Advancing Safe Medication Practices

Medication errors and patient safety: tools for system improvement

PHM 301

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ISMP Canada

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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.

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Supported by Health Canada

Medication Reconciliation

SafeMedicationUse.ca

Reporting and Prevention Systems

REPORT a Medication Incident

Medication Incident and Near Miss Reporting Programs for:

- Practitioners
- General Public
  SafeMedicationUse.ca

MOHLTC Supported Initiatives

Ontario Critical Incident Learning

- Safe Use of Insulin Interventions
- Medication Safety Support Service (MSSS)
- Ontario Antimicrobial Stewardship Project
- Operating Room Medication Safety Checklist®
- FMEA Report - Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use
- Multiple IV Infusions: Project | Webinar
- Safer Medication Use in Older Persons

Multi-Stakeholder Projects

Canadian Pharmaceutical Bar Coding Project

MyMedRec App- Keep track of your medicines and vaccines

Canadian Incident Analysis Framework

Consumers Can Help Prevent Harm from Opioid Use!

Upcoming ISMP Canada Events

Webinars	Thursday, September 19, 2013	Development of a Guide to Support the Design of Safe Health Product Labels and Packages
	Wednesday, October 2, 2013	The Risk of Look-Alike Arterial Blood Gas Syringes: A Blinded Experiment
	Tuesday, October 8, 2013	Promoting the Safe Use of Insulin in Hospitals
	Wednesday, September 18, 2013	**This session is full.** BPMH Training for Pharmacy Technicians - Toronto, ON Request to be placed on the wait list of this session.
	Thursday, September 26, 2013	Root Cause Analysis (RCA) Workshop for Pharmacists - Toronto, ON
	Friday, September 27, 2013	Incident Analysis Framework Train-the Trainer Workshop For PSEP-Canada Trainers - Toronto, ON
	Friday, September 27, 2013	Proactive Risk Assessment in Pharmacy Practice using Failure Mode and Effects Analysis (FMEA) - Toronto, ON
	Wednesday, October 9, 2013	Root Cause Analysis (RCA) Workshop for Nurses - Toronto, ON

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

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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 connection between nerves and muscles. Notably, the muscles that are essential for breathing become paralyzed in patients who receive these medications—these patients need to be immediately ventilated. Serious injuries and deaths have occurred with substitution errors involving these drugs.[1-4] Incidents involving inadvertent administration of neuromuscular blocking agents and recommendations for prevention of error have been highlighted in previous issues of the ISMP Canada Safety Bulletin.[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 2006, ISMP Canada convened a meeting of representatives of Canadian manufacturers of neuromuscular blocking agents. The intent was to collaborate in identifying opportunities to reduce the risk for accidental administration of a neuromuscular blocking agent because of a product mix-up.[5]

The pharmaceutical representatives agreed upon several ideal packaging and labelling features for neuromuscular blocking agents to help differentiate them from all other drugs:[5]

- 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 Anesthesiologists (ASA; www.asahq.org)
- space 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.

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Consumers Can Help Prevent Harmful Medication Incidents

SafeMedicationUse.ca Newsletter

Volume 5 - Issue 4 - June 19, 2014

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 lead to consumers 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 tacrolimus and the dose was one 0.5 mg capsule to be taken twice daily. This medicine is used after organ transplantation to prevent rejection. It is also used to treat rheumatoid arthritis. The consumer picked up the prescription for tacrolimus at the pharmacy and took it for 4 weeks. Over this period, the consumer began to feel worse and lost a lot of weight. The consumer noticed that the capsules looked different from those of a previous prescription, but continued to take the medicine. During a follow-up visit with a doctor, it was discovered that the pharmacy had dispensed the incorrect strength of tacrolimus. Even though the label on the prescription vial stated the strength as 0.5 mg, the vial actually contained 5 mg capsules (see Figure 1). The consumer was taking 10 times the amount of medicine that the doctor had prescribed.

Figure 1: Tacrolimus 0.5 mg and 5 mg capsules

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

Ontario
CRITICAL Incident Learning

Improving quality in patient safety

Issue 9
June 2014

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee and nursing leadership committees with a recommendation to examine the use of insulin pens for inpatients
- Circulate bulletin to physicians and front-line staff
- Use bulletin, in addition to other tools such as the insulin pen e-Learning module, as an educational resource in your hospital's safety huddles or rounds

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.[1] 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.[2] Since insulin cartridges and reservoirs can be contaminated with blood and other biologic material after their first use, sharing insulin pens carries the potential for transmission of blood-borne pathogens (e.g., HIV, hepatitis B, hepatitis C).[2,3]

ISMP Canada, with support from the Ontario Ministry of Health and Long-Term Care, led a knowledge translation* project to develop evidence-based interventions and resources 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.[4]

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 only.
- Place patient-specific labels on the barrel of the insulin pen, not on the cap.
- Use insulin cartridges only with an insulin pen. Do not use a needle and syringe to withdraw insulin from 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.

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
5. Optimize human and environmental factors
6. Recognize, respond to and disclose adverse events

The Safety Competencies

Enhancing Patient Safety Across the Health Professions

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

Patient safety, defined as the reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices shown to lead to optimal patient outcomes, is a critical aspect of quality health care.

The *Safety Competencies* provide a framework of six core domains of abilities that are shared by all health care professionals. By contributing to the patient safety education of health care professionals, the *Safety Competencies* can contribute to safer patient care.

- Domain 1: *Contribute to a Culture of Patient Safety*
  A commitment to applying core patient safety knowledge, skills and attitudes to everyday work.
- Domain 2: *Work in Teams for Patient Safety*
  Working within interprofessional teams to optimize both patient safety and quality of care.
- Domain 3: *Communicate Effectively for Patient Safety*
  Promoting patient safety through effective health care communication.
- Domain 4: *Manage Safety Risks*
  Anticipating, recognizing and managing situations that place patients at risk.
- Domain 5: *Optimize Human and Environmental Factors*
  Managing the relationship between individual and environmental characteristics in order to optimize patient safety.
- Domain 6: *Recognize, Respond to and Disclose Adverse Events*
  Recognizing the occurrence of an adverse event or close call and responding effectively to mitigate harm to the patient, ensure disclosure, and prevent recurrence.

Snapshot of the *Safety Competencies* framework
- 20 Key Competencies
- 140 Enabling Competencies
- 37 Knowledge Elements
- 34 Practical Skills
- 23 Essential Attitudes

The Safety Competencies - produced in collaboration with The Royal College of Physicians and Surgeons of Canada - September 2008

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, GreenallJ. Take a proactive approach with the 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 (2011-13)

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

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

Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Reports, 2013 and 2014. Available from: http://www.ismp-canada.org/download/ocil/ON_Critical_Incidents_Analysis_Report_31May2013.pdf and http://www.ismp-canada.org/download/ocil/ON_Critical_Incidents_Analysis_Report_3JUL2014.pdf

Medications most commonly involved in critical incidents in Ontario hospitals

Year 1: 2011-2012

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage %
Hydromorphone	3	2	5	11.1
Fentanyl	2	1	3	6.7
Heparin	2	0	2	4.4
Morphine sulphate	2	0	2	4.4
Norepinephrine	0	2	2	4.4
Oxycodone	2	0	2	4.4
Oxytocin	2	0	2	4.4

Year 2: 2013

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

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's List of High-Alert Medications. Available at: www.ismp.org/Tools/highalertmedications.pdf.

Incident Analysis
(Root Cause Analysis)

Why is analysis important?

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

Case Example

- Insulin dependent diabetic
- Rx for Novolin® ge 30/70 Penfill twice daily via insulin pen

Case Example (cont'd)

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

How can we analyze this incident effectively?

- Designed to provide a standardized approach to analysis of critical incidents and near miss events in healthcare environments.

