Medication Error and Patient Safety: A Systems Approach

Building the Foundation

November 18, 2015

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ISMP Canada

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

Our goal is the creation of **safe** and **reliable systems** for managing medications in all healthcare environments.

www.ismp-canada.org
To advance the patient safety agenda, in August 2011 the Ontario Ministry of Health and Long-Term Care issued a directive that hospitals must report critical incidents involving medications and intravenous fluids to the Canadian Institute for Health Information National System for Incident Reporting (NSIR). A critical incident is an “unintended event that occurs when a patient receives treatment in the hospital that results in death, or serious disability, injury or harm, and does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing treatment”.

ISMP Canada has been identified as the lead organization for analysis of the reported incidents. A multidisciplinary team reviews each submitted critical incident report to ensure effective identification of the contributing factors. In addition, ISMP Canada will periodically conduct aggregate analysis of reported incidents to provide a more in-depth assessment of events involving a particular medication or care setting. On the basis of these analyses, ISMP Canada will develop and disseminate outcome-directed recommendations, with an emphasis on high-leverage actions that take into account human factors engineering principles and the need to design systems with integrated safeguards.

Bulletins:
- Naloxone Saves Lives - Iss.10/2014
- Sharing Insulin Pens is a High-Risk Practice - Iss.9/2014
- Safe Pain Control in the Emergency Department - Iss.8/2014
- Smart Pumps Need Smart Systems - Iss.7/2014
- Monitoring Processes Contribute to Safe Use of Warfarin - Iss.6/2013
- Promoting the Safe Use of Insulin in Hospitals - Iss.5/2013
- Designing Effective Recommendations - Iss.4/2013
- Quality Medication Reconciliation Processes Are Critical - Iss.3/2013
- HYDROmorphine remains a high-alert drug - Iss.2/2013
- Mandatory Reporting—Can We Do Better? - Iss.1/2012

Analysis Report:
- Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report - 2014
- Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report - 2013

Webinars:
- Medication Safety Learning from Ontario Coroners’ Cases - Focus on Opioids - 2013/03/06
Help Prevent Harmful Medication Incidents

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

Reporting Medication Incidents benefits all Canadians.

Latest News and Resources

- SafeMedicationUse.ca’s Jennifer Turpie talks about medication safety and drug interactions on CBC (interview starts at the 22nd minute)
- NEW! One Simple Solution for Medication Safety – Doc Mike Evans Video now available!
- Additional information on Mylan Pharmaceuticals nitroglycerin spray recall
- Health Canada Advisory - Mylan Pharmaceuticals recalling nitroglycerin spray due to defective pump
- Sharing Opioid Medicines Can Be Deadly 2014-09-03

More links:
- About SafeMedicationUse.ca
- About Medication Incidents
- Why Report?
- Resolving Concerns About the Safety of Your Care
- Frequently Asked Questions (FAQs)
- Your privacy

Ca/newsletter/newsletter_Travelling.html
Safety Bulletins

ISMP Canada Safety Bulletin

Volume 14 - Issue 8 - September 10, 2014

Aggregate Analysis of Medication Incidents in Home Care

Safety in home care is becoming a national focus. The shift from institutional to community care presents new challenges as governments, healthcare organizations, and families try to help patients maintain their independence as long as possible in the comfort of their own homes. As a result, a growing number of medically complex patients are receiving care in the community with the support of multiple caregivers coordinated by home care agencies. Many of these caregivers (including family members and personal support workers) are attempting to manage complex medication regimens with limited training or education, which may increase the risk of a medication error. Recent home care safety reviews have confirmed that medications are a major cause of preventable adverse events.1 ISMP Canada undertook a multi-incident analysis to better understand the underlying challenges faced by individuals involved in supporting medication use in the home care setting. This bulletin shares findings from the analysis, highlighting the major themes and selected contributing factors, to identify opportunities for system-based improvements.

