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

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Disclosure

- No personal financial relationships with industry
- The Institute for Safety Medication Practices Canada (ISMP Canada) has strict guidelines on the types of activities that can be funded by the pharmaceutical industry in order to maintain our independence
- This presentation was made possible through grant funding from Health Canada

Presentation Outline

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

Learning Objectives

At the conclusion of this presentation, participants will understand:

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

About ISMP Canada

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

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

www.ismp-canada.org

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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.

CMIRPS
Supported by Health Canada »

Community Pharmacy PROGRAMS

SafeMedicationUse.ca
for consumers

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**

June 11-12, 2015 — Medication Safety for Pharmacy Practice: *Incident Analysis and Prospective Risk*

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ismp CANADA

A COMPONENT OF THE

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program

REPORT a Medication Incident

Practitioners:
Healthcare Professional - (e.g., nurse, pharmacist, physician)

SafeMedicationUse.ca *for consumers*

General Public:
Preventing harm from medication incidents is a responsibility of health professionals. **Consumers like you** can also play a vital role.

ISMP Canada Activities for the CMIRPS:

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

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

SafeMedicationUse.ca

SUPPORTED BY HEALTH CANADA

Help Prevent Harmful Medication Incidents

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

Preventing harm from medication incidents is a responsibility of health professionals. **Consumers like you** can also play a vital role.

Reporting Medication Incidents benefits all Canadians.

REPORT NOW

- About SafeMedicationUse.ca
- About Medication Incidents
- Why Report?
- Resolving Concerns About the Safety of Your Care
- Frequently Asked Questions (FAQs)
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Sign up to receive the latest Alerts and Newsletters:

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Latest News and Resources

SHARE

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

ISMP Canada Safety 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

Tacrolimus 0.5 mg Tacrolimus 5 mg

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[4] 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.[5]

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.

Definitions

Safety:

Freedom from accidental injuries.

From Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC, National Academy Press, 1999.

Medication Safety:

Freedom from preventable harm with medication use.

ISMP Canada, 2007

Foundational Principles

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

Numerous high profile examples of medication errors causing harm

Case Example

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

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

Treated with naloxone (opioid antidote) and charcoal.

Fortunately no adverse outcome…

How many patients do you think experience preventable adverse events in Canadian hospitals?

1. 1%
2. 2.5%
3. 5%
4. 7.5%
5. 10%

International Comparison

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

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

World Health Organization. (2004). *World Alliance for Patient Safety: forward programme 2005*. Geneva, Switzerland: World Health Organization. Retrieved from http://www.who.int/patientsafety/en/brochure_final.pdf

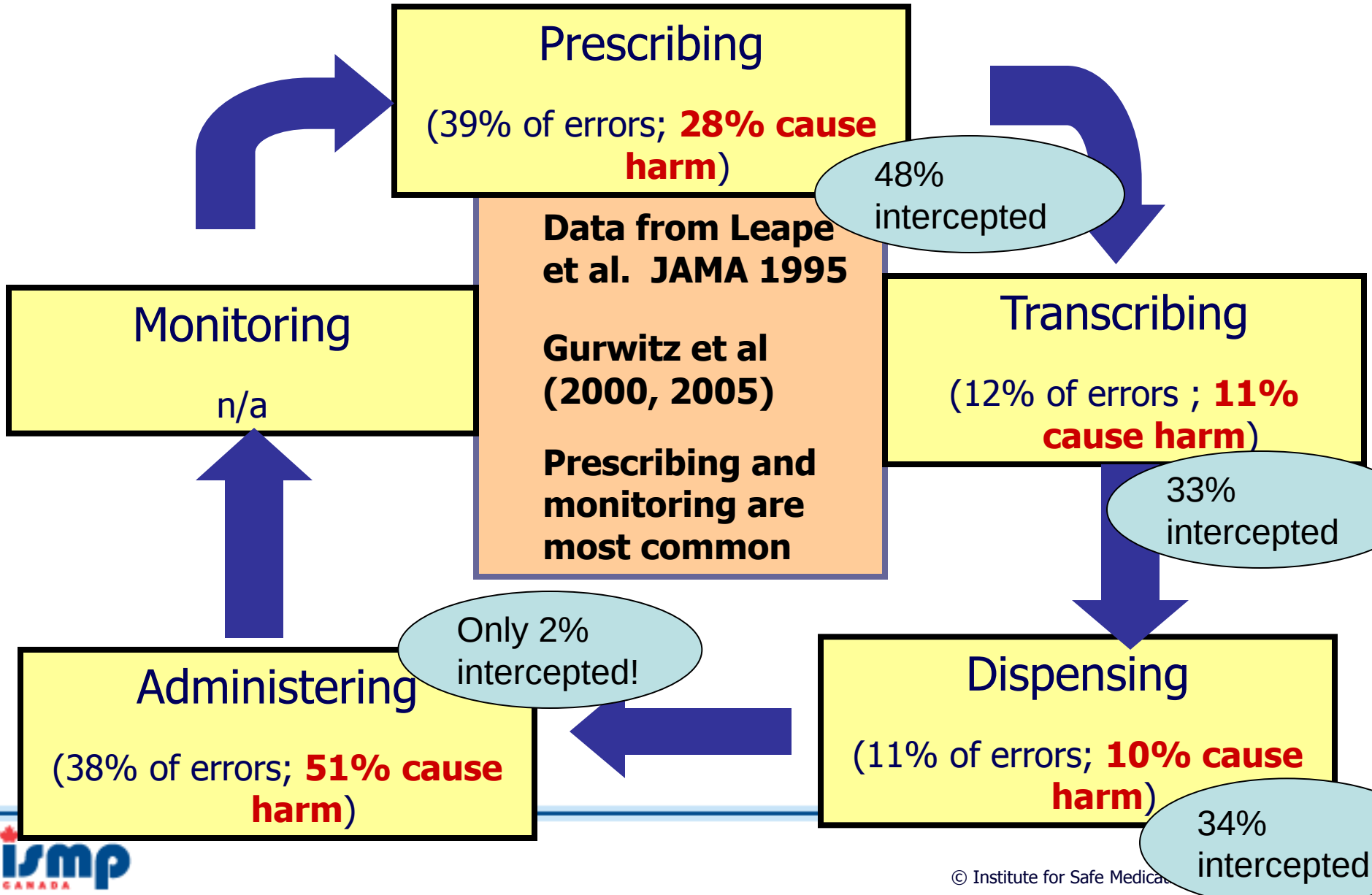
Of the adverse events that occur, how many do you think are related to medication use?

