	3	0	0	0
Infection-Related Event	182	13	12	4
Inpatient Drug Overdose	102	8	8	3
Maternal Death	127	7	11	2
Med Equipment-Related	228	20	9	6
Medication Error	452	38	18	18
Op/Post-op Complication	884	77	52	36
Other Unanticipated Event***	613	81	73	34
Perinatal Death/Injury	327	35	32	21
Radiation Overdose*	39	4	4	1
Restraint Related Event	128	4	2	5
Self-Inflicted Injury	77	9	5	8
Severe Neonatal Hyperbilirubinemia*	7	0	0	1
Suicide	905	90	82	48
Transfer-Related Event	28	2	1	1
Transfusion Error	134	7	7	6
Unassigned	97	0	31	66
Unintended Retention of a Foreign Body*	1037	102	112	50
Utility System Failure	7	0	0	0
Ventilator Death	51	5	3	2
Wrong-patient, wrong-site, wrong-procedure	1162	109	67	58
Total Incidents Reviewed	9119	887	764	474

http://www.jointcommission.org/sentinel_event_statistics_quarterly/



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







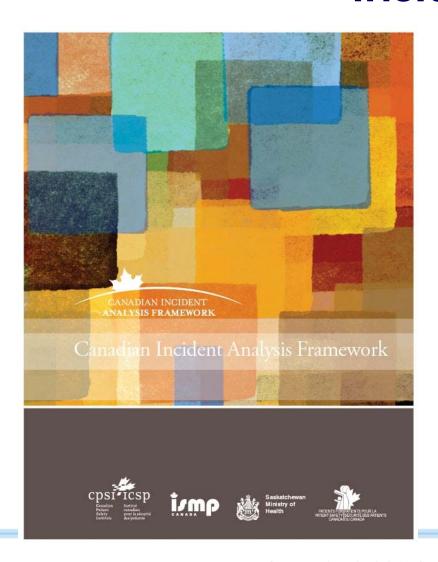
Case Example (cont'd)

- 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.

Canadian Patient Safety Institute (CPSI), ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie; available from:

http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM



Canadian Incident Analysis Framework

When are other processes appropriate?

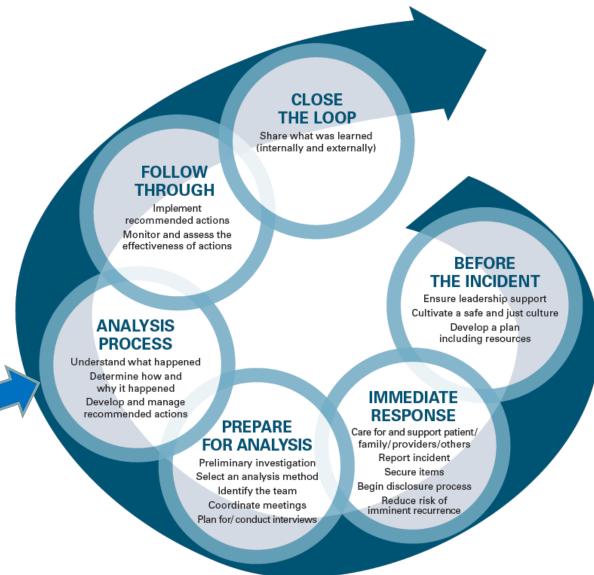
- Was the event thought to be the result of:
 - a criminal act;
 - a purposefully unsafe act;
 - an act related to substance abuse by provider/staff;
 - or events involving suspected patient abuse of any kind (i.e. situations outside the scope of the risk management / quality improvement program)?
-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

Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM



Canadian Incident Analysis Framework

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:

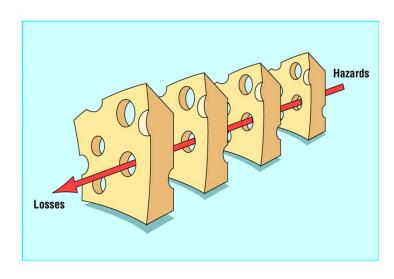
- Literature search, ISMP Canada Safety Bulletins, CPSI Global Patient Safety Alerts
- Environmental scan, including consultation with colleagues or other experts

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.



