Advancing Safe Medication Practices

Hospital Related Deaths: The Role of the Coroner's Office in Enhancing Patient Safety

Dr. Dan Cass, MD FRCPC

January 31, 2013

Advancing Safe Medication Practices

About 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 environments.

www.ismp-canada.org

Canadian Medication Incident Reporting and Prevention System (CMIRPS)

ISMP Canada is a key partner in CMIRPS with Health Canada, the Canadian Institute for Health Information (CIHI), with support from the Canadian Patient Safety Institute (CPSI)

Goals of CMIRPS:

- Collect data on medication incidents;
- Facilitate the implementation of reporting of medication incidents;
- Facilitate the development and dissemination of timely, targeted information designed to reduce the risk of medication incidents (*e.g.* **ISMP Canada Safety Bulletins**); and
- Facilitate the development and dissemination of information on best practices in safe medication use systems.

Advancing Safe Medication Practices

We encourage you to report medication incidents

Practitioner Reporting

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

Consumer Reporting

www.safemedicationuse.ca/

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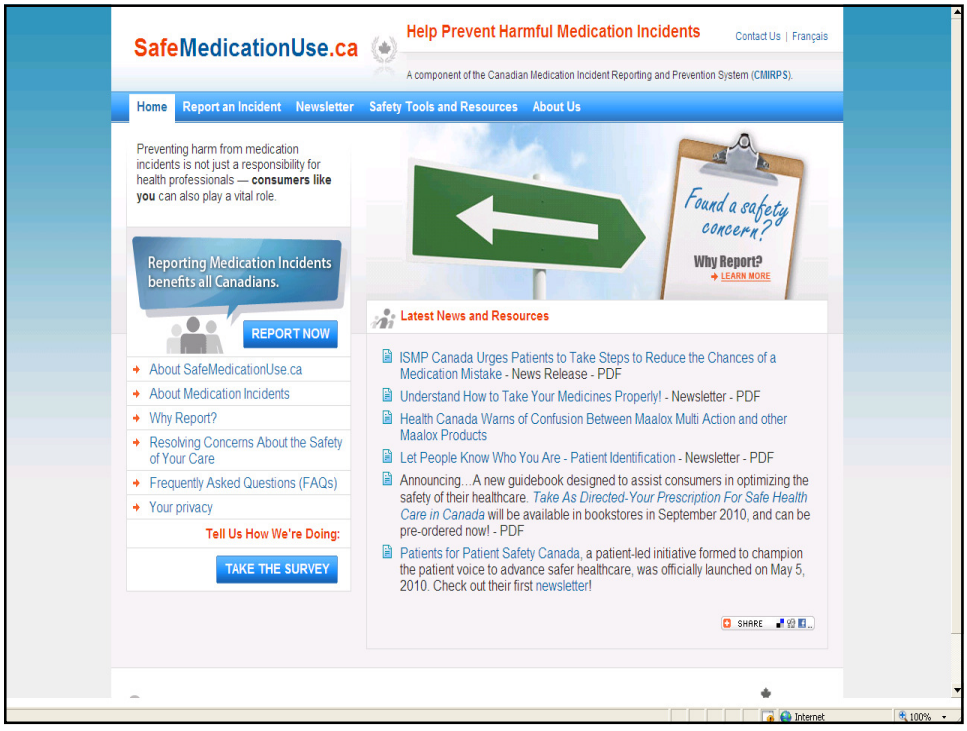
To Keep Up to Date with the Latest News on Medication Safety Follow Us on: Twitter @SafeMedUse

Facebook: www.facebook.com/MedicationSafety



Upcoming Webinars

all webinars start at 12 noon ET unless otherwise indicated

- **Medication Safety Learning from Ontario Coroners' Cases – Focus on Opioids - March 6, 2013**

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UPCOMING WORKSHOPS

Root Cause Analysis (RCA) for Pharmacists

March 21, 2013 - Toronto, ON

Failure Mode and Effects Analysis (FMEA) for Pharmacists

March 26, 2013 - Toronto, ON

Multi-Incident Analysis Workshop

April 10, 2013 – Toronto, ON

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Advancing Safe Medication Practices

Development of a Model to Translate Learning from Fatal Medication Incidents into Evidence-Based Interventions
("the Coroners' Project")