1. 10%
2. 25%
3. 50%
4. 75%

Where do you think medication incidents occur most often?

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

Sources of Harm



What is "Root Cause Analysis"

Definition:

An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents.

It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

From: Hoffman C, Beard P, Greenall J, U D, White J. Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, Edmonton, March, 2006.

Goals of Analysis

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

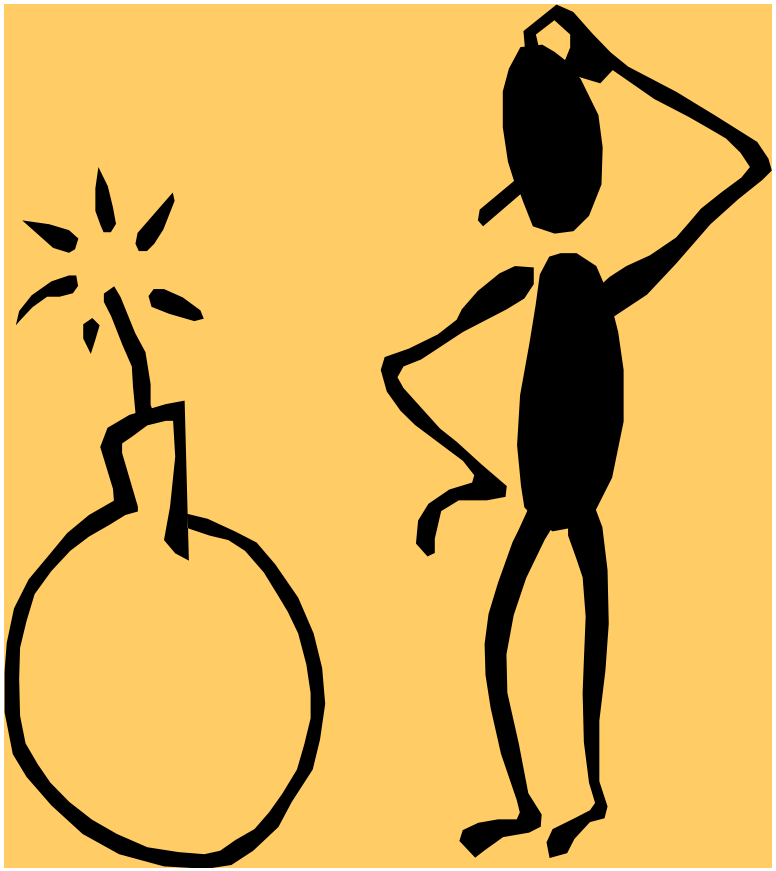
AND

- What was learned and how can the learning be shared?

Why do incidents happen?

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

Why do incidents happen?



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

But…. we work in an imperfect system

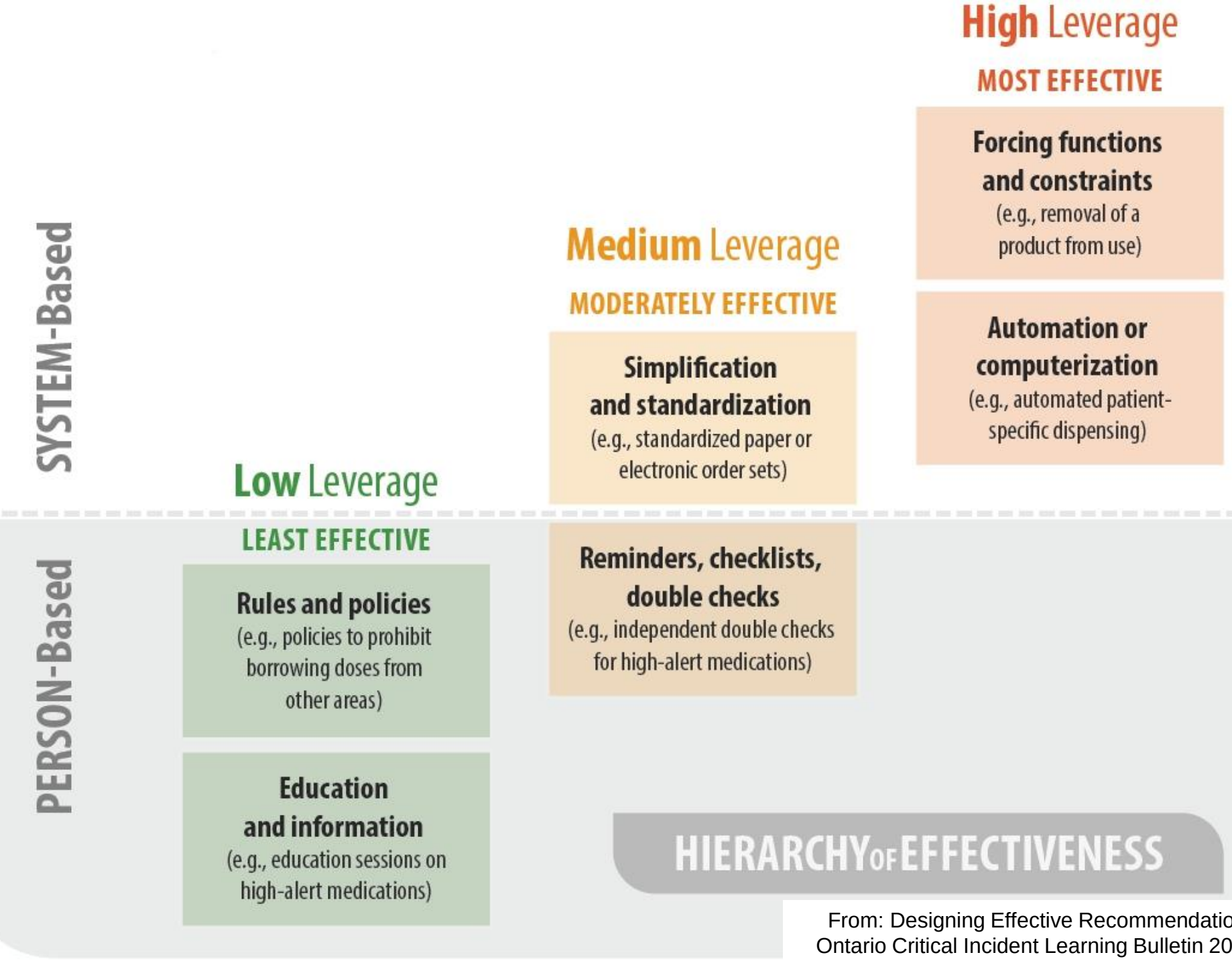
Reality of Health Care Environments

- Cognitive overload
- Workloads
- Multitasking
- Interruptions
- Difficult technology