Reason, J. (2000). Human error: models and management. *BMJ*, 320(7237): 768-770. Retrieved from:

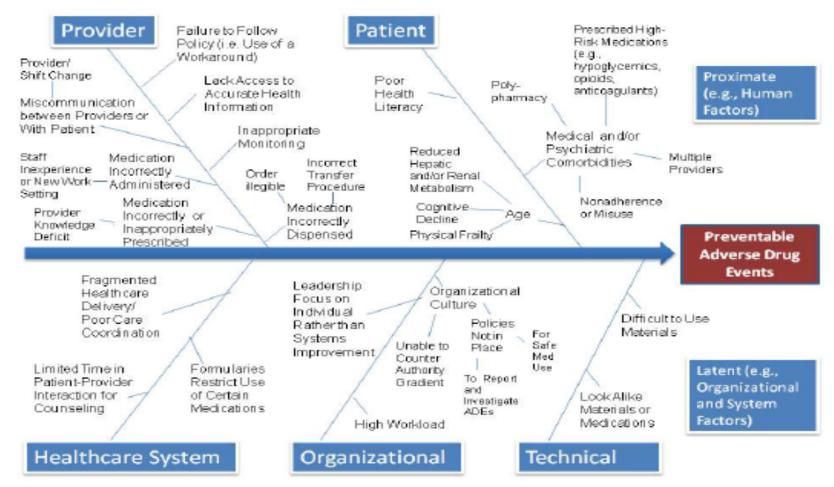
http://www.bmj.com/cgi/content/full/320/7237/768

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



U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2013).

National Action Plan for Adverse Drug Event Prevention. Washington, DC: Author.

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

(Resulting in death or permanent loss of function)

2004 through 2Q 2015 (N=452) The majority of events have multiple root causes		
Medication Use	393	
Leadership	346	
Human Factors	339	
Communication	328	
Assessment	198	
Information Management	170	
Physical Environment	75	
Care Planning	46	
Continuum of Care	42	
Health Information Technology- related	27	



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.

Office of Quality and Patient Safety - 19

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.

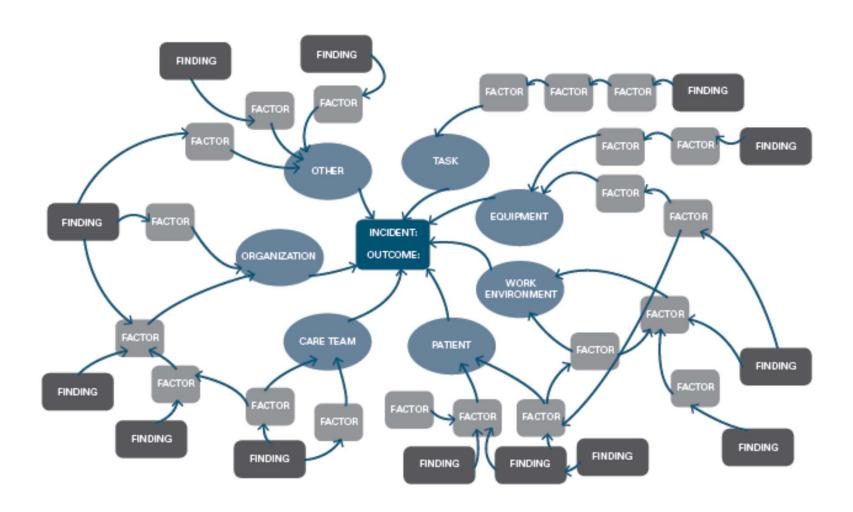
American Association of Critical Care Nurses

www.silencekills.com (2005)

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

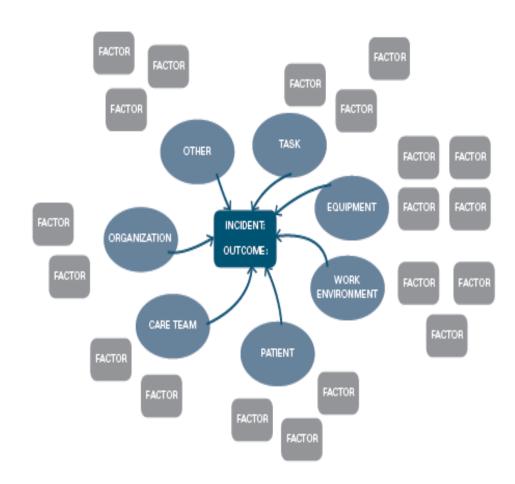
First, list the contributing factor categories in a circle around the incident