Methodology and Overview of Findings

Reports of medication incidents that occurred at home were extracted from voluntary reports submitted to ISMP Canada’s medication incident reporting database from August 1, 2009, to February 18, 2014. Of the 240 incident reports reviewed, only those with descriptive text suggesting the provision of home care (e.g., terms such as “service provider,” “care management,” “home visiting”) were included in the final analysis, which was conducted according to the methodology outlined in the Canadian Incident Analysis Framework.2 Fifty-six (23%) of these incidents resulted in harm to the patient. High-alert medications in the community setting (anticoagulants, opioids, hypoglycemic agents, pediatric liquids, amnosteroid suspensions)3 accounted for 21% (24%) of the total. Administrators, prn group inhibitors, and medications for inhalation were involved in 15 (10%), 10 (7%), and 10 (7%) of the incidents, respectively.

Findings of the Qualitative Analysis

Analysis of the incidents identified 3 main themes (see Figure 1). Some incidents were categorized under more than one theme. The following sections describe each of the main themes in some detail, along with an illustrative example.

Figure 1. Main Themes from the Qualitative Analysis

- Medication Transition Failure
- Complex Communications
- Medication Handling Error

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Naloxone has a shorter duration of action than some opioids, and once it has been metabolized by the body, there is a risk that the pharmacological effects of the opioid will re-emerge, causing harm to recur! Therefore, patients receiving naloxone must be monitored closely for a prolonged period to ensure that any re-emergence of toxic effects is immediately addressed. Further administration of naloxone along with a higher level of care and medical intervention may be required.

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ISMP Canada
Self-Assessment Programs
Learning Objectives

After attending this lecture and completing the assigned readings, students should be able to:

1. Define key terms associated with patient safety in health care.
2. State the evidence that medical error, and medication error in particular, is a significant problem in healthcare.
3. Understand the latent failure model and human factors engineering to explain medication error as multisystem failures.
4. Understand the impact of medication error on the individual patient and/or family.
5. Understand how the traditional culture and values in healthcare interfere with health care providers ability to acknowledge and respond to error.
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
Background Reading


Objective 1

Define key terms associated with patient safety in health care.
Key Terms and Concepts

Adverse Event:
Undesired and unplanned occurrence, directly associated with the care or services provided to a patient/client in the health care system. Includes both preventable and non-preventable injuries.

Adverse Drug Event:
An injury from a medicine or lack of an intended medicine. Includes adverse drug reactions and harm from medication incidents.

Adapted from Bates DW et al by the collaborating parties of the CMIRPS, 2005
Key Terms and Concepts

Safety:
Freedom from accidental injuries.

Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system, 1999.

Harm:
Temporary or permanent impairment in body functions or structures. Includes mental, physical, sensory functions and pain.

Developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System (CMIRPS), 2005.
Key Terms and Concepts

Critical Incident:

An incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof.

Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.

Key Terms and Concepts

Near Miss

An event that could have resulted in unwanted consequences, but did not because, either by chance or through timely intervention, the event did not reach the patient.

Developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System. 2005.
Key Terms and Concepts

High-Alert Medications

Drugs that bear a heightened risk of causing significant patient harm when they are used in error.

High Alert Medications

Can you think of examples of medications that might be considered high alert?
Objective 2

To state the evidence that medical error, and medication error in particular, is a significant problem in healthcare.

“Is there a problem?”
To Err Is Human: Building A Safer Health System

- Institute of Medicine (IOM) Report in 1999
- Estimated 44,000 to 98,000 deaths yearly due to error.
  - 44,000 = 8th leading cause of death in U.S.
  - 7,000 die from medication errors
Preventable medical mistakes cause more deaths per year than car accidents, breast cancer or AIDS.