Human Factors Engineering Principles

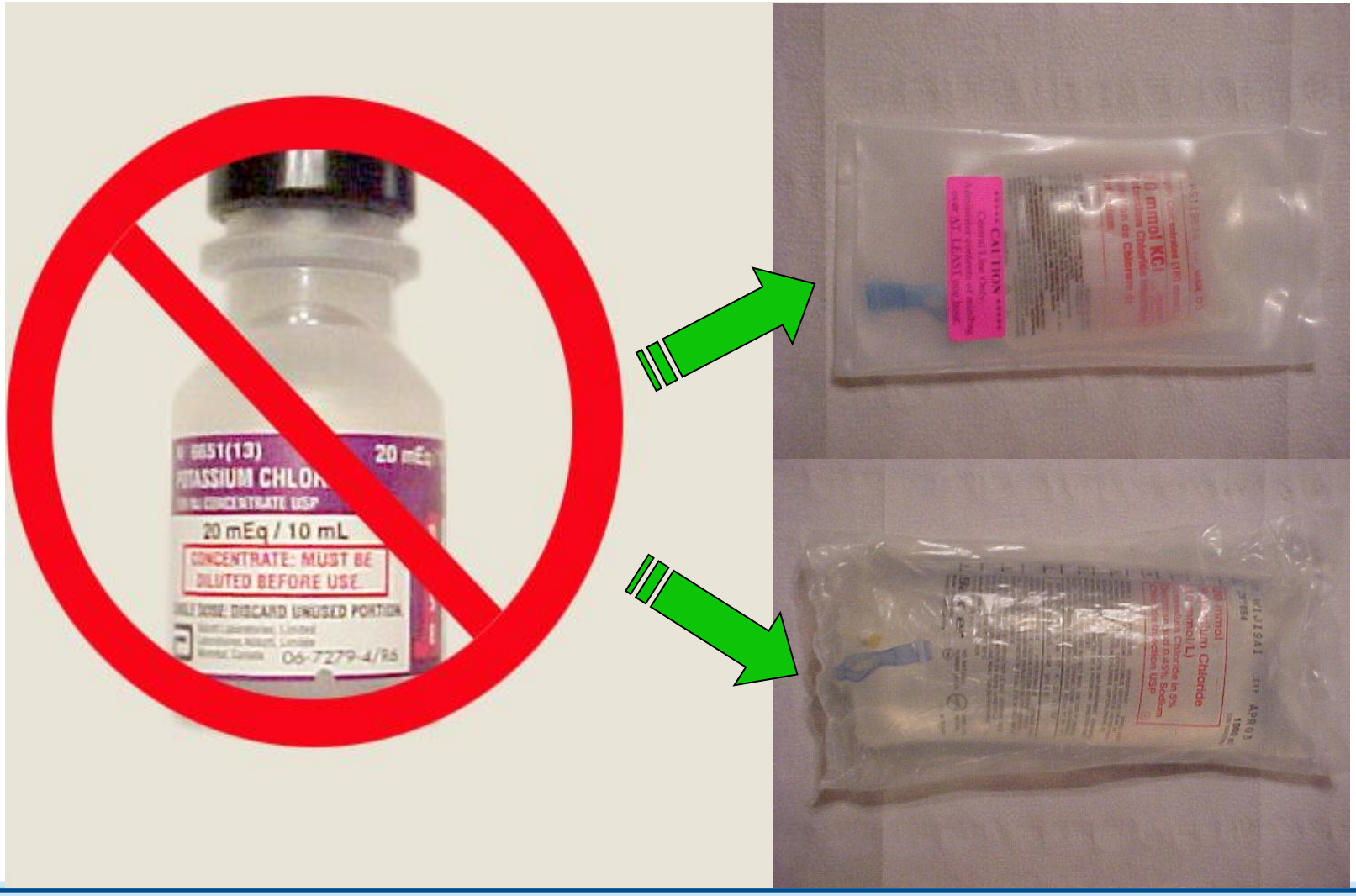
- The design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics

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



From: Designing Effective Recommendations. Ontario Critical Incident Learning Bulletin 2013;

Constraints and Forcing Functions



Using Technology to Re-engineer Medication Management

Physician Order Entry/Pharmacist Clinical Order Screening

Electronic MAR and To Do List

Just-In-Time Inventory

Or, automated med/supply depot door or drawer opens

Smart Drawer Opens

Scan Medication

Scan Patient's Wristband

Simplification and Standardization

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

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

McLaughlin R. Redesigning the crash cart. AJN 2003; 103(4): 64A-E.

Infant receives hydromorphone 4 mg orally intended for an adult patient

Contributing factors:

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

Examples of Recommended Actions

Actions	Leverage
Use 2 patient identifiers at each stage of the medication use process	Medium – Reminders/Checklists/Double Checks
Include identifiers in all communications	Low – Rules and Policies
Include the calculated dose (mg/kg) in all pediatric medication orders	Low – Rules and Policies
Require documentation of medical assessment process prior to medication administration (exception: emergency situations)	Low – Rules and Policies
Use distinctly different charts for adult and paediatric patients	High – Constraints

How does ISMP Canada analyze incidents?

- Canadian Incident Analysis Framework (2012)
  - CPSI, ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada, Paula Beard, Carolyn Hoffman, Micheline Ste Marie
- Systematic approach to incident analysis
- Applicable to all incident analyses