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 (CIAF 2012, p. 89)

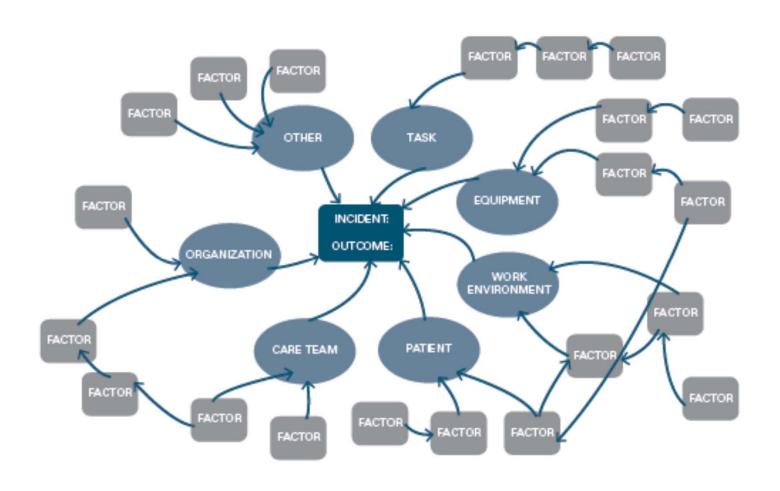
Examples of Guiding Questions

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?

2012. Canadian Incident Analysis Framework, page 89

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

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

CLOSE THE LOOP Share what was learned (internally and externally) **FOLLOW THROUGH** Implement recommended actions Monitor and assess the effectiveness of actions **BEFORE** THE INCIDENT Ensure leadership support Cultivate a safe and just culture **ANALYSIS** Develop a plan including resources **PROCESS** Understand what happened Determine how and why it happened **IMMEDIATE** Develop and manage recommended actions **RESPONSE PREPARE** Care for and support patient/ FOR ANALYSIS family/providers/others Report incident Preliminary investigation Secure items Select an analysis method Begin disclosure process Identify the team Reduce risk of Coordinate meetings imminent recurrence Plan for/ conduct interviews

Canadian Incident Analysis Framework

How can we share learning with others??

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety



The Healthcare Insurance Reciprocal of Canada (HIROC) is a memberowned expert provider of professional and general liability coverage and risk management support

Volume 7. Issue 6

ISMP Canada Safety Bulletin

December 8, 2007

Patient Report of Insulin Mix-Up Shared

A patient shared the following incident with ISMP Canada, in the hope of preventing similar incidents in the future.

A patient with insulin-dependent diabetes had a prescription for Novolin®ge 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®ge 30/70. A dose of Novolin®ge 30/70 consists of 30% short-acting insulin and 70% intermediate-acting insulin.1 In contrast, NovoRapid* is an ultrashort-acting insulin.

The following contributing factors were identified in this report:

- Novolin*ge 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.



Figure 1. From left to right, Novolin®ge 30/70 Penfill® (name highlighted with brownish band) and NovoRapid® Penfill® (name highlighted with orange band).



Figure 2. From left to right: Novolin®ge 30/70 cartridges and NovoRapid® cartridges as they appear after removal from the box, still in their over-wrap.