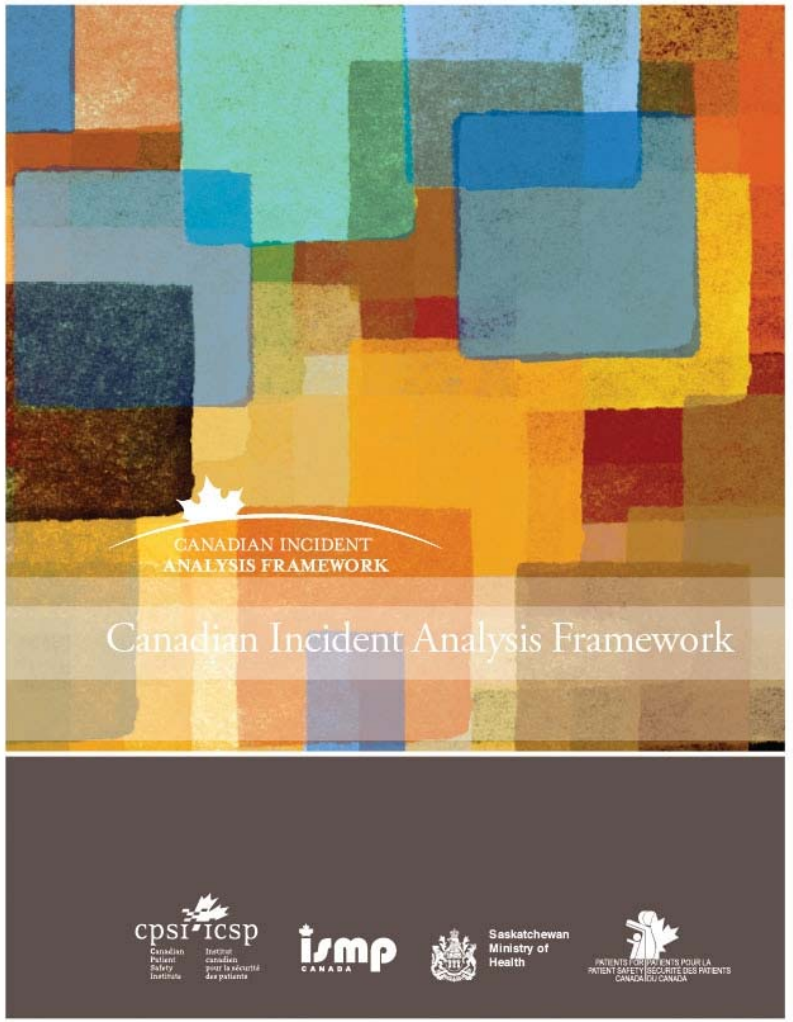
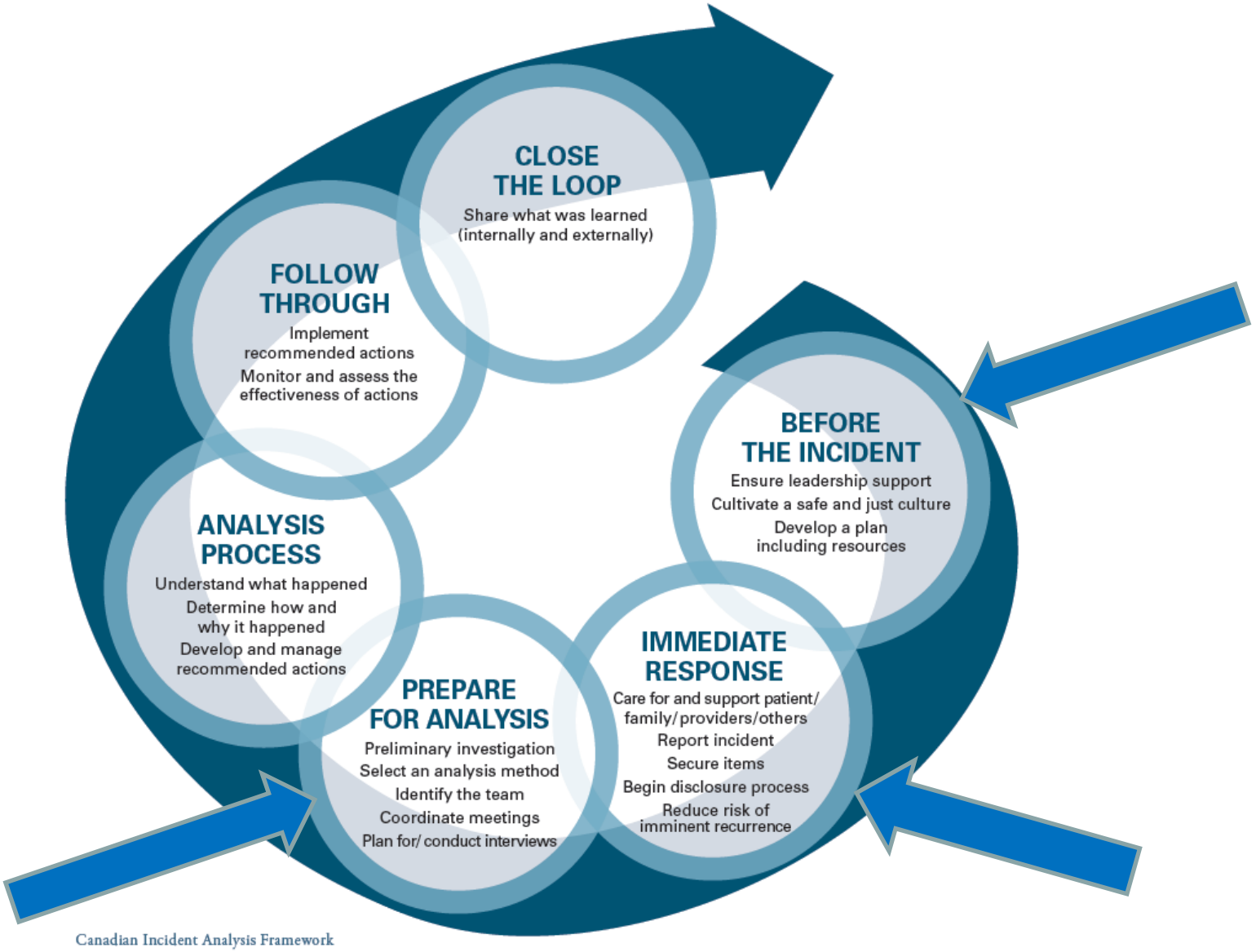


Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM



Canadian Incident Analysis Framework

Preliminary Investigation

- An initial understanding is prepared based on the facts known at the time.
  - Effective ways to provide this information may be a flow chart or narrative timeline, or chronological description.
- The team reviews the initial understanding to determine next steps and where the information gaps exist.

When are other processes appropriate?

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

(Based on VA Triage Questions for RCA, 2000)

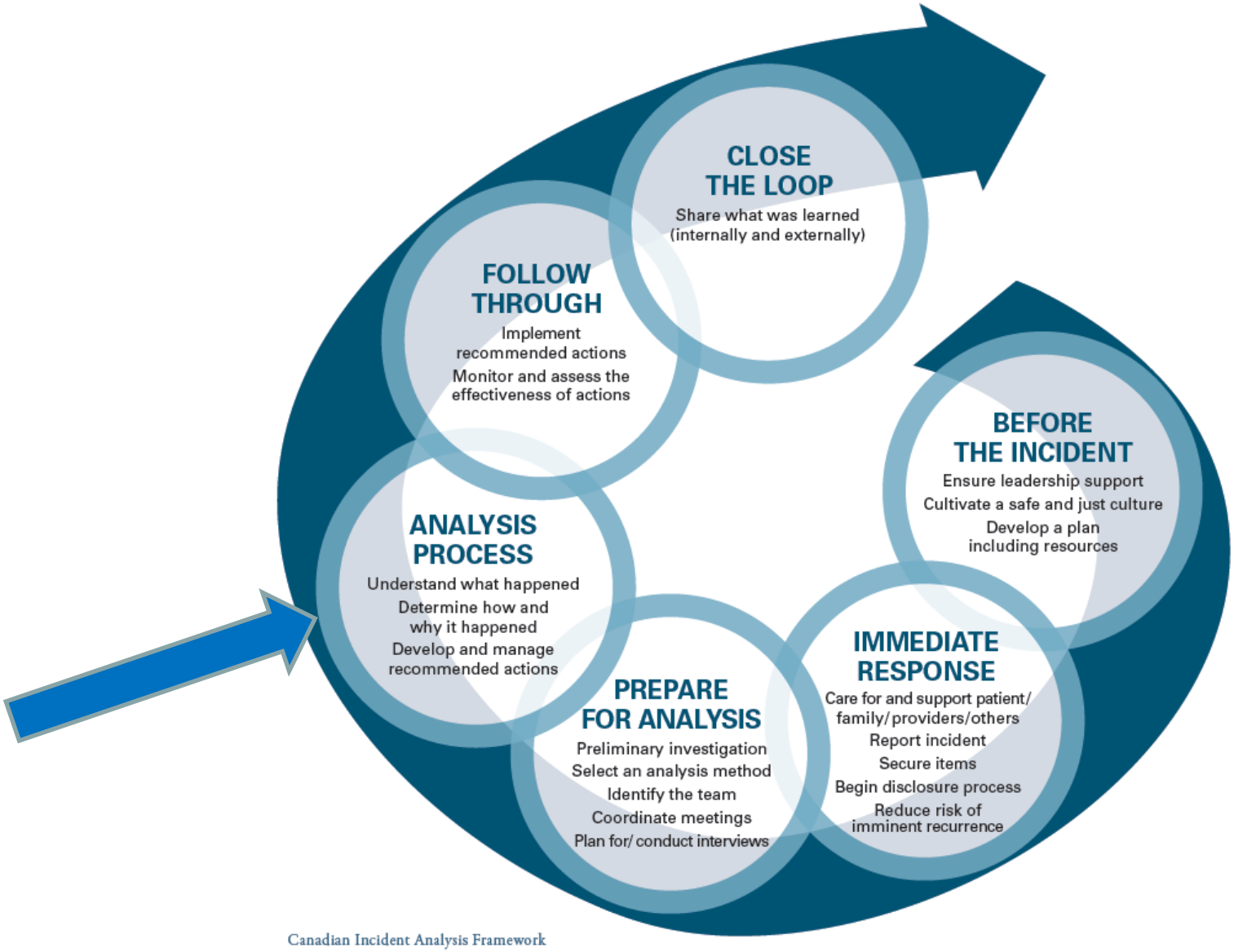
Interdisciplinary Team-Based Approach

- Provides important perspective
  - Practitioners with different clinical backgrounds will view situations with a different “lens”
  - Detailed examination often identifies information not known by all team members
- Invaluable to involve frontline staff
  - Staff understand and have direct knowledge of care processes
  - Participation creates greater visibility and acceptability for the recommendations
  - Will ultimately be responsible for implementing and sustaining process change(s)

Interview Process

- As soon as possible after the event
- One person at a time
- Interview all staff involved in event as well as patient/ consent provider and family as appropriate.
- Cooperative approach is important

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



Canadian Incident Analysis Framework

What Happened

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

What Happened

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

Packaging and Labelling

What Happened

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

Timeline

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

Timeline

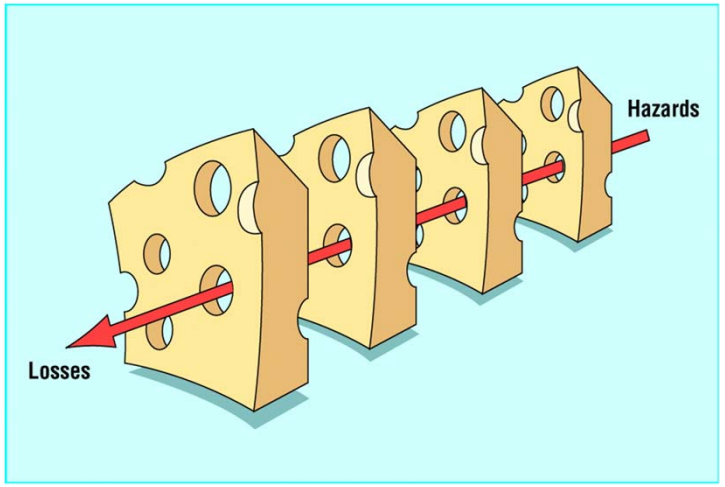
Time	Item	Information Source
7:30 am day of event	Patient reloads cartridge into insulin pen and administers as usual	Patient/family interview
7:45 am	Patient found with decreased level of consciousness, sweating and with dilated pupils by family member	Patient interview
7:50 am	Patient given sugar,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