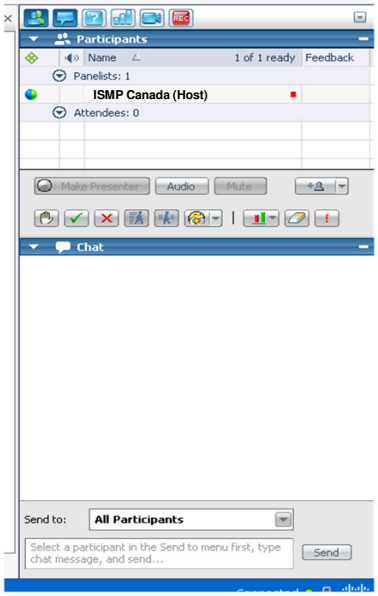
Purpose:

To develop a model that uses information obtained from in-depth analyses of serious or **fatal medication incidents** to enable the development and dissemination of evidence-based interventions.

The interventions will be designed to reduce the occurrence of serious and fatal events in future, and/ or to mitigate harm.

Questions

1. Raise your hand. If you have a phone icon by your name we will un-mute your phone and you can ask your question



2. Type your question in the chat box

3. Email your question to webinars@ismp-canada.org

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ISMP CANADA

Speaker

Dr. Dan Cass, MD FRCPC

The Role of the Coroner in Enhancing Patient Safety

Dan Cass MD FRCPC
Interim Chief Coroner for Ontario
Chair, Patient Safety Review Committee, OCC
Associate Professor, Emergency Medicine, U of T

Objectives

After this presentation, participants will understand:

- the role of the death investigation system in preventing medically-related deaths
- the importance of close collaboration between health care providers, hospitals, coroners and pathologists in medical death investigations
- ways in which the death investigation system can help enhance patient safety

Death Investigation Systems

- Death investigation systems vary by jurisdiction
- Coroner systems
  - Physicians (ON, QC*, PEI)
  - Judges / lawyers / laypersons (BC, SK, NB, YK, NWT, NU)
  - Elected officials (some US states)
- Medical examiner systems (AB, MB, NS, NL)
  - Pathologist-led

What is a Coroner?

- Derivation:
  - from Anglo-French, "*corone*" (crown)
- Initially, an agent of the king or queen
- "Crowners"
  - Determined who died, when, where, and ***who was to blame***
  - Collected taxes owed to Crown upon death

What does a Coroner do?

"We speak for the dead to protect the living"

What does a Coroner do?

- Investigate non-natural deaths
  - Homicide
  - Suicide
  - Accident
  - Undetermined

What does a Coroner do?

- Investigate certain natural deaths:
  - Concerns about care
  - During / following pregnancy
  - Certain institutional deaths
  - Deaths in custody
  - Not under care of physician
  - "Suddenly and unexpectedly"

What does a Coroner NOT do?

- A Coroner does not make judgments regarding:
  - Culpability / accountability (criminal; civil)
  - Quality / appropriateness of medical care

Role of the Death Investigation

- Investigative:
  - Answering the "five questions"
    - Who, when, where, cause, manner
  - Certifying death
- Preventative:
  - Aimed at preventing similar deaths in future

Public Safety Mandate

- *Coroners Act* sets out basis for preventative mandate of OCC
  - Public safety
  - Patient safety
    - System level
    - Individual level

What does this mean?

- We must answer the five questions
- We may make recommendations to prevent deaths in future
- We can disclose personal information, if necessary, to protect the public

Patient Safety: What's the Issue?

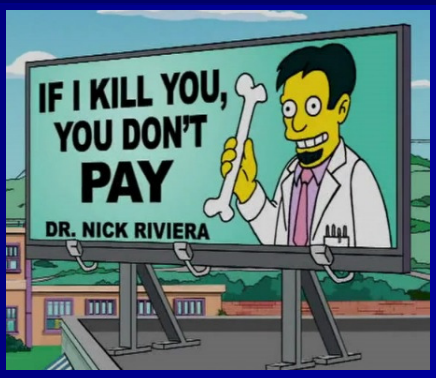
- Canadian Adverse Events Study (2004)
  - 7.5% of people admitted to hospitals in Canada experienced at least on adverse event
    - Almost 21% of such adverse events are fatal
  - 37% of all adverse events are preventable
- 2.5 million annual hospital admissions in Canada
  - 14,000 preventable deaths due to adverse events!