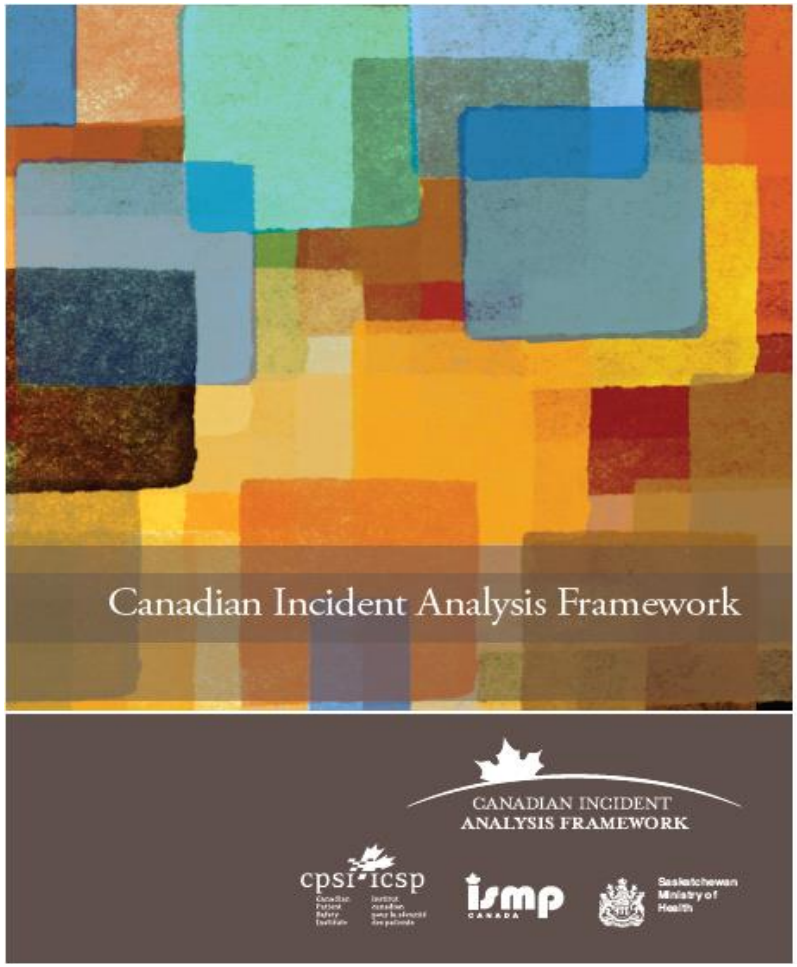
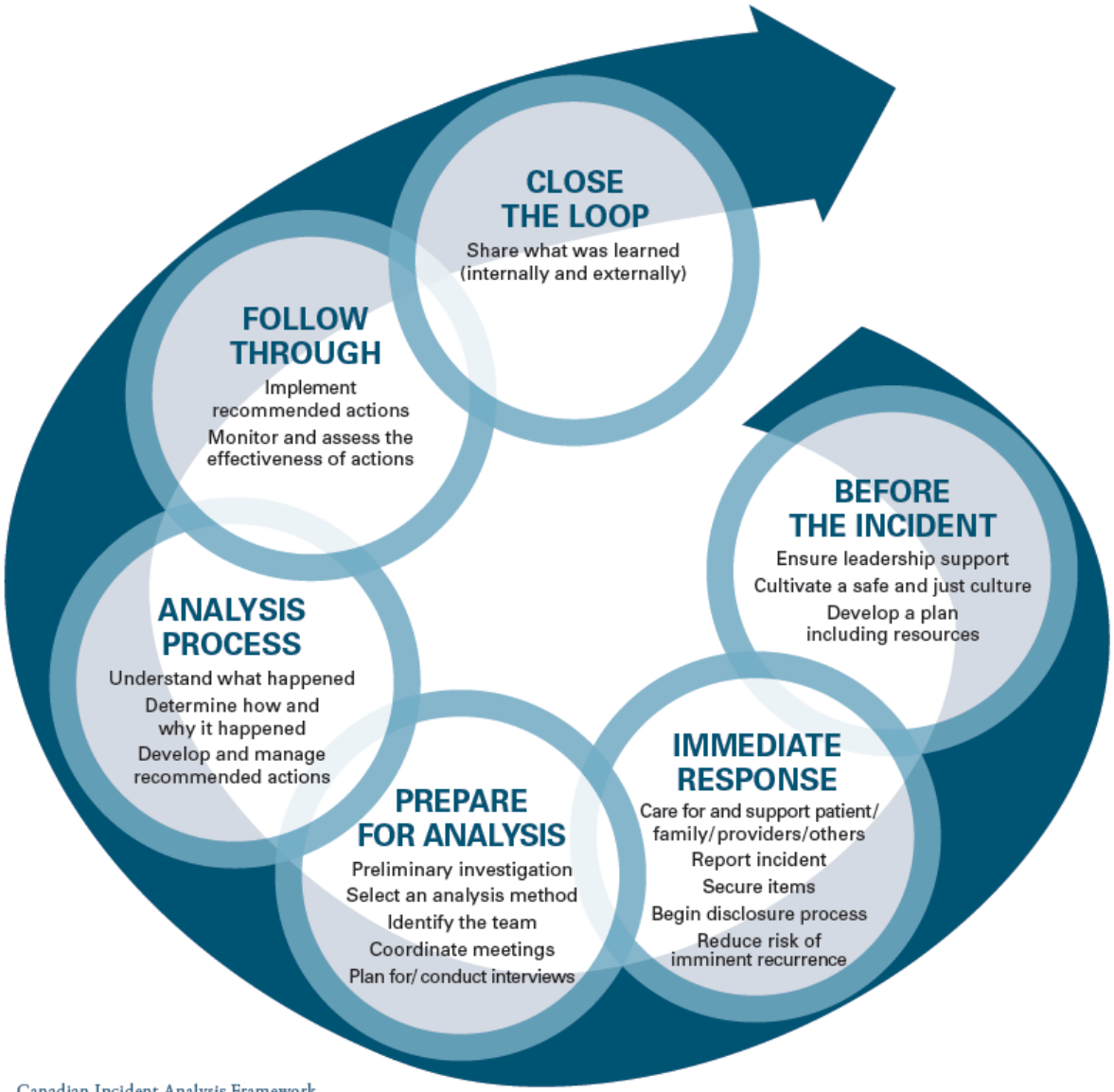