Figure 3. From left to right: Novolin®ge 30/70 cartridge and NovoRapid® cartridge

In addition to these factors, NovoRapid* and Novolin*ge 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) in wellHow 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

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

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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Step 3	Brainstorm potential failure modes	Step 7	Analyze and test the changes
Step 4	Identify the effects and causes of the potential failure modes	Step 8	Implement and monitor the redesigned processes

2a: Diagram the Process



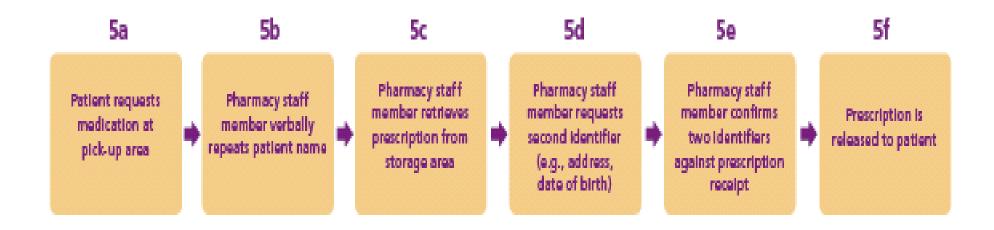
Diagrams from The Systems Approach to Quality Assurance:

A Framework for Mitigating Risk

(Alberta College of Pharmacists and ISMP Canada)

Available from: https://pharmacists.ab.ca/Content_Files/Files/FMEA_web.pdf

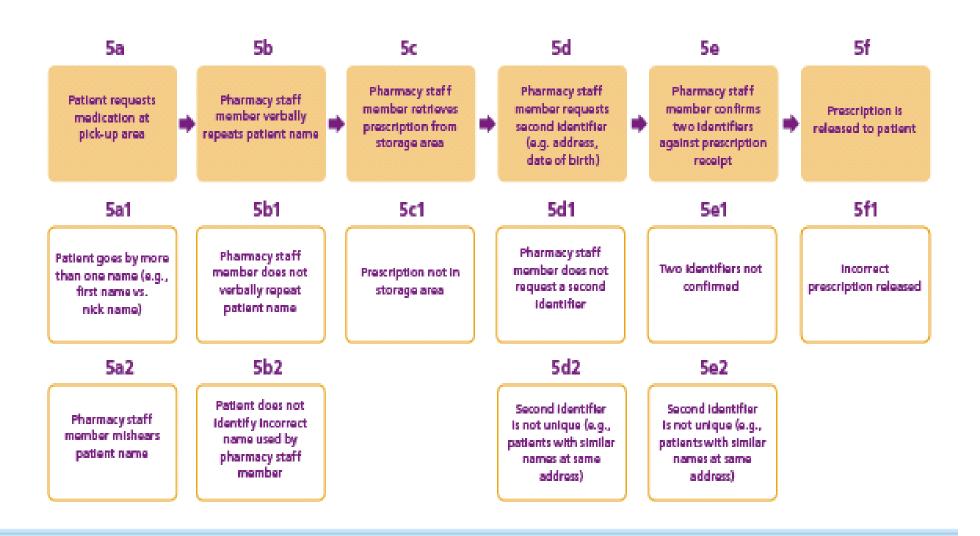
2b: Diagram the Sub-process



Conducting an FMEA: 8 Steps

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

3: Brainstorm Potential Failure Modes



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

Sub	FMEA subject: Patient Identification in the dispensing process Sub-process component: 5d: Pharmacy staff member requests second Identifier (e.g., address, date of birth)								Process: #5: Prescription is released to patient		
Fallure mode number	Potential failure modes	Effect(s) of fallure	Cause(s) of fallure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Oriticality score	Proceed? Yes or no	Actions to reduce risk and time frame		
Sd1	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 re: medication prescribed									
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1									

4b. Identify Causes of Potential Failure Modes

FMEA subject: Patient Identification in the dispensing process #5: Prescription is released Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									is released to patient
Fallure mode number	Potential failure modes	Effect(s) of fallure	Cause(s) of fallure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
Sd1	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 re: medication prescribed	Incomplete Identification.						
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./5r.); apartment building	Same as 5d1	Second Identifier is not unique						

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

Sub	FMEA subject: Patient Identification in the dispensing process Sub-process component: 5d: Pharmacy staff member requests second Identifier (e.g., address, date of birth)							Process: #5: Prescription is released to patient		
Fallure mode number	Potential failure modes	Effect(s) of fallure	Cause(s) of fallure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame	
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 re: medication prescribed	incomplete identification	4	2	3	24	Yes		
Sd2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1	Second Identifier is not unique	4	2	3	24	Yes		