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

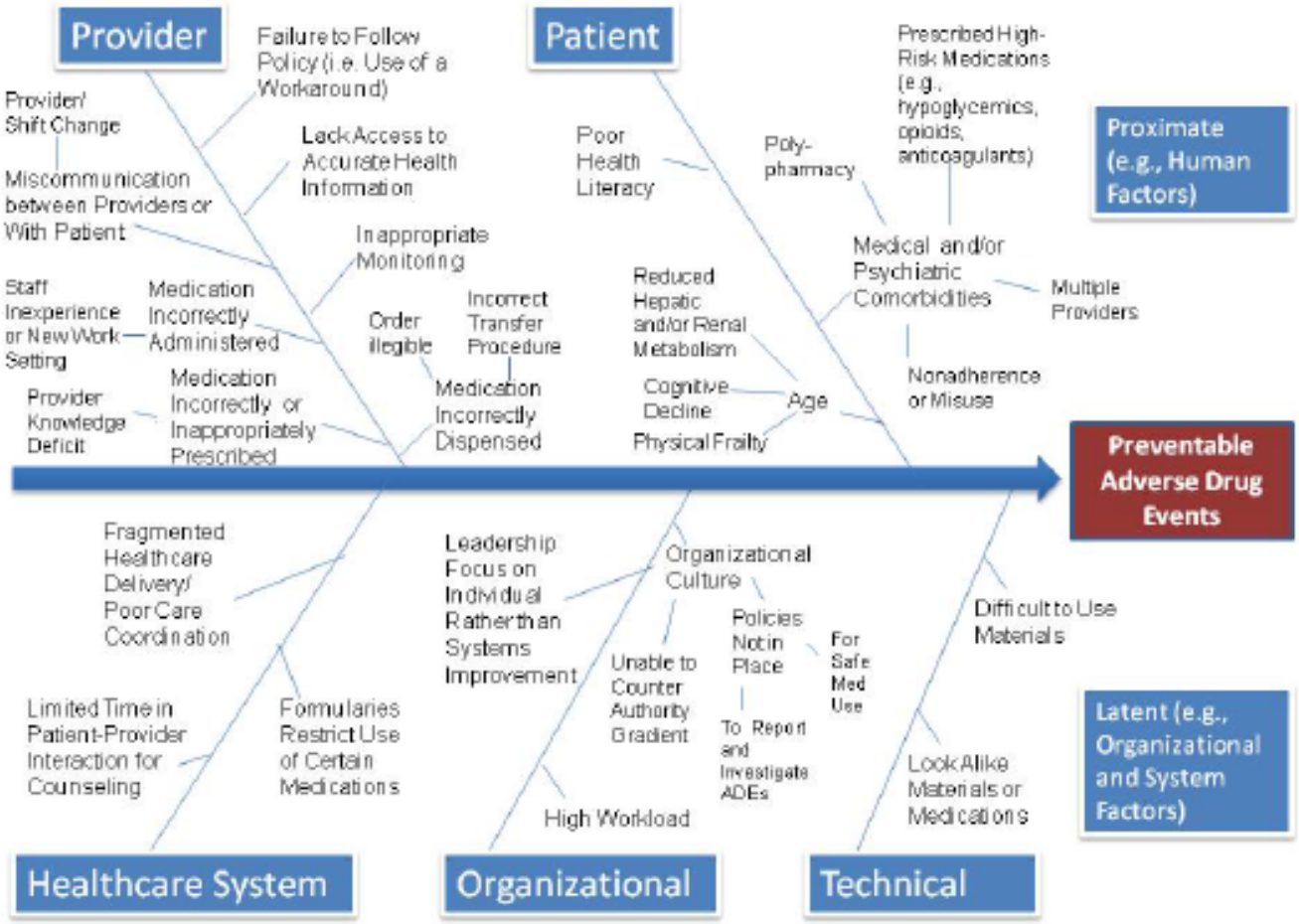
- The design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics.

- Human factors engineers work to make the environment function in a way that seems natural to people.

How and Why the Incident Happened

- Reasons for incidents are multi-factorial
- Need to consider
  - System/process design
  - Workflow
  - Individual accountability – e.g., workarounds

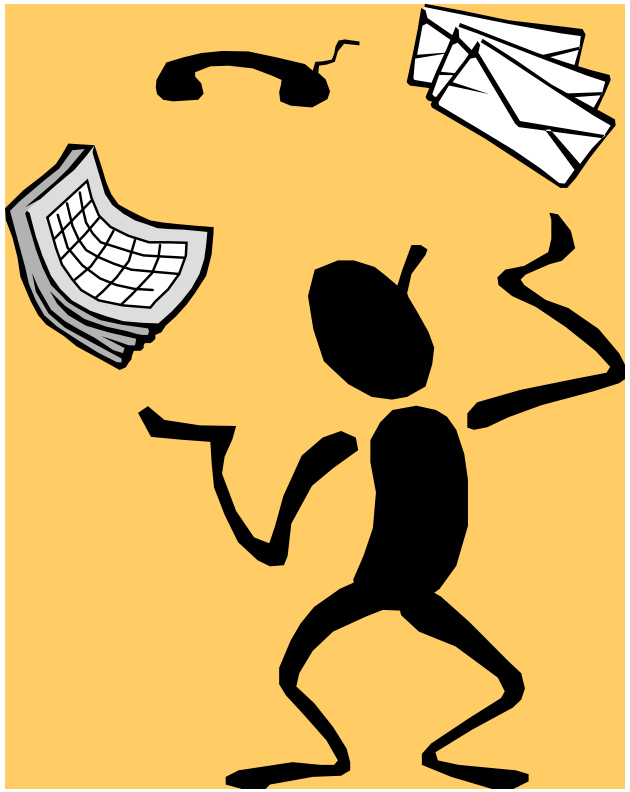
Key Determinants of Adverse Drug Events



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.

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.

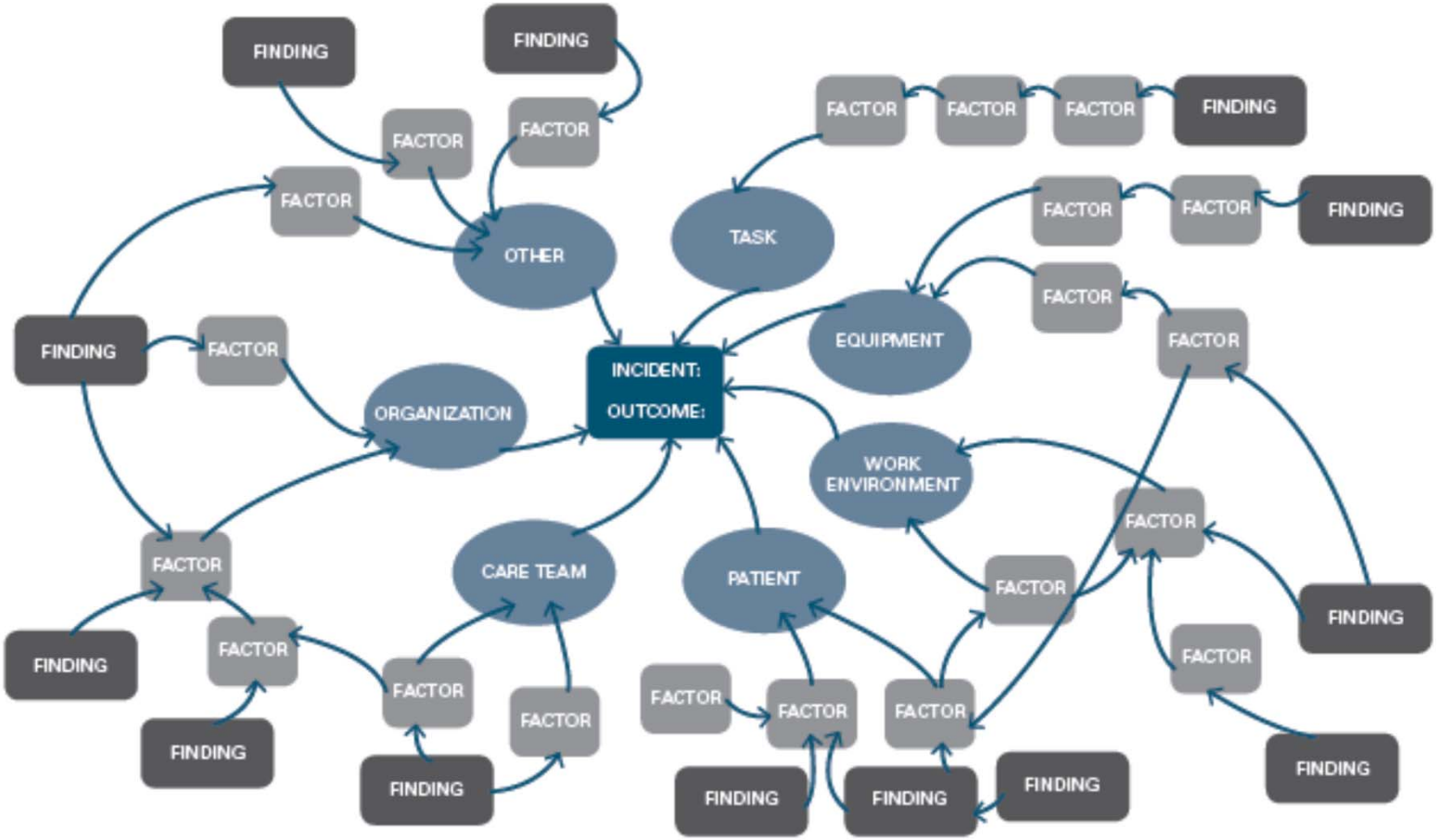
American Association of Critical Care Nurses

www.silencekills.com (2005)