Deaths per Year

- Preventable Medical Mistakes: 98,000
- Car Accidents: 43,458
- Breast Cancer: 42,297
- AIDS: 16,516

The Canadian Adverse Events Study

- 3745 charts reviewed from 5 provinces
- 360 adverse events identified in 255 patients
- 24% of adverse events were related to medication or fluid administration
- 37% of adverse events were determined to be preventable

Extrapolation:

- 7.5% (or 187,500) patients in Canadian hospitals were seriously harmed by their care.
- As many as 9,250 to 23,750 people died in a Canadian hospital as a result of medical errors.

Medications harm too many – at least 1.5 million people per year

- **Hospitals**
  - 400,000 preventable ADEs per year
  - *About 1 medication error per patient per day*

- **Outpatient setting**
  - Also frequent, though data less solid
  - 530,000 ADEs/year in Medicare patients
Canadian Paediatric Adverse Events Study

- 3669 children admitted from April 2008-March 2009
- 8 academic paediatric centres and 14 community hospitals in Canada
- Weighted rate of adverse events was 9.2%
  - 10.2% academic paediatric centre vs. 3.3% in community hospitals
  - Preventable adverse events 3.9% in academic centres vs. 2.0% in community hospitals
  - Surgical events 32.9%; drug-related 13.5%
Numerous high profile examples of errors causing harm
Heparin Mix-Ups

Sept 06

• 3 premature infants died after having vascular access lines flushed with 10,000 units of heparin instead of 10 units

Nov 07

• Similar error in 3 neonates – all survive
Opening Session

Dennis Quaid
Monday, December 7, 9:00am - 10:30am
Venetian Ballroom, Level 2 (Venetian Conference Center)

Widely acclaimed as one of the most charismatic actors of our time, Dennis Quaid is also an advocate for reducing medical errors. In his keynote address to ASHP, Quaid will tell how he and his wife, Kimberly, became motivated to launch The Quaid Foundation, an organization whose mission is to help minimize the impact of human error in patient medical care.

With insight into how such potentially catastrophic errors evolve, Quaid doesn’t blame the healthcare workers. “Individually, nurses, doctors, and pharmacists are good people,” he says, “but they’re hamstrung by working in a broken system.”

As hospital pharmacists, we welcome Dennis Quaid’s efforts. His keynote address at our Midyear Clinical Meeting will be a memorable, must-see event.

You can read more about The Quaid Foundation and their efforts to help reduce medication errors on their website at www.thequaidfoundation.org.
Adverse Drug Events in LTC

- Retrospective chart review in 2 facilities
- 42%\(^1\) - 51%\(^2\) of adverse drug events are considered preventable
- Errors associated with preventable events most often related to ordering and monitoring stages of the medication use process
- Increased risk of events with antipsychotics, diuretics and antiepileptic agents.

What about community pharmacy?

- Observational study in 50 pharmacies in 6 US cities – one pharmacist inspected 100 prescriptions
- Overall dispensing accuracy 98.3%
  - 77 errors in 4481 prescriptions
  - 5 clinically important
- Extrapolation
  - Approximately 4 errors per day if pharmacy fills 250 prescriptions
  - 51.5 million errors in the US annually (3 billion prescriptions filled annually)

Flynn EA, Barker KN, Carnahan BJ

Stages in the medication use process

Errors 39% 12% 11% 38%

Prescribing  Transcribing  Dispensing  Administering

Source  JAMA 1995;274:35-43
Sources of harm

Prescribing 39% 12% 11% 38%
Transcribing 11%
Dispensing 10%
Administering 28%

Source: JAMA 1995;274:35-43
Video Presentation

Beyond Blame 2:
https://youtu.be/OkTiCY3qJJk
Objective 3

Understand the latent failure model and human factors engineering to explain medication errors as multisystem failures.

“Why and how do errors happen?”
As healthcare professionals we are taught to maintain competence, practice due diligence and take care to avoid mistakes.