Conducting an FMEA: 8 Steps

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

6: Redesign the Process

Sul	FMEA subject: Patient Identification in the dispensing process Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)						Process: #5: Prescription is released to patient		
Fallure mode number	Potential fallure modes	Effect(s) of fallure	Cause(s) of fallure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
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 re: 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 (I month) Develop a standardized process requiring documentation of the second identifier used to verify the patient's identity (I-3 months) Post information for patients explaining the identity verification process and the rationale; request their assistance in ensuring it takes place (I-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

	ubject: Patient identification in ensing process	Process: #5: Prescription is released to patient		Sub-process step: #5c: Pharmacy staff member requests second identifier			
Fallure mode number	Recommended action	Strength of action	Timeframe for implementation	individual(s) responsible	Measurement plan		
5d1	Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedure	Low (policy development / education)	1 month	Licensee / senior pharmadst	Education sessions completed and written reminders posted and included in orientation information for new staff		
5d1	Develop a standardized process requiring documentation of the second identifier used to verify the patient's identity	Medium (simplification / standardization)	1-3 months	Senior pharmacist /senior pharmacy technician	Periodic audits of documentation by senior pharmacist		
5d1	Post information for patients explaining the identity verification process and the rationale and requesting their assistance in ensuring it takes place	Low (policy development / education)	1-3 months	Liconsee	Information posted and visible to patients		
5d1	Implement photo identification for selected high-alert medications (e.g., methadone)	Medium (reminders, checklists, double-checks)	3-6 months	Licensee, senior pharmacy technician	Periodic audit and patient satisfaction survey		
5d1	Assess opportunity for automation (e.g., barcoding) as a long-term goal	High (automation / computerization)	More than 12 months	Licensee	Implemented and periodic system audits of overrides (i.e., electronic)		
5d2	Flag known patients with the same or similar names in the pharmacy computer system indicating requirement for date of birth identification for all prescriptions	Medium (reminders / checklists / double checks)	1 month	Senior pharmacist /senior pharmacy technician	Periodic testing of known similar names to check that flagging system is in place and working by senior pharmacy technician		
5d2	Ensure addresses for multi-unit dwellings include the specific unit	Low (policy development / education)	1 month	Senior pharmacy technician	Periodic audits by senior pharmacy technician of dispensed prescriptions to check that unit numbers are being recorded and entered by staff		

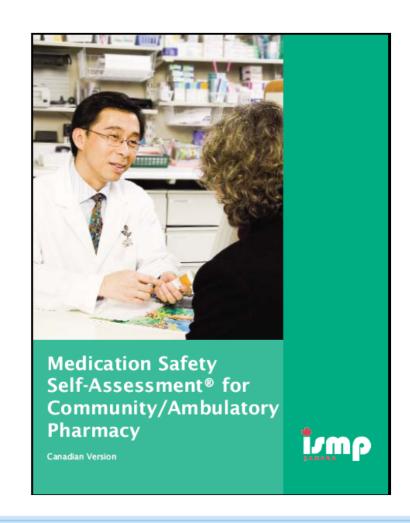
Can you think of examples of processes that FMEA could help you to improve??

- pharmacy setting?
- other workplace?
- outside work/ school?

Another Type of Prospective Assessment: MSSA

Medication Safety Self-Assessment® (MSSA)

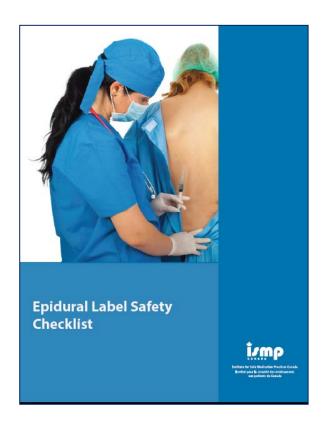
- Designed to help practitioners assess the safety of their own practice sites
- Web-based program allows comparison to aggregate data as well as monitor individual progress over time