Figure 3.1: INCIDENT ANALYSIS AS PART OF THE INCIDENT MANAGEMENT CONTINUUM



Canadian Incident Analysis Framework

Case Example

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

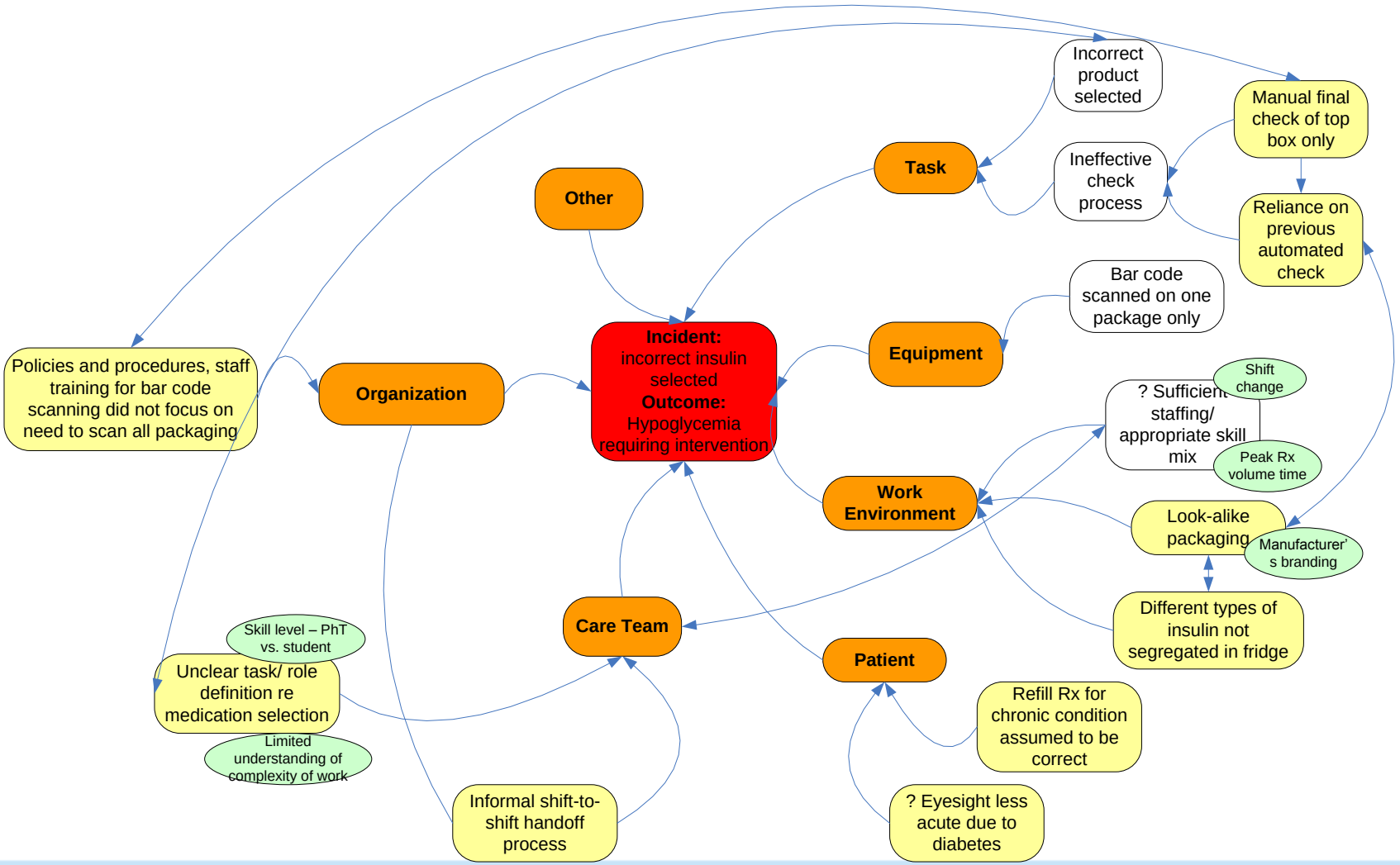
What Happened

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

How and Why it Happened

- Diagramming can be a helpful tool to:
  - Visualize relationships
  - Move away from the "sharp end"
  - Avoid "hindsight bias"

Insulin Incident



"Just telling doctors and nurses to be more careful won't do much. We need to change the systems that allow errors to happen."

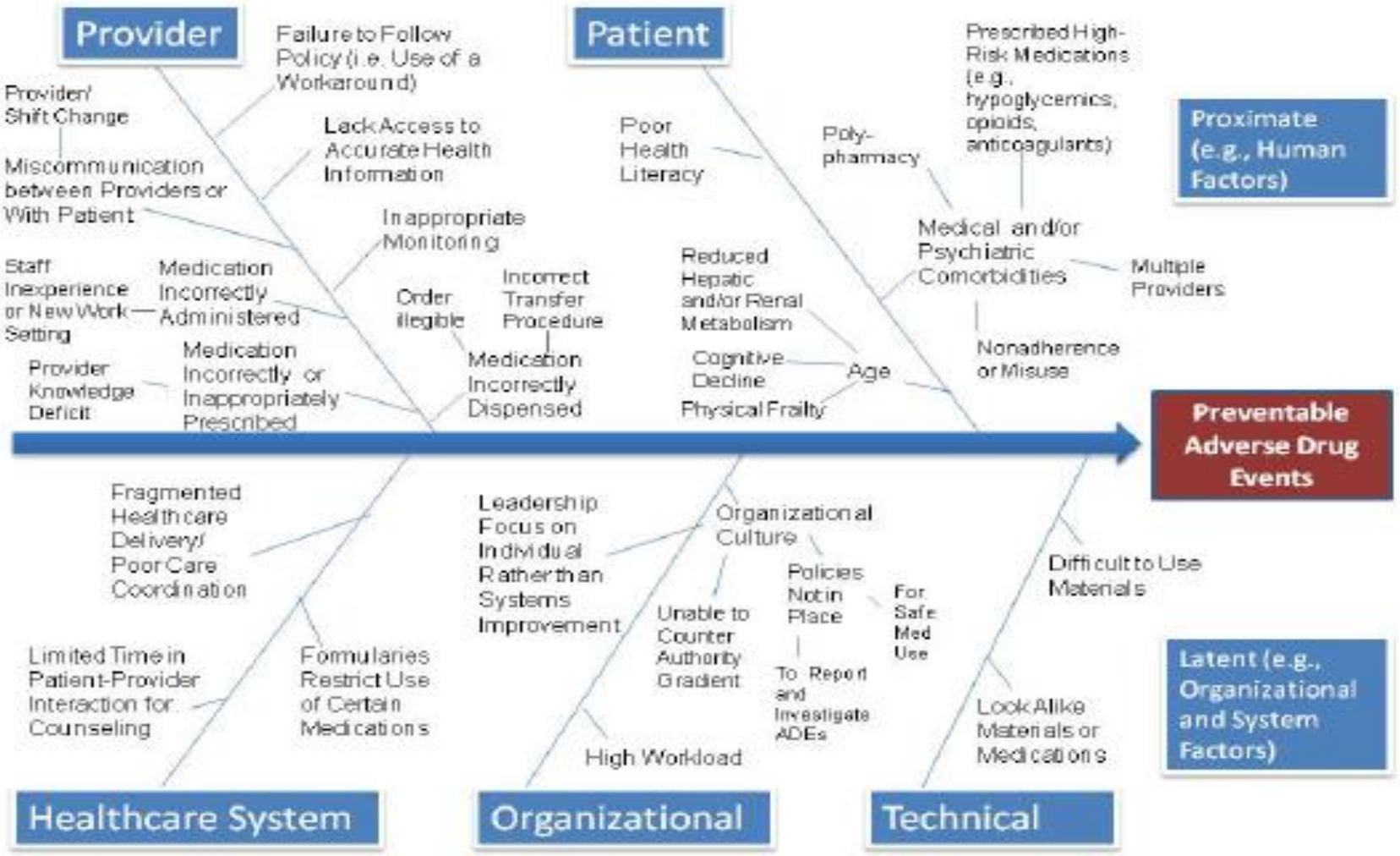
James Bagian, Director, VA Center for Patient Safety
Anesthesiologist and Astronaut