Systems theory states that although this is necessary, it is not enough. The way to prevent mistakes or mitigate harm from mistakes is to re-design systems with integrated safeguards, in addition to practicing due care.
Systems Approach

Focus on improving the processes, systems, and environment in which people work rather than attempting only to improve individual skills and performance.

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.
“...though we cannot change the human condition, we can change the conditions under which humans work”


*BMJ*, 320(7237): 768-770. Retrieved from: [http://www.bmj.com/cgi/content/full/320/7237/768](http://www.bmj.com/cgi/content/full/320/7237/768)
Quality in Health Care

“The degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge.”

Institute of Medicine, 1990
Safety is not the same as quality

- Quality focuses on elimination of defects (six-sigma)
  ⇒ Safety focuses on elimination of injury (i.e., “what doesn’t happen”)

Safety is not the same as risk management

- Risk management focuses on organizational risk reduction
  ⇒ Safety focuses on patient/staff risk reduction
Safety Relationship to Quality

- **Safety** is the foundation upon which **Quality** is built
- **You can have safety without quality but not vice versa**
Safety and Quality

Figure 1. Relationship between quality improvement and patient safety

Healthcare vs. High Reliability Organizations
(E.g. aviation, nuclear power)

Health Care (in transition)
• Errors are the result of human failures
• Humans generally perform flawlessly
• Perfect performance is the expectation
• Use retraining and punishment to root out “bad apples”

High Reliability Organizations
➤ Begin with the premise that anything can and will go wrong
➤ Don’t expect humans to perform perfectly
➤ Design systems accordingly in a proactive way
Human Factors Engineering (HFE) 101

**HFE:** a discipline concerned with design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics
Why does it matter?

- Some problems are inconvenient
- Some problems are unsafe
STOP

NO STOPPING
ANY TIME
Reality of Health Care Environments

- Cognitive overload
- Workloads
- Multitasking
- Interruptions
- Difficult technology
“Abundant research has demonstrated that the term **multitasking** is a misnomer-- performance degrades rapidly when people try to do several things simultaneously, whether it’s your kids doing homework while texting or a pharmacist checking orders while answering the phone.

Psychologists speak of the concept of “cognitive load”—the overall volume of things a mind is grappling with at a given time.

While there are some individual differences in the ways we manage cognitive load, one thing is clear: none of us does this as well as we think we do.”

**The Overdose: Harm in a Wired Hospital**

[https://medium.com/backchannel/the-overdose-harm-in-a-wired-hospital-8e5ac74fe73c](https://medium.com/backchannel/the-overdose-harm-in-a-wired-hospital-8e5ac74fe73c)
Human Factors Engineering Health Care Applications

- Medical devices
- Computer software design
- Labelling and packaging
- Medication distribution systems
- Work environment design
- Workflow design
Confirmation Bias

Leads one to “see” information that confirms our expectations, rather than information that contradicts our expectations.
Can you read this?
Packaging and Labelling
Packaging and Labelling
Attention:
Inherent human limitations
Inattentional Blindness

• Failing to see what should have been plainly visible
  • Because attention is not focused on it

• Most of our perceptual processing occurs outside of conscious awareness
Safety Strategies

Eliminate
- Remove the hazard

Control
- Provide safeguards

Accept
- Not an option – if a serious hazard is identified, the minimum safety strategy is a control measure
From: Designing Effective Recommendations.
Ontario Critical Incident Learning Bulletin 2013;

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
- Rules and policies (e.g., policies to prohibit borrowing doses from other areas)
- Reminders, checklists, double checks (e.g., independent double checks for high-alert medications)

PERSON-Based
SYSTEM-Based
Using Technology to Re-engineer Medication Management

Physician Order Entry/Pharmacist Clinical Order Screening → Electronic MAR and To Do List → Just-In-Time Inventory

Smart Drawer Opens → Or, automated med/supply depot door or drawer opens → Scan Medication → Scan Patient’s Wristband
Standardization
Reducing the Probability of Error – Independent Double Checks

\[
\frac{1}{100} \times \frac{1}{100} = \frac{1}{10,000}
\]
Incident Reporting

• Risk management processes needed to track all unusual occurrences / incidents.