New MSSAs in 2015







Other MSSAs Available



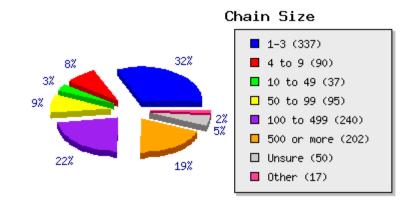
Benefits of MSSA

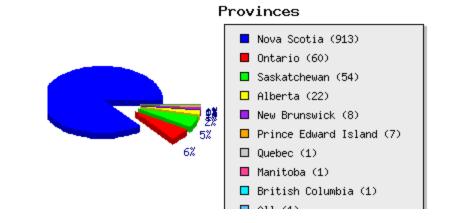
- Assists with identification of areas of risk in an individual practice site
- Provides focus for quality improvement projects
- Generates local interest in system and culture change
- Provides a record of improvement over time
- Development of provincial / national database for comparative purposes

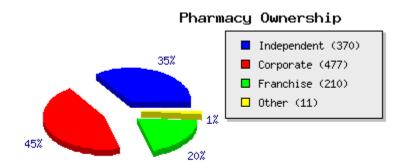
Internal and External Comparisons

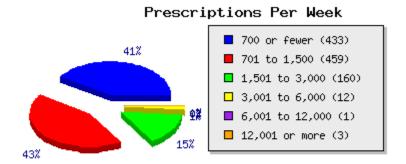
- Web-based program allows comparison to:
 - Previous in-house surveys
 - Total aggregate
 - Select fields:
 - Pharmacy size and type
 - Ownership
 - Prescriptions dispensed per week
 - FTEs
 - Services offered
 - Province

Demographics

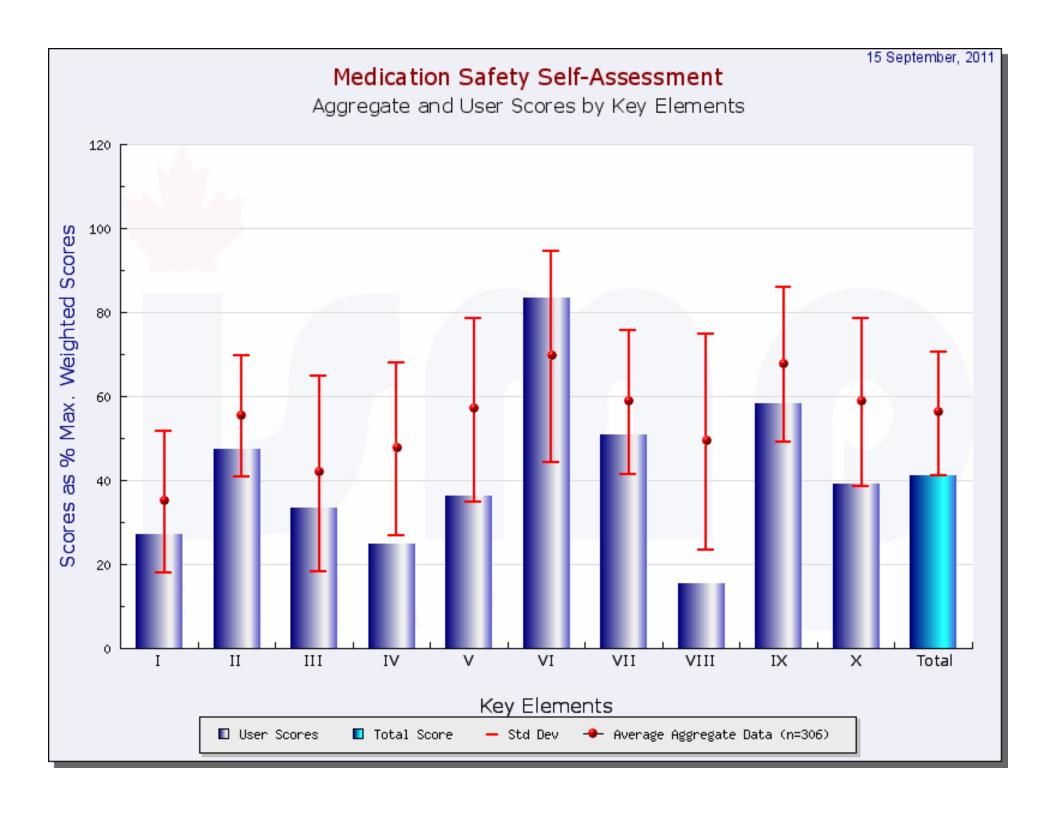








Demographics as of 28Aug2015 (n = 1068)