The Systems Approach

Recognizes that:

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

Key Determinants of Adverse Drug Events



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.

High Alert Medications

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

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

When are other processes appropriate?

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

(Based on VA Triage Questions for RCA, 2000)

How can we share learning with others?

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

Prospective risk assessment

Examples of Prospective Analysis Processes used in Industry

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

Commonalities

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

What is FMEA?

Definition:

FMEA is a technique used to identify process and product problems before they occur.

Failure Mode and Effects Analysis

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

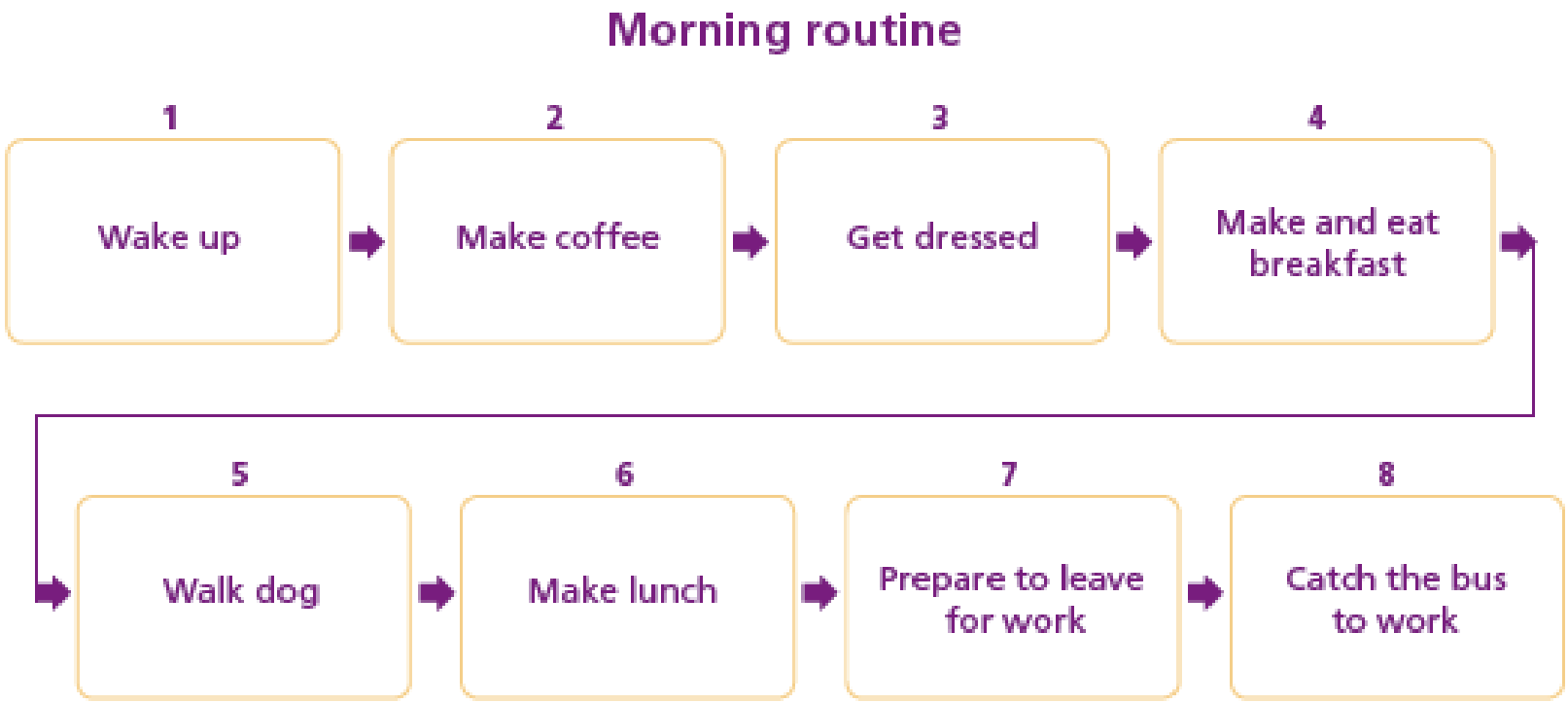
Conducting an FMEA: 8 Steps

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

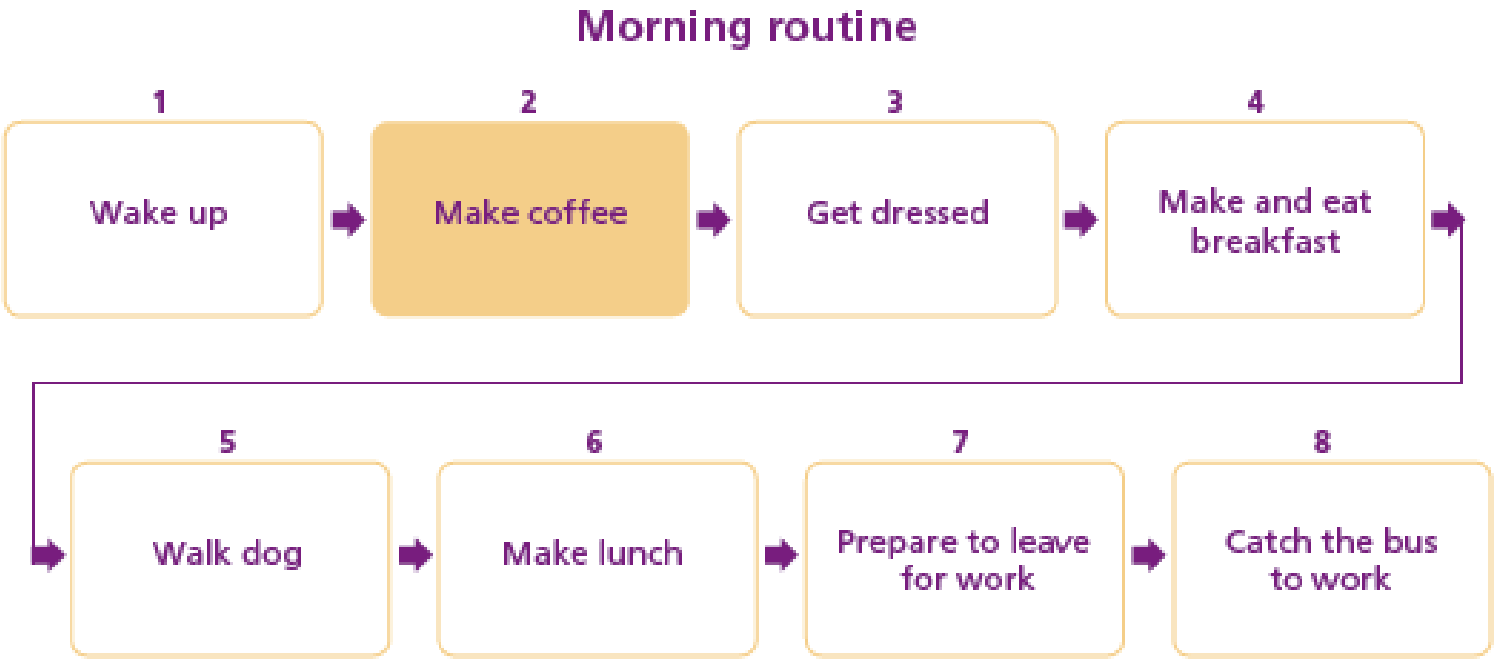
High Risk Processes (Definition)

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.

Example – Everyday FMEA



Everyday FMEA (cont'd)



Potential Failure Modes

Prioritization and Action Planning

FMEA subject: Morning routine									**Process:** #2: Make coffee
Sub-process component: 2b – Remove old filter/grounds									
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**
2b1	Basket won't open	Cannot add new coffee	Latch broken	4	1	3	9	No	Not predictable; no action required– would likely require new coffee maker if occurred
2b2	Filter rips	Old coffee grounds spill, causing delay	Poor quality paper; mishandling	2	3	4	24	Yes	Purchase reusable filter (1 month)

Shared Learning from FMEA

A Collaborative Failure Mode and Effects Analysis Project with an Ontario Hospital:

Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit 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 11, Number 6 — **ISMP Canada Safety Bulletin** — September 30, 2011

Updated Operating Room Standards Include Strategies to Prevent Inadvertent Injection of Epinephrine Intended for Topical Use

Information published by the Institute for Safe Medication Practices Canada (ISMP Canada), and others has highlighted substitution errors involving the inadvertent injection of concentrated epinephrine (1 mg/mL) intended for topical application during elective outpatient ear, nose, and throat procedures.[1-7] In a collaborative effort to enhance the safety of epinephrine use, the Operating Room Nurses Association of Canada (ORNAC) worked with ISMP Canada to incorporate incident learning into its 2011 *Standards, Guidelines and Position Statements for Perioperative Registered Nursing Practice* (http://www.ornac.ca/standards).

The purpose of this bulletin is to raise awareness of the following important *additions* to the practice standards for Canadian perioperative nurses:

2.11.13 When using medication intended for topical use, such as concentrated epinephrine, place medication in a solution bowl not parenteral syringe.

2.11.14 When using medication intended for injection by the surgeon, the medication is drawn up into a syringe directly from the vial not from an open solution bowl.