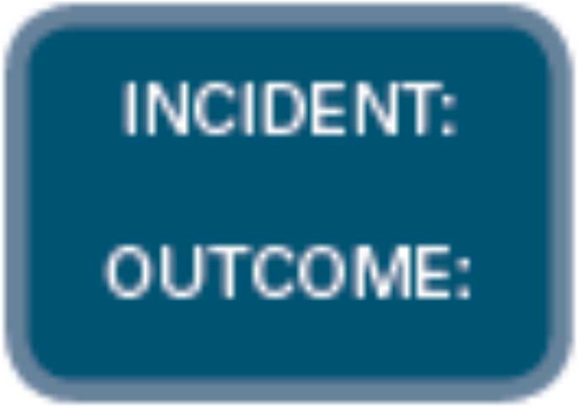
How and Why the Incident Happened

- 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

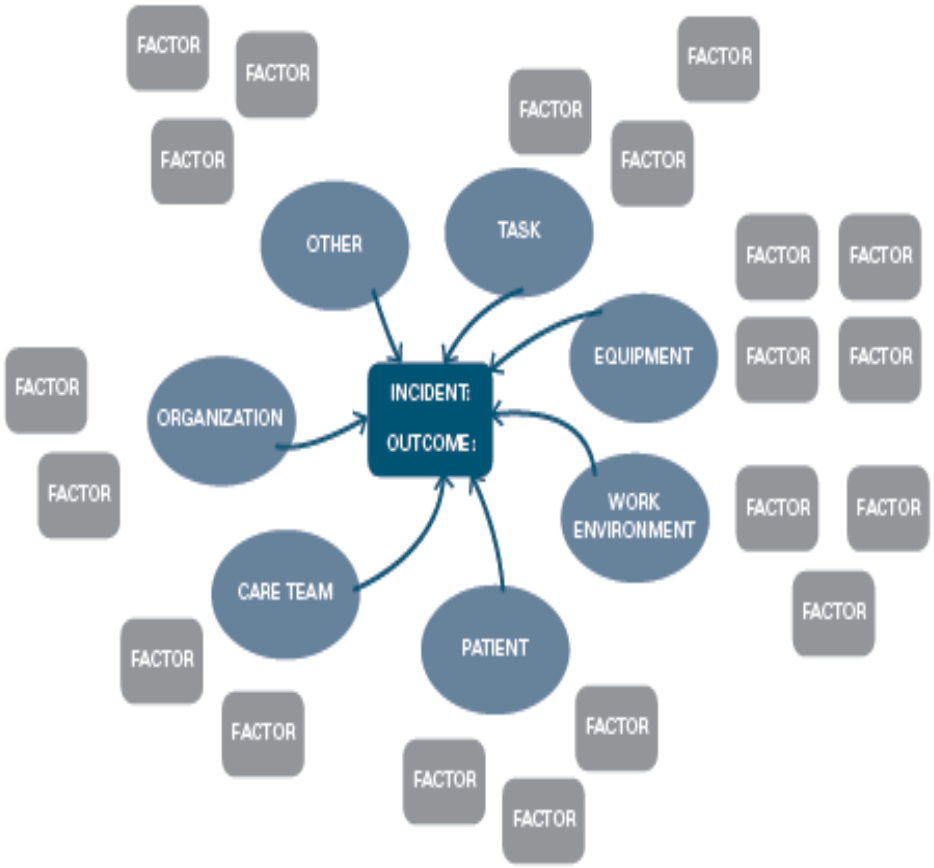
Step 2: Identify potential contributing factors

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

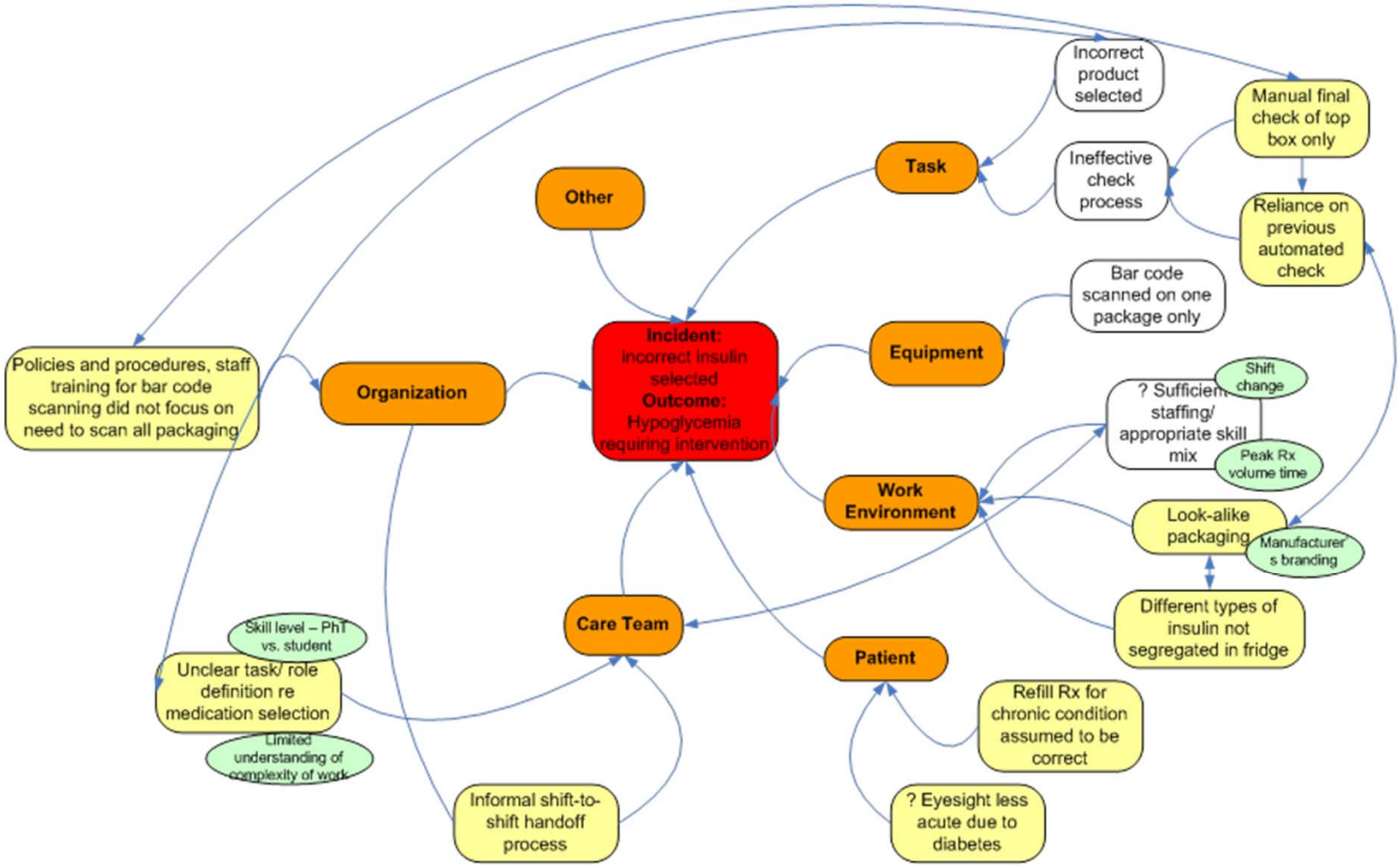
Step 4: Identify the findings

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

Step 5: Confirm the findings with the team



Summarize findings

- Statement of findings:
  - Focus on the contributing factors
  - Be as specific as possible
- Statement format:
  - *"the contributing factor(s), within the context of the incident, increased/decreased the likelihood that this outcome would occur"*
- Provides the backbone for development of recommended actions

Sample Statement

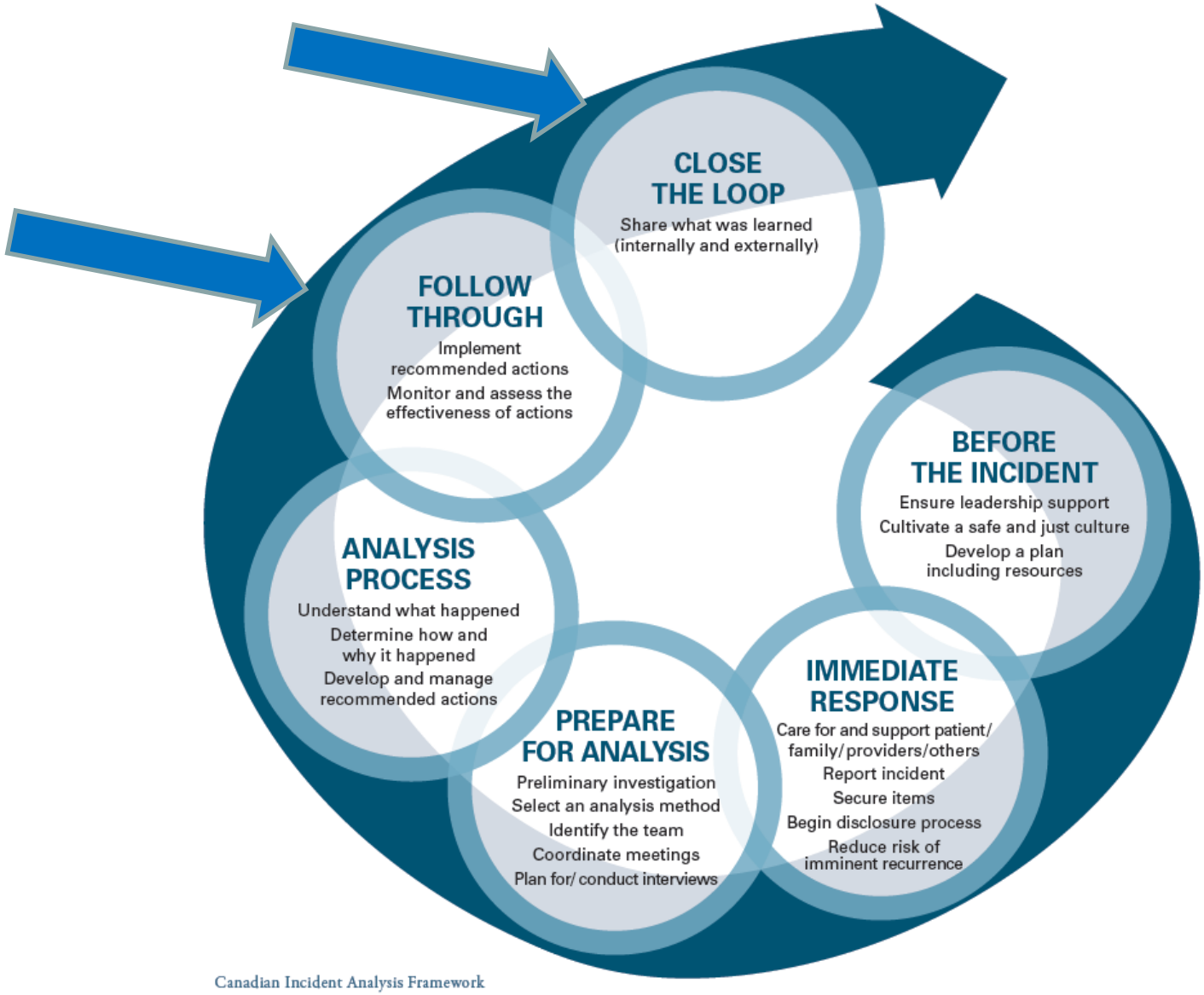
Unclear task and role definition *increased the likelihood that* a student would be responsible for selecting medications during dispensing, in turn *increasing the likelihood of* a medication selection error leading to a patient receiving and self administering an incorrect medication.