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

Medium Leverage

Simplification and standardization

(e.g., standardized paper or electronic order sets)

High Leverage Most Effective

Forcing functions and constraints

(e.g., removal of a product from use)

Automation or computerization

(e.g., automated patientspecific dispensing)

Low Leverage

LEAST EFFECTIVE

Rules and policies

(e.g., policies to prohibit borrowing doses from other areas)

Education and information

(e.g., education sessions on high-alert medications)

Reminders, checklists, double checks

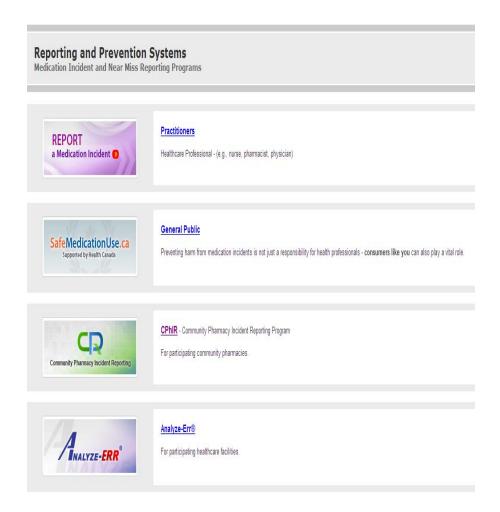
(e.g., independent double checks for high-alert medications)

HIERARCHYOF **EFFECTIVENESS**

Incident Reporting

Why report incidents?

How can you report incidents?





CPhIR Demo Site:

Login at http://www.cphir.ca/trai ning

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

Powered by





Analysis of Medication Incidents in Community Pharmacy

90 (5.87%)

Certina Ho, Nell J. MacKinnon, Todd A. Boyle, Tom Mahaffey, Bey Zwicker, Heldi Deal, Andrea Scoble, Sean Higgins, Roger Cheng, Patricia Hung, Gary Lee

-1(0.07%)



Objectives

The Community Pharmacy Incident Reporting (CPhIR)¹ 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. CPhIR contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS)².

SafetyNET-Rx² 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 SafetyNET-Rx Phasel pilot project. There were 12 duplicates or test entries, so 1532 incidents were analyzed, with a focus on the severity of outcome of the incidents and medication-use areas associated with these incidents in community pharmacy.



Severity of Outcome

 84% (1281 of 1532) of the incidents were near misses (Figure 1).

160 (10.44%)=

- 16% (250 of 1532) of the incidents resulted in no harm, of which 36% (90 of 250) involved patients who actually received and ingested the medication (Rgure 1).
- Only 0.07% (1 of 1532) resulted in temporary patient harm, which required the intervention of contacting the physician immediately Figure 1.

Medication-Use Areas

- The majority of incidents occurred during the Order Entry/Transcription and the Dispensing/Delivery stages – the two most common stages in community pharmacies (Flaure 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 metoprolol, amaxicillin, rosuvastatin,
 lorazepam, and metformin. (Note: It is possible that the likelihood of a
 medication to be involved with an incident is correlated with the frequency the
 medication is dispensed in community pharmacy.)
- Possible cause(s) of medication incidents (Figure 3).

Conclusion

REPORTED MEDICATION INCIDENTS CLASSIFIED BY OUTCOME (n=1532)

18.415 No Harry - Patient received the medication but did not ingert it

589% No Harm - Patient received and ingested the medication, but did not cause patient harm)

REPORTED MEDICATION INCIDENTS CLASSIFIED BY STAGES

MAIN THEMES AND POSSIBLE CAUSES OF MEDICATION INCIDENTS DERIVED FROM ANALYSIS

Medication rums with suffices

Incorrect daug in stock bottle

Specialized Dispensing Proces

Same or similar patient name

incorrect medication is basket or bac

incorrect medication due to storag

Look-eille / sound-eilke reed kartine

Use of the "copy" Yeature is dispensing system a time-saving mechanism during order entry

Combination products

Incorrect strength

Wronglabel

Transcription

Oraginteractions Allergies

incorrect dose prescribed

oos Harm

Product Mbr-Ups

Changes in

Wrong Patient

Compliance Alds

This analysis of medication incidents serves as an initial attempt to study factors that may contribute to medication incidents in community pharmacies.