A failure mode and effects analysis (FMEA) confirmed the importance of these additions to the standards (refer to the sidebar on page 2 of this bulletin for additional information).

ORNAC has taken a leading role on this issue and has set an example among national and international standard-setting organizations.

ISMP Canada continues to work with manufacturers and other stakeholders to influence improvements to packaging for sterile products intended for topical use.

Acknowledgements:

Reporting is the first step in enhancing medication safety. Sincere appreciation is extended to the healthcare professionals who have reported information related to epinephrine intended for topical use, for their initiative, efforts, and demonstrated support for a culture of safety, exemplified by their willingness to share information about medication incidents and related findings.

Please refer to page 3 for references.

Medication Reconciliation Update

ISMP Canada is co-leading, with CPSI, the National Medication Reconciliation Strategy and is pleased to support the Canada Health Infoway *ImagineNation Outcomes* Challenge.

Canada Health Infoway seeks to accelerate the use and spread of innovative solutions in healthcare information and communication technologies. They have selected four key areas with the potential to improve health care quality and the patient experience in Canada.

1. e-Scheduling
2. Patient access to health information
3. Medication reconciliation
4. Clinical synoptic reporting

Up to $1 million in awards are being offered through this team-based Challenge to demonstrate the use and growth of e-solutions. ISMP Canada is a supporting organization for the ImagineNation Outcomes Challenge, providing expertise related to medication reconciliation.

More information is available from: http://www.imaginenationchallenge.ca/

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit 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 12, Number 11 — **ISMP Canada Safety Bulletin** — November 22, 2012

Usability Testing in Proactive Risk Assessments

Success in conducting a prospective analysis, such as a failure mode and effects analysis (FMEA), is contingent upon identifying risks or "accidents waiting to happen". A previous bulletin introduced a human factors engineering method called *cognitive walkthrough* and described how such a method can be included in an FMEA.[1] The current bulletin discusses a complementary method known as *usability testing*, which can be employed to identify risks, evaluate interventions designed to mitigate risks, and identify potential unintended consequences.[2] ISMP Canada uses both of these methods in conducting its analyses of medication incidents.

What Is Usability Testing

Usability testing is a metho
in evaluating a product o
method allows observation
with the system and measu
fulfills its intended purpose.

In a typical usability test, an
task or set of tasks with the
process or device) while spe
measured. These performan
or difficulty with which the
system, and hence the risk
that might be measured
complete a certain task, the
the number of steps that ca
nature of errors made by
competence after periods o
also be gathered to augment

The results of usability
information gathered during
the more qualitative findings
usability testing yields quan
comparing systems (or t
mitigate risks).