Develop and Manage Recommended Actions

- What can be done to reduce the risk of recurrence and make care safer:
  - Develop recommended actions
  - Suggest an order of priority
  - Prepare a summary report for endorsement by leadership as appropriate
  - Delegate recommended actions for implementation and empower implementation

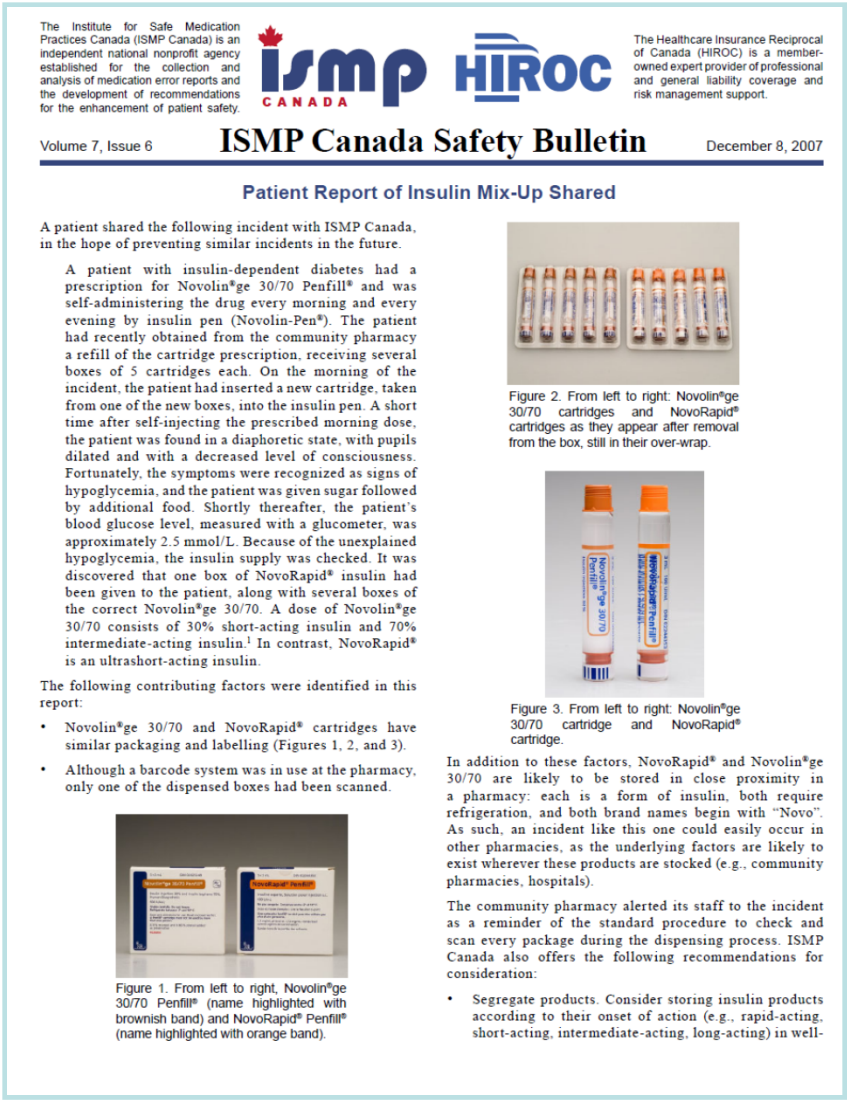
Ideas for redesign???

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



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.

ismp CANADA HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned 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 well-

How do we prevent errors from occurring in the first place.....

.....***prospective risk assessment***

Examples of Prospective Analysis Processes used in Industry

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

Commonalities

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

Failure Mode and Effects Analysis

- FMEA focuses on how and when a system will fail, **not if** it will fail.
- Future, preventive, proactive
  - Opposite to incident analysis (root cause analysis) which is retrospective (after the event or close call occurs)

Gains Using FMEA

- Safety minded culture
- Proactive problem resolution
- Fault tolerant systems
- Lower waste and higher quality
- Engagement of front-line staff
- Improved team communication

Conducting an FMEA: 8 Steps

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

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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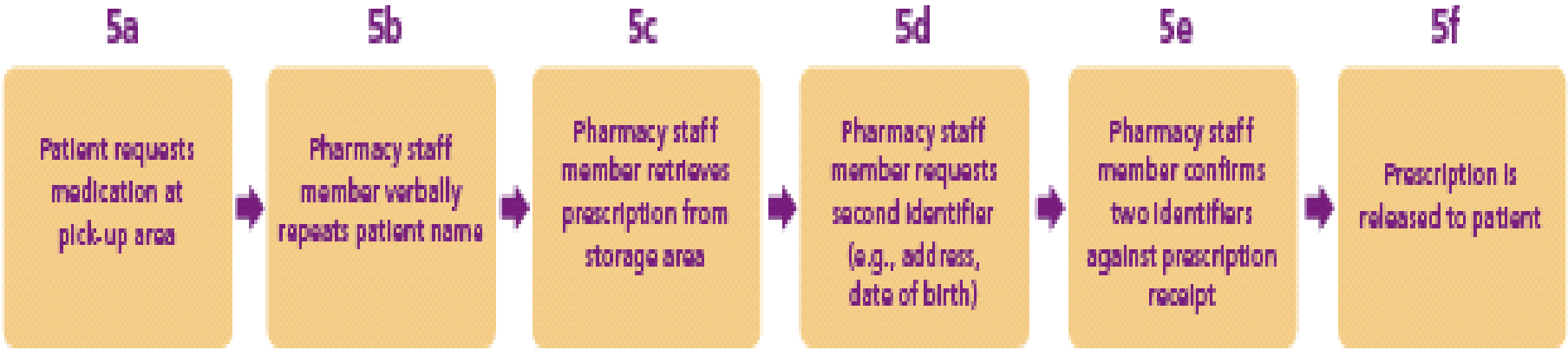
2a: Diagram the Process

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



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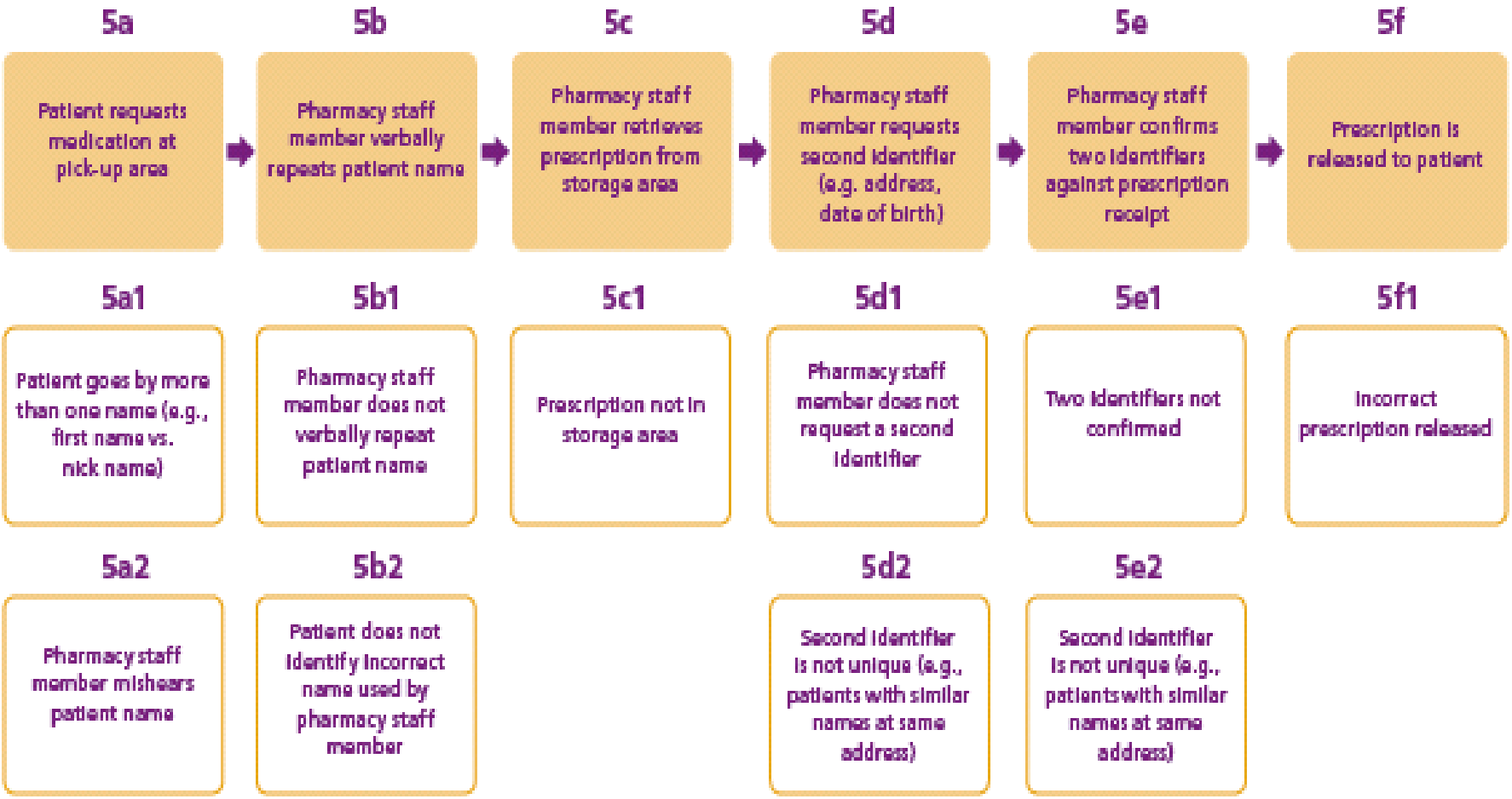
3: Brainstorm Potential Failure Modes