Errors versus Negligence

- Most errors not made by incompetent, careless or "bad" people!
- Shift from "naming, shaming and blaming" to identification and correction of system issues
- Consistent with *Coroners Act*
  - No finding of legal responsibility
  - Fact-finding, not fault-finding

What About Negligence?

- Some errors do result from poor care!
- Role of DI system is to identify care issues, and raise through:
  - Hospital Quality of Care reviews
  - Professional colleges



How Does the Death Investigation System Help Improve Patient Safety?

- Investigative Role
  - Coroner reviews circumstances; applies clinical experience and expertise
  - Pathologist connects the clinical story with the pathology
  - Develop fulsome understanding of cause and manner of death
    - Known complication of treatment = natural
    - Error (dose; technical; equipment) = accident

How Does the Death Investigation System Help Improve Patient Safety?

- Preventative Role
  - Regional Coroner's Review
  - Death Review Committees
  - Inquests
  - Special death reviews

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Cluster of Post-Op Deaths

- Series of post-operative deaths following elective laparoscopic bariatric surgery at one hospital
- March, 2008 – November, 2009
- 6 deaths
  - Same institution / program
  - 4 different surgeons
  - 2 different procedures

Initial Discussions

- Hospital reviewed cases
- Did not feel was a "surgical" issue
  - Within accepted complication rates
  - Different surgeons
- Implemented changes in post-op assessment
  - Frequency of post-op vital signs, blood work
  - Emergency Department returns

Two Further Deaths…

- January, 2010
- February, 2010

- PM in each → anastomotic leak

Regional Coroner's Review

- Attendees:
  - Regional Coroner
  - Deputy Chief Coroner
  - Chief of Staff
  - VP responsible for program
  - Risk Management
  - Surgical Director of Bariatric Surgery program

Regional Coroner's Review

- Process:
  - Summary of each case and PM findings
  - Identification of themes
    - Post-operative monitoring / assessment
    - Late recognition of complications
    - Late return to OR for "re-look"
- Outcome:
  - Development of recommendations

Recommendations - RCR

1. External review of program
   - Focus on six deaths April / 08 – Feb. / 10
2. Temporary stop of all laparoscopic bariatric surgery at site pending review
3. Inform regional health authority (LHIN) and Ministry of Health
4. Continue accreditation process through American Bariatric Society

External Review

- Conducted over 2 days
  - Review of all post-op deaths, including PM reports
  - Reviewed videotapes of procedures (all bariatric surgeons)
  - Observed three surgeons in OR
  - Reviewed post-op policies / procedures
  - Visited OR / PACU / ICU / ward

Conclusions of Ext. Review

- Incidence of surgical complications within accepted rates
  - No issue with surgical skill / technique
- Opportunities for improvement
  - Selection and medical optimization of patients
  - Medical Director for program
  - Clinical nurse specialist
  - Higher nurse : patient ratio post-op
  - More liberal diagnostic laparoscopy
  - Enhanced collaboration between surgeons

Results

- In 12 months following review:
  - 450 cases
    - **30 day mortality = 0**
      - 1 death between 30 and 90 days (0.22%)
    - 19 patients returned to OR (4.2%)
      - 3 leaks – all diagnosed and managed early
- All recommendations from external review implemented
- Hospital has become first non-US site accredited by American Bariatric Society

How Does the Death Investigation System Help Improve Patient Safety?

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  - **Death Review Committees**
  - Inquests
  - Special death reviews

Death Review Committees

- Patient Safety Review Committee
- Pediatric DRC + Deaths Under Five
- Maternal and Perinatal DRC
- Geriatric and Long-Term Care DRC
- Domestic Violence DRC
- Construction Fatality Review Committee

Death Review Committees

- Chaired by Regional Coroner
- Members:
  - Clinical experts in relevant fields
  - Non-clinicians
    - e.g. – child welfare experts on PDRC
  - Pathologists

Cases Reviewed by PSRC

- Since its inception in 2005, PSRC has:
  - Reviewed 68 cases
  - Made 249 recommendations
  - Issued two Annual Reports
    - 2010
      - Includes review of cases 2005-2009
    - 2011

Cases Reviewed by PSRC

Year	Cases	Recommendations
2005	7	42
2006	5	15
2007	20	59
2008	5	8
2009	4	18
2010	8	26
2011	12	45
2012*	7*	36*