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

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 CPhIR Program continues to accumulate data over time, trends and changes in medication incident patterns can be identified. CPhIR will continue contributing to CMIRPS, and help identify new areas of focus to enhance medication safety.

References

SWF Canada Community Pharmacyl reident Reports
 KPHR) Program, www.cpbk.cs

Canadias Medication Incident Reporting and Prevention System
 CALERS, experience and experience

Pharmacy CQI Program - Safety NET-Rs - Carea
 www.safetyNETRs.ca



Institute for Safe Medication Practices Canada

Funding for this study was provided by the Social Sciences and Humanities Research Council of Canada.

The authors would like to thank the Nova Scotia College of Pharmacists for their in-kind support, and acknowledge the community pharmacies who participated in the SafetyNET-Rx Phase I pilot project in Nova Scotia, Canada.

-1281 (83.62%)

SafetyNET-







Continuous Quality Assurance Pilot Project in Saskatchewan Community Pharmacies

CMIRPS # SCDPIM



Certina Ho, RPh, BScPhm, MISt, MEd; Jim Hanwen Kong, BSc, Pharm D Candidate; Carol Lee, C.H.I.M.

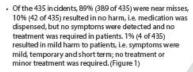
Objectives

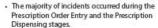
- Continuous quality assurance (CQA) is necessary for advancing safe medication practices in community pharmacies.
- COMPASS™ (Community Pharmacists Advancing Safety in Saskatchewan) (http://saskpharm.ca/site/cga_pp?na v=03) is a CQA pilot project for community pharmacies in Saskatchewan, Canada.
- · 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's Community Pharmacy Incident Reporting (CPhIR) Program (www.cphir.ca) 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 areas associated with these incidents in community

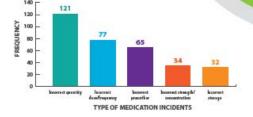
Results





- · The most common types of incidents reported were incorrect quantity (28%), incorrect dose/frequency (18%), and incorrect prescriber (15%). (Figure 2)
- · Possible contributing factors of these near misses and medication incidents include illegible prescription orders, dangerous abbreviations, look-alike/sound-alike drug names, and interruptions in workflow. (Figure 3)

FIGURE 2. TYPE OF MEDICATION INCIDENTS





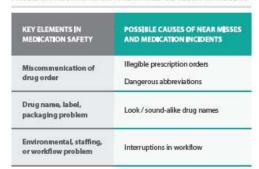


Discussion

9.66% 42

- · 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 CPhIR Program continues to accumulate data over time, trends and changes in medication incident patterns can be identified. CPhIR will continue contributing to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (www.ismp-canada.org/cmirps/), and help identify new areas of focus to enhance medication safety.

POSSIBLE CONTRIBUTING FACTORS TO NEAR MISSES AND MEDICATION INCIDENTS



The authors would like to acknowledge the support from the Ontario Ministry of Health and Long-Term Care for the development of the CPhiR program. CPhiR contributes to the Canadian Medication incident Reporting and Prevention System (CMIRPS). The authors would like to acknowledge the Saskatchewan College of Pharmacists for its support and facilitation of this CQA pilot project. The incidents anonymously reported by community pharmacy practitioners in Saskatchewan to CPhiR were extremely helpful in the preparation of this poster.

Near Misses

No Harm

Mild Harm

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."

Marx D, Comden SC, Sexhus Z (2005). Our inaugural issue – in recognition of a growing community. *The Just Culture Community News and Views,* 1(1).

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...)

Collier R, The art and science of naming drugs. CMAJ 2014. available from: http://www.cmaj.ca/site/earlyreleases/3sept14_the-art-and-science-of-naming-drugs.xhtml.)

If you were counselling a patient about a high-alert drug tomorrow, is there something different you would tell them about?



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