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

FMEA subject: Patient Identification in the dispensing process

Process: #5: Prescription is released to patient

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

Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	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							
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

Process: #5: Prescription is released to patient

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

Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	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.						
5d2	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						

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

FMEA subject: Patient identification in the dispensing process

Process:
#5: Prescription is released to patient

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

Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	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	
5d2	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
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6: Redesign the Process

FMEA subject: Patient identification in the dispensing process

Process:
#5: Prescription is released to patient

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

Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	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 (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

FMEA subject: Patient identification in the dispensing process		**Process:** #5: Prescription is released to patient		**Sub-process step:** #5c: Pharmacy staff member requests second identifier	
Failure 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 pharmacist	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	Licensee	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

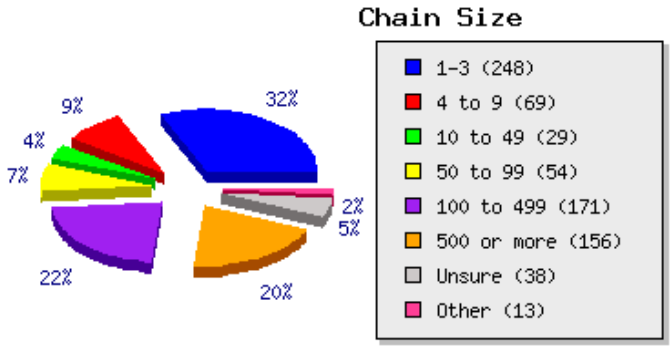
Benefits of MSSA

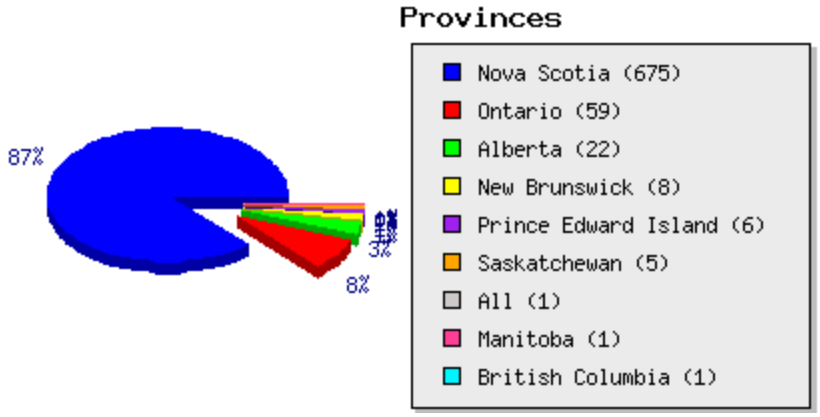
- Assists with identification of areas of risk in an individual practice site
- Provides focus for quality improvement projects
- Generates local interest in system and culture change
- Provides a record of improvement over time
- Development of provincial / national database for comparative purposes

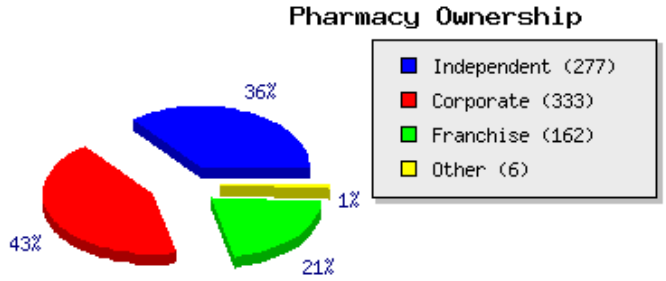
Internal and External Comparisons

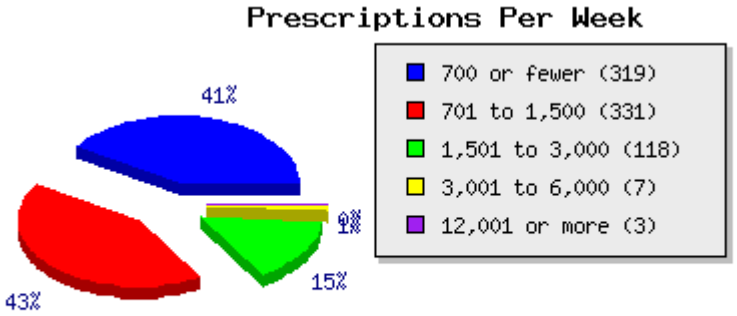
- Web-based program allows comparison to:
  - Previous in-house surveys
  - Total aggregate
  - Select fields:
    - Pharmacy size and type
    - Ownership
    - Prescriptions dispensed per week
    - FTEs
    - Services offered
    - Province