Why Conduct Usability T

The goal of usability testi
system that may lead to
physical workload, and err
the identification of potentia
their likely causes. During
FMEA), information from
team's understanding of the
perspective. Unlike intervie

are inherently subjective and can be biased by preference or opinion, usability testing is based on observation and measurement of actual human performance and is therefore an objective method of collecting information about potential risks.

When and Where Should Usability Testing be Conducted?

Usability testing can be conducted as part of any risk analysis or evaluation process. It is a helpful addition to the planning of process changes and can be applied to written instructions (e.g., policies and procedures) or to equipment

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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of Canada (HIROC) is a mer
owned expert provider of profess
and general liability coverage an
management support.

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Include *Cognitive Walkthrough* in Proactive Risk Assessments

One of the goals of a robust medication safety culture is to create systems in which potential failures or risks can be identified and addressed before a patient experiences any actual harm. This is only possible if one can proactively identify the precise nature of any "accidents waiting to happen", along with interventions to address these situations that do not unintentionally introduce other potential risks. The discipline of human factors engineering* is increasingly being adopted to help with this process. Within this discipline, a method called cognitive walkthrough is a useful technique to identify risk. This bulletin provides information about cognitive walkthrough and offers a practical introduction on how it should be carried out for a proactive risk assessment such as failure mode and effects analysis (FMEA).[1,2]

What Is a Cognitive Walkthrough?

A cognitive walkthrough involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced. This method goes beyond the current practice in healthcare of relying on incident data, individual opinion, or collective "brainstorming" by a team to identify potential risks, errors, or failure modes. It is one of many tools employed by human factors engineers to gain an in-depth understanding of a process or task from the perspective of the primary end-user (e.g., front-line practitioner).

A cognitive walkthrough can be used to help identify risks and assess solutions. In this technique, a participant (i.e., a representative user, such as a front-line practitioner) is asked to simulate all or part of a task and to "think out loud" while performing the simulation. The intent of thinking out loud is to allow observers to comprehend the task from the participant's viewpoint as it is being carried out. The participant expresses the reasons for any decisions made or actions taken during the simulated task, any frustrations, confusion, or doubts. The walkthrough can help to identify specific pa process or task that may not match the pa goals, understanding, or abilities, along with may be inefficient or that pose an excessive physical burden.

Why Conduct a Cognitive Walkthrough?

A cognitive walkthrough helps the FMEA understand, from the perspective of the pr process or task under review. Its approach failure modes (potential risks) is more structu brainstorming, and can be complementary Interestingly, it can also help to identify modes not recognized through incident report

When Should a Cognitive Walkthrough

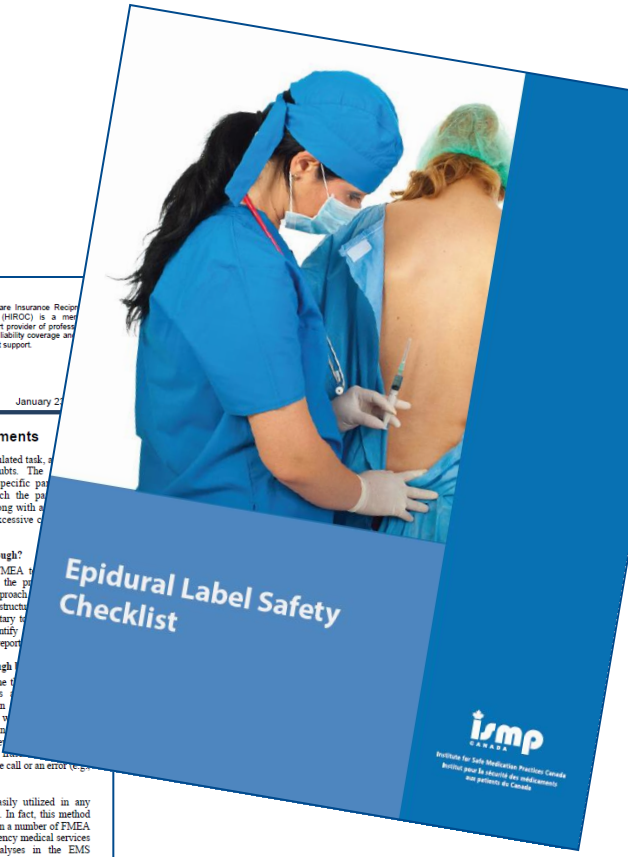
This technique should be used anytime in understanding the potential risks particular task or set of tasks. An encounter many situations in which it a cognitive walkthrough, such as durin assessment, before implementing a ne when learning about a practitioner's retrospectively, after discovering a close call or an error through a root cause analysis).

A cognitive walkthrough can be easily utilized in any setting, from acute care to home care. In fact, this method has been employed by ISMP Canada in a number of FMEA projects, such as one involving emergency medical services (EMS).[2] Cognitive walkthrough analyses in the EMS project were used to proactively evaluate a medication kit and protocol forms, all of which had been recently redesigned. The goal of this project was to improve the usability of materials involved in the medication use process and, ultimately, to reduce the potential for errors.[2]

Who Can Facilitate a Cognitive Walkthrough?

Any individual on the FMEA team or within the organization that wants to learn about potential risks can facilitate a cognitive walkthrough, even someone without specialized knowledge of the process, task, or equipment being evaluated. However, it is important that the facilitator

* Human factors engineering is the discipline concerned with understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology, and cognitive science, to define the parameters and restraints that influence human performance. This knowledge can be used to design systems so that they are compatible with human characteristics. Conversely, if systems are not compatible with human characteristics, performance can be adversely affected.[1]



Goal is harm reduction

- High alert medications
- Vulnerable populations
- Gaps in medication use processes

Importance of Incident Reporting

Healthcare thinking is evolving

Who did it? → What allowed it?

Punishment → Thank you for reporting?

Errors are rare → Errors are everywhere

Add more layers → Simplify/ standardize

International Efforts in Medication Safety

IMSN INTERNATIONAL MEDICATION SAFETY NETWORK

HOME | ABOUT IMSN | IMSN ADVOCACY | PUBLIC EVENTS | MEMBERS RESOURCES | MEMBERS ONLY

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

10th IMSN annual meeting

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

MAIN IMSN EVENTS

25 AÑOS ACQFH Asociación Colombiana de Químicos Farmacéuticos Hospitalarios

2-3 October 2015 Cartagena, Colombia
III International ACQFH Symposium

We encourage you to report medication incidents!

REPORT
a Medication Incident

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

SafeMedicationUse.ca
Supported by Health Canada

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

Contact information:

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www.ismp-canada.org