• Need to respond to and review critical incidents
High Reliability Organizations

- Collective preoccupation with the possibility of failure
- Expect to make errors and train their workforce to recognize and recover from them
- Continual rehearsal of familiar scenarios of failure

E.g. aviation, nuclear power
Aviation Error Reduction Over Time

Accidents per million departures

- US. & Canada operators
- Rest of World

© Institute for Safe Medication Practices Canada 2015®
British Airways Incident Reports

Air Safety Reports (UK)
Volume & Risk

- Total
- High Risk

Year


Volume

0 1000 2000 3000 4000 5000 6000 7000 8000 9000

Risk

0.0% 0.5% 1.0% 1.5% 2.0% 2.5%
Incident Review Process: Lessons for Health Care

• Transparent to all health care providers

• Fair treatment applied consistently

• Human resources processes (discipline) separated from quality review
Ignorance is not bliss!
Objective 4

To understand the impact of medication error on the individual patient and/or family
A patient’s perspective

• Serious medication errors lead to profound suffering and grief for the patients / family affected:
  • A patient with advanced nasopharyngeal cancer inadvertently received an infusion of fluorouracil over 4 hours that was intended to be administered over 4 days.
  • Profound mouth sores and reductions in red blood cells, white blood cells and platelets developed.
  • The patient died 22 days after the medication incident occurred.

Josie King - http://www.josieking.org/

John Lewis – Beware the Grieving Warrior
Objective 5

To understand how the traditional culture and values in healthcare interfere with health care providers ability to acknowledge and respond to error.
Hippocratic Oath

“First do no harm”
Health Care Culture: Perfection Myth

“We have created systems that depend on idealized standards of behaviour that require individual physicians, nurses and pharmacists to perform tasks at levels of perfection that cannot be achieved by human beings.”


“Patients, who have an understandable need to consider their doctors infallible, have colluded with doctors to deny the existence of error. Hospitals react to every error as an anomaly...with a promise that ‘it will never happen again’.”

“Blame and Shame”

• Actions directed at individuals
  • Errors are the result of human failures
  • Use re-training, and punishment to root out “bad apples”
Medication Error Response

“I should have read the label.”
“This has not happened before.”
“This is unlikely to happen again.”

Physician who reported a medication error
The 2\textsuperscript{nd} Victim

• Reporting situations that have caused harm or \textit{could cause harm} is a \textbf{vital} step in protecting our patients and our colleagues.

• Health care professionals involved in an error that causes patient harm can be as devastated, or more devastated, than the patient and family involved.

\textit{Wu A. Medical Error: the second victim. BMJ 2000; 320:}
Lack of Reporting Due to:

Many reasons including:

- Failure to recognize error
- Failure to look beyond incident to the whole system
- Lack of certainty if it “really is an error”
  - definition (? related to harm)
- Punitive culture
  - Fear of reporting: self and others
What about professional accountability?

Does “non-punitive” mean “blame-free”?  

Does a “system” approach mean that individual practitioners are not accountable for their actions?
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.”

…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.”

“…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.”

Need to move away from “blame & shame”

Who did it?  What allowed it?

Punishment  Thank you for reporting!

Errors are rare  Errors are everywhere

Add more layers  Simplify/standardize
“A smart person learns from his or her own experiences....a wise person learns from the experiences of others.”

Captain Chesley “Sully” Sullenberger
US Airways
“Miracle on the Hudson”
We encourage you to report medication incidents

Practitioner Reporting
https://www.ismp-canada.org/err_report.htm

Consumer Reporting
www.safemedicationuse.ca/
Contact information:
Julie Greenall:
  jgreenall@ismp-canada.org

ISMP Canada
  416-733-3131
  1-866-544-7672
www.ismp-canada.org