Demographics







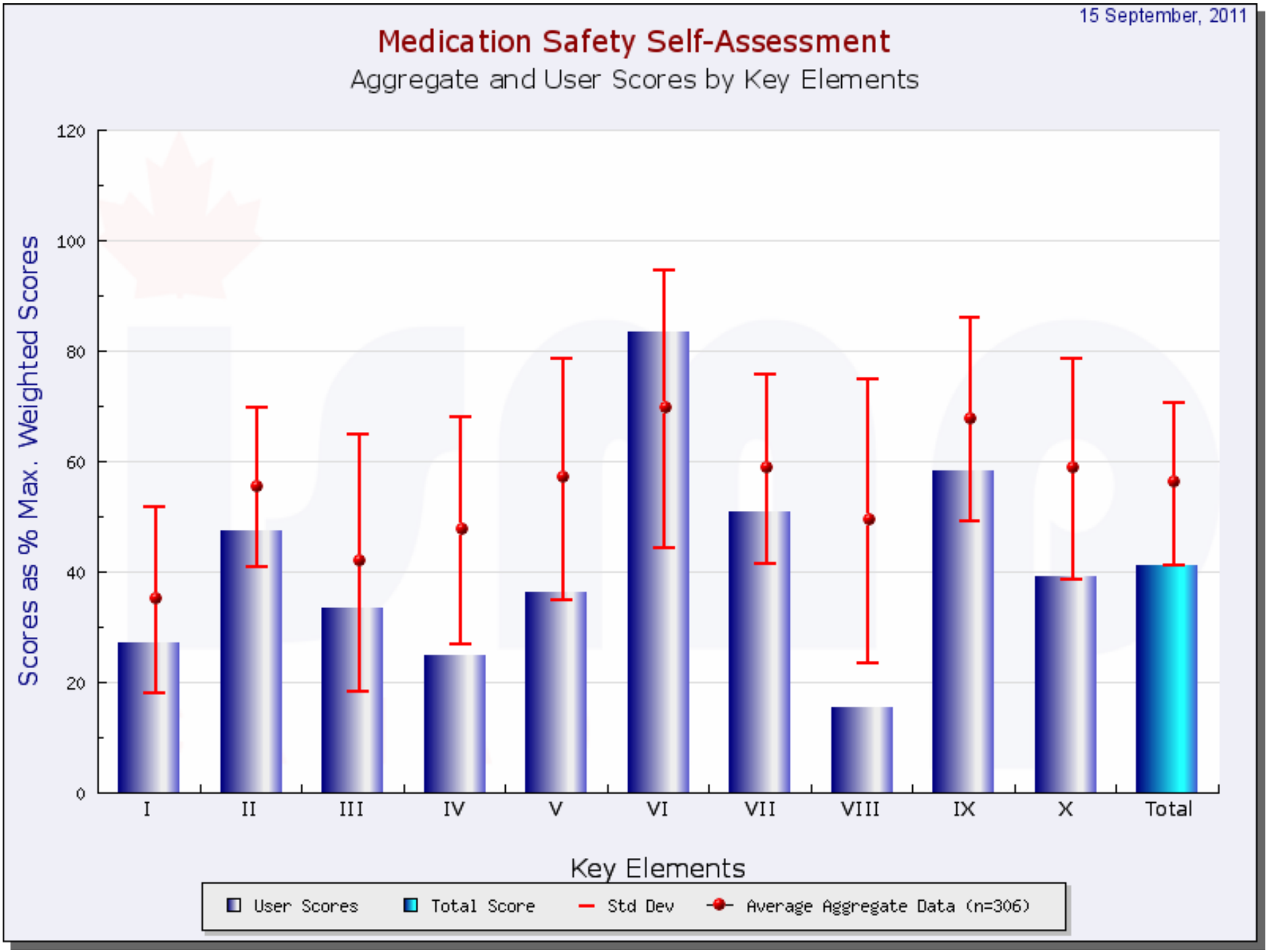


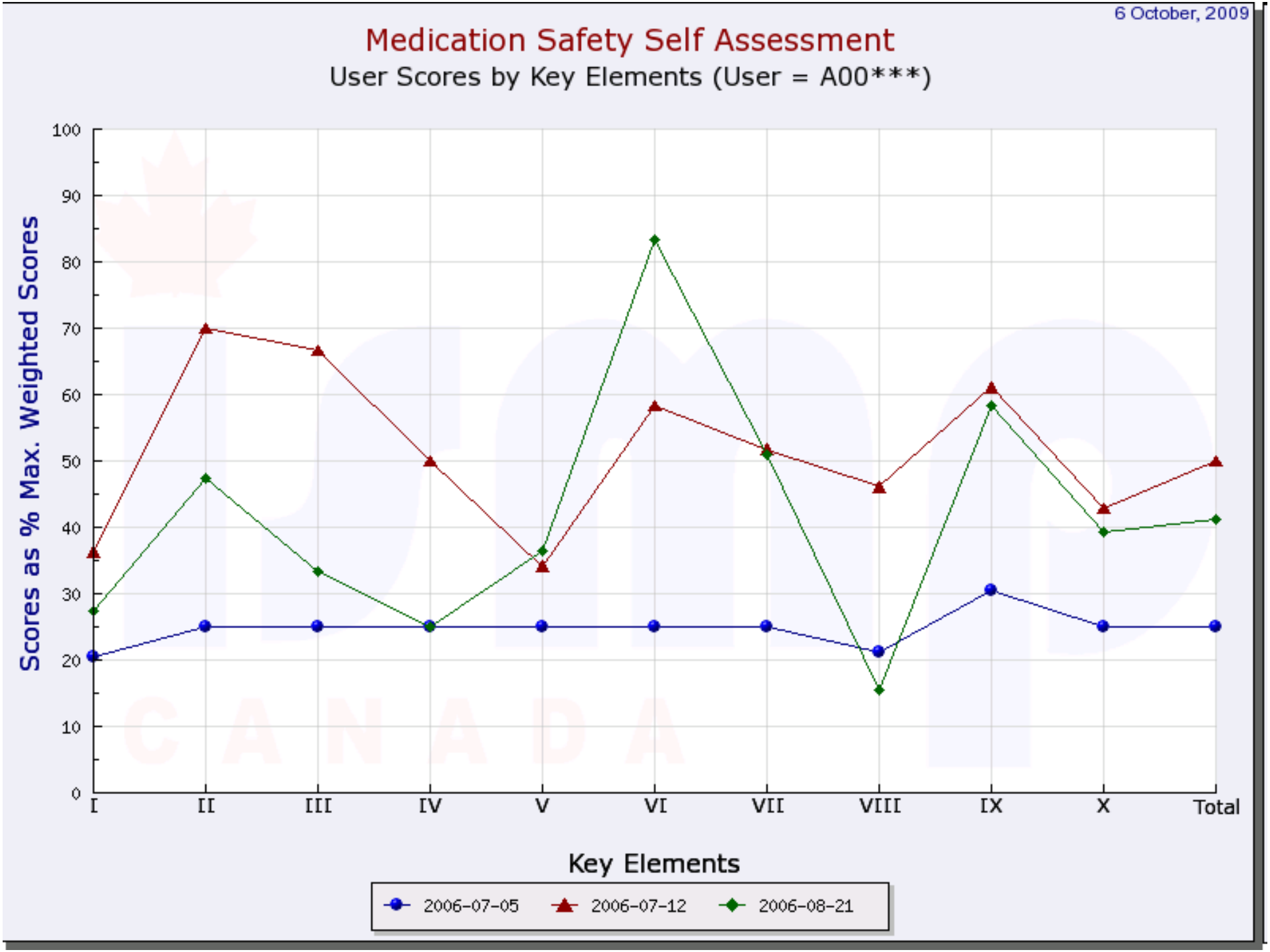
Demographics as of 10Sept2014
(n = 778)

15 September, 2011

Medication Safety Self-Assessment

Aggregate and User Scores by Key Elements

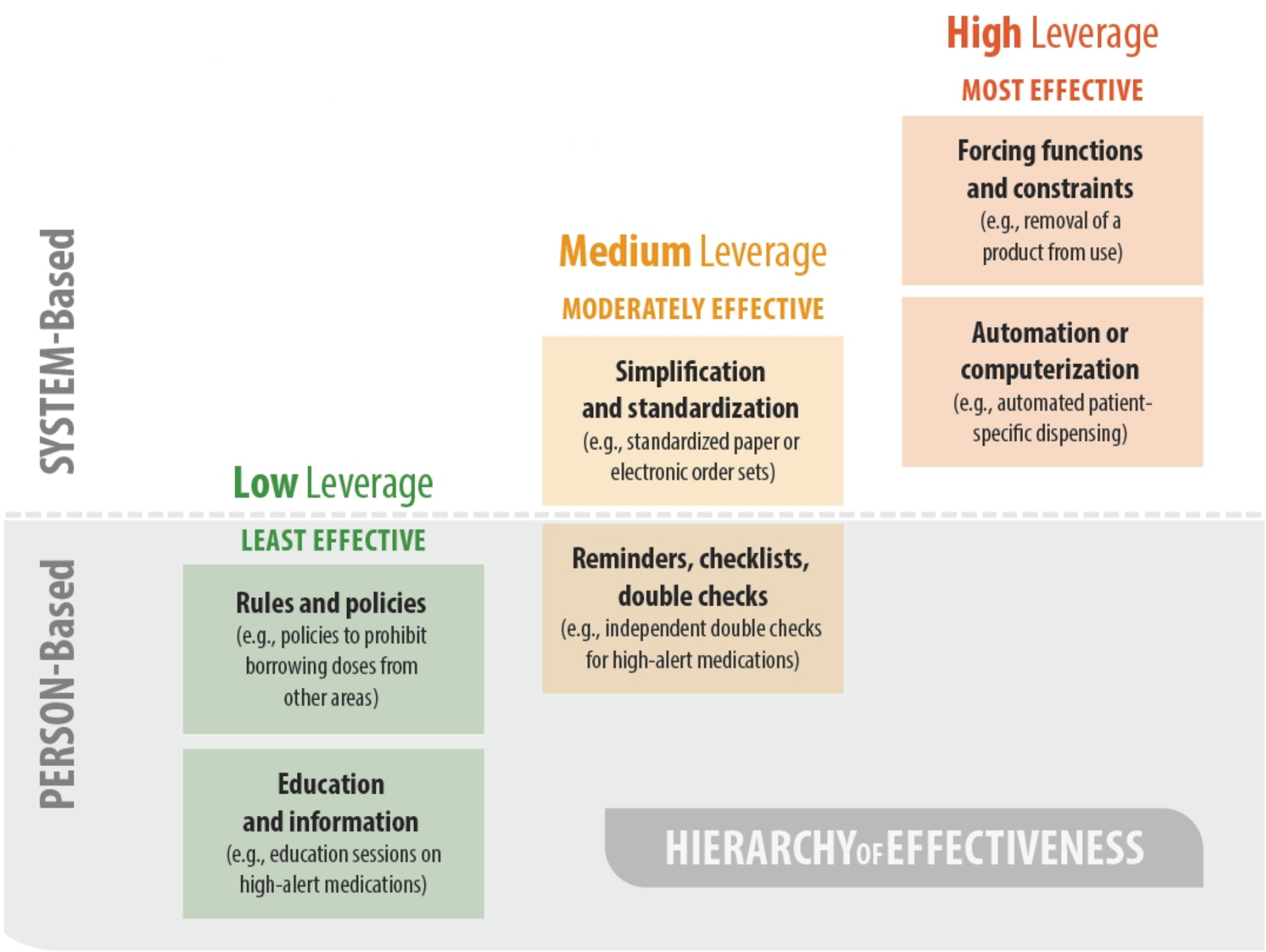



6 October, 2009
Medication Safety Self Assessment
User Scores by Key Elements (User = A00***)
Scores as % Max. Weighted Scores
100
90
80
70
60
50
40
30
20
10
0
I
II
III
IV
V
VI
VII
VIII
IX
X
Total
Key Elements
2006-07-05
2006-07-12
2006-08-21

Three Ways to Improve Safety

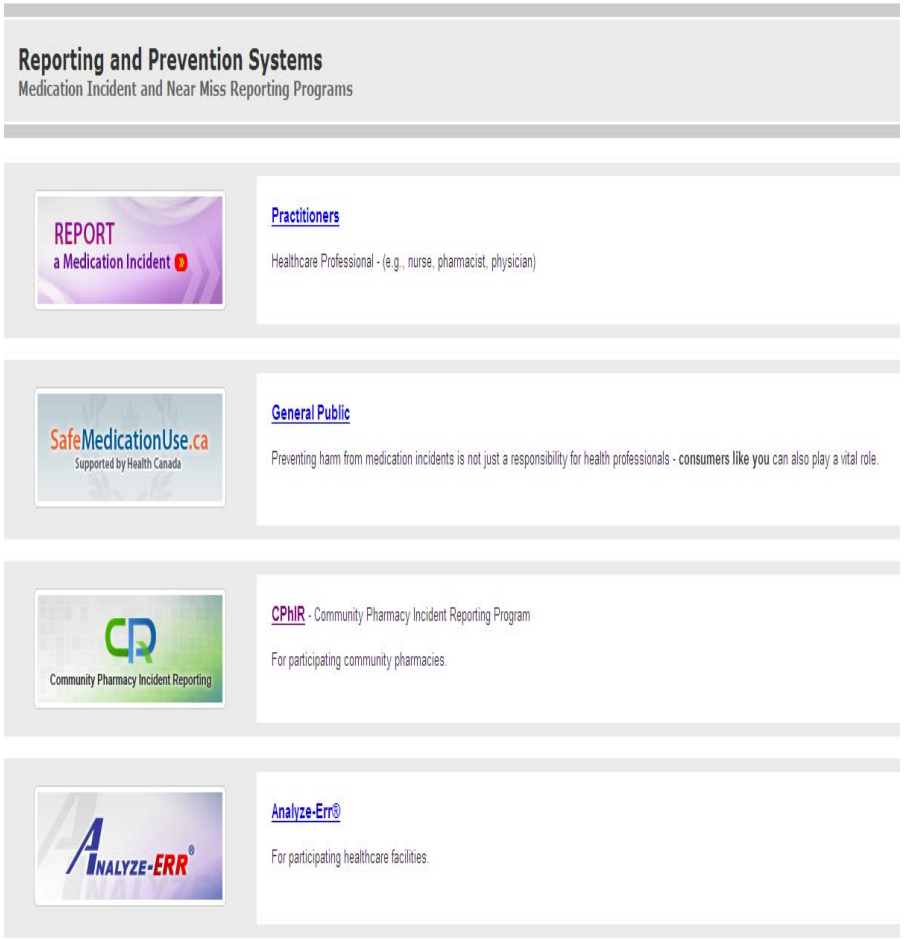
3 goals that guide safety efforts:

1. **Mitigate or minimize harm from errors**
   - ↓ Severity
2. **Reduce or eliminate risks that cause error**
   - ↓ Frequency
3. **Make the error visible**
   - ↑ Detectability


High Leverage
MOST EFFECTIVE
Forcing functions and constraints
(e.g., removal of a product from use)
Automation or computerization
(e.g., automated patient-specific dispensing)
Medium Leverage
MODERATELY EFFECTIVE
Simplification and standardization
(e.g., standardized paper or electronic order sets)
Low Leverage
LEAST EFFECTIVE
Reminders, checklists, double checks
(e.g., independent double checks for high-alert medications)
Rules and policies
(e.g., policies to prohibit borrowing doses from other areas)
Education and information
(e.g., education sessions on high-alert medications)
SYSTEM-Based
PERSON-Based
HIERARCHY OF EFFECTIVENESS

Incident Reporting

- Why report incidents?
- How can **you** report incidents?



CPhIR Demo Site:

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

Username: testuser

Password: testuser

Analysis of Medication Incidents in Community Pharmacy

Certina Ho, Neil J. MacKinnon, Todd A. Boyle, Tom Mahaffey, Bev Zwicker, Heidi Deal, Andrea Scobie, Sean Higgins, Roger Cheng, Patricia Hung, Gary Lee

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-Rx[3] 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 Phase I 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.

Results

Severity of Outcome

- 84% (1281 of 1532) of the incidents were near misses (**Figure 1**).
- 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 (**Figure 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 (**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 *metoprolol*, *amoxicillin*, *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**).

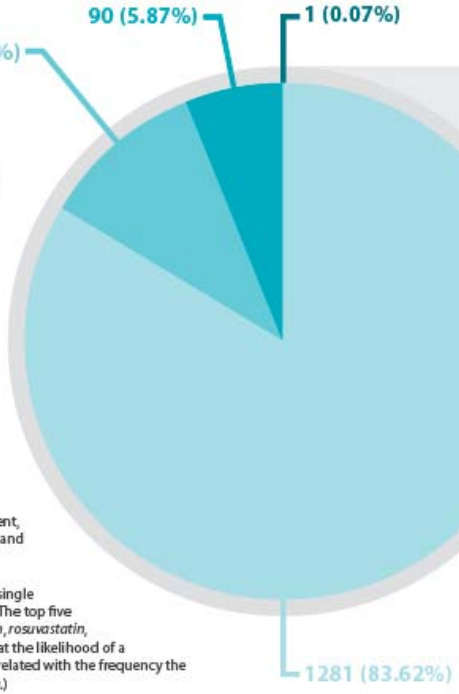


FIGURE 1.
REPORTED MEDICATION INCIDENTS CLASSIFIED BY OUTCOME (n=1532)

FIGURE 2.
REPORTED MEDICATION INCIDENTS CLASSIFIED BY STAGES

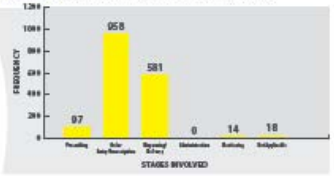


FIGURE 3.
MAIN THEMES AND POSSIBLE CAUSES OF MEDICATION INCIDENTS DERIVED FROM ANALYSIS

Main Themes	Possible Causes of Medication Incidents
1 Product Mix-Ups	Medication name with suffixes Combination products Look-alike / sound-alike medications Incorrect strength Incorrect drug in stock bottle
2 Incorrect Instructions	Dangerous abbreviations or illegible handwriting Wrong label
3 Changes in Treatment	Use of the "copy" feature in dispensing systems as a time-saving mechanism during order entry
4 Compliance Aids	Transcription Specialized Dispensing Process
5 Wrong Patient	Same or similar patient name Incorrect medication in basket or bag Incorrect medication due to storage
6 Drug Therapy Problem	Drug interactions Allergies Incorrect dose prescribed

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 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

1. ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program. www.cphir.ca
2. Canadian Medication Incident Reporting and Prevention System (CMIRPS). www.ismp-canada.org/cmirps
3. Pharmacy CQI Program - SafetyNET-Rx – Canada. www.safetynetrx.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.

SafetyNET-Rx

Continuous Quality Assurance Pilot Project in Saskatchewan Community Pharmacies

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/cqa_pp?nav=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 pharmacy.

Results

- Of the 435 incidents, 89% (389 of 435) were near misses, 10% (42 of 435) resulted in no harm, i.e. medication was dispensed, but no symptoms were detected and no treatment was required in patients. 1% (4 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 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 1.
MEDICATION INCIDENTS CLASSIFIED BY OUTCOME (*n* = 435)

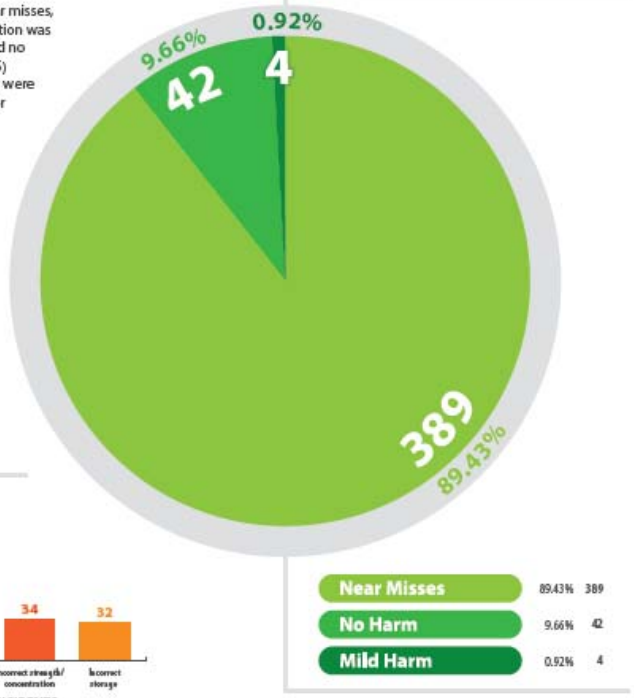
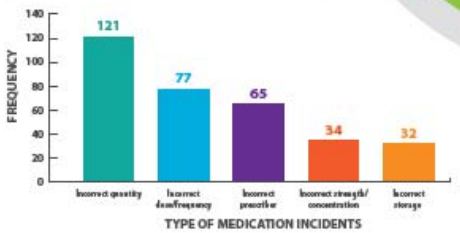


FIGURE 2.
TYPE OF MEDICATION INCIDENTS



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 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.

FIGURE 3.
POSSIBLE CONTRIBUTING FACTORS TO NEAR MISSES AND MEDICATION INCIDENTS

KEY ELEMENTS IN MEDICATION SAFETY	POSSIBLE CAUSES OF NEAR MISSES AND MEDICATION INCIDENTS
Miscommunication of drug order	Illegible prescription orders Dangerous abbreviations
Drug name, label, packaging problem	Look / sound-alike drug names
Environmental, staffing, or workflow problem	Interruptions in workflow

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.

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.)

Top Ten U.S. Medications, 2000 Survey

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

http://www.qfever.com/2000/08/23/little-blue-pill-now-most-commonly-prescribed-medication-in-u-s/#.VBCYlxbz_Tr

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

"The healthcare industry has not sufficiently developed a healthy preoccupation with system failures...."

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

ISMP Medication Safety Alert! 2007; 12(24)

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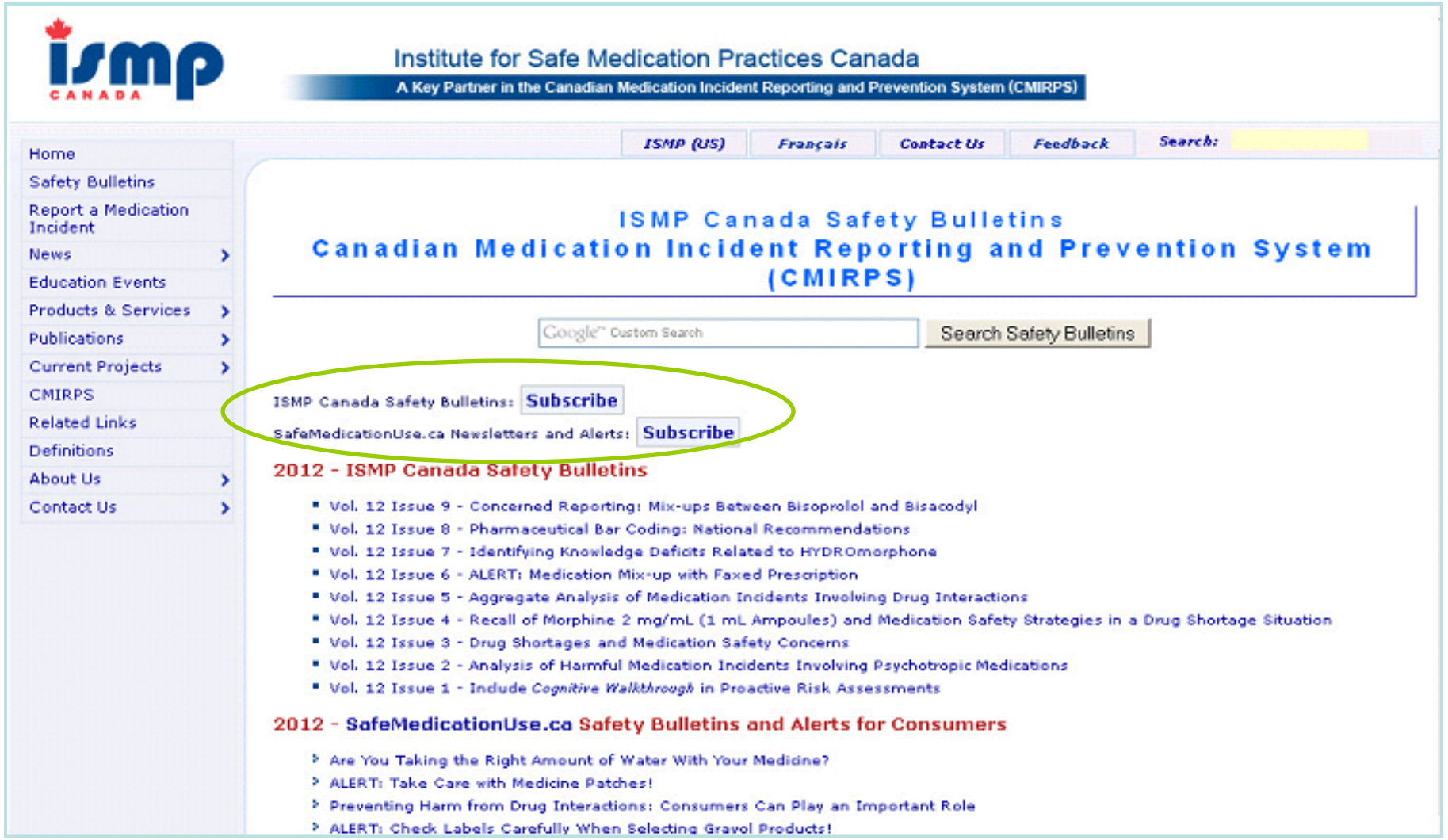

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