* Year to date

PSRC 2011 Annual Report

- 12 cases reviewed
  - 45 recommendations
- Two special case series
  - Pneumonitis deaths after chemotherapy
  - Post-operative bariatric surgery deaths

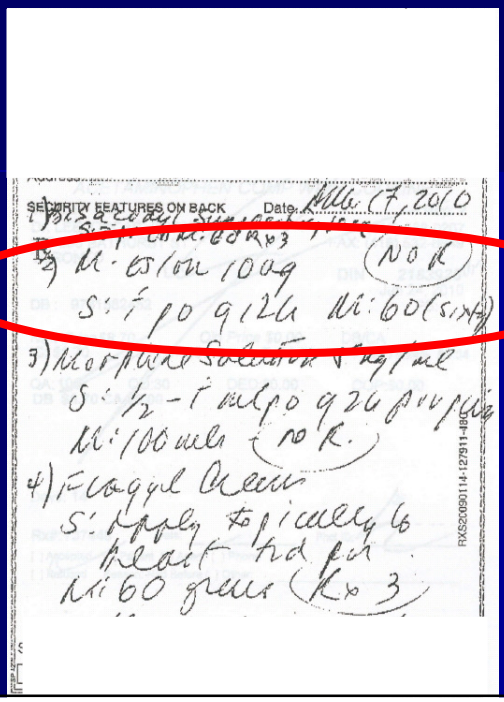
Themes – 2011 Cases

- All 12 cases in 2011 fit into 3 themes:
  - Opiate use (5)
  - Access to Care (2)
  - Complications of therapy (5)
- Both special reviews deal with "Complications of Therapy" issues

Case 1 – Opiate Use

82 y.o. female

- Hx breast CA with mets
  - Pain previously controlled with Tylenol #3
    - Required only 1 – 2 / day
- Pain increasing; no longer controlled
- Prescribed long-acting morphine (M-Eslon)
  - Took first dose @ 1030h
  - Later in day – found VSA



Case 1 - Continued

- Ordered as M-Elson 10mg po q12h
- Dispensed as M-Eslon **100 mg** po q12h

- PM
  - Natural disease not enough to cause death alone
  - Levels below usual lethal range; however:
    - Limited tolerance
    - Dose =**11 times** opiate dose of 2 Tylenol #3
    - Opiate overdose + relatively opiate-naïve + underlying condition → death

Case 1 - Recommendations

- **To CPSO:**
  - Remind prescribers of best practices in handwriting prescriptions
  - Expedite computerized prescribing

- **To Ontario College of Pharmacists:**
  - Four recommendations around dispensing of new or seemingly high-dose narcotic prescriptions

Case 2 - Complications of Therapy

65 y.o. female

- Prior Rx of breast CA
- 2010 - Acute myelogenous leukemia
  - Refractory to first round of induction chemo
  - Starting second-line (salvage) chemo
- Given amsacrine IV infusion
  - Started in evening (2130-2230h) on ward
  - Not on cardiac monitor
- Found unresponsive when pump alarm signalled end of infusion
  - Unwitnessed cardiac arrest
  - Resuscitated → died 8 days later in ICU

Case 2 - Complications of Therapy

- Amsacrine
  - Risk of arrhythmias low (<1%), but higher with:
    - Prior cardiotoxic chemo (prior chemo not documented)
    - Long QT on cardiogram (present on decedent's ECG)
    - Low potassium (last checked ~14 hours prior)
- Product monograph:
  - ECG and K+ immediately prior to infusion
  - Cardiac monitoring during & 4 hours after
- Most Canadian oncology centres do not monitor during infusion
  - Not part of monograph in Europe

Case 2 - Recommendations

- **To all Ontario Cancer Centres; OMA sections on Hematology / Medical Oncology and Cardiology:**
  - Amsacrine should be administered with cardiac monitoring and with check of potassium immediately prior
  - Ensure documentation of prior cardiotoxic chemotherapies

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Coroner's Inquests

- Mandatory
  - Custody deaths
  - Construction / mining
  - While restrained in psychiatric facility
  - Child while access restricted by court order

Coroner's Inquests

- Discretionary
  - To answer the five questions
  - Public ascertainment of facts
  - Recommendations aimed at avoiding future deaths in similar circumstances

Positive Changes Resulting from Inquests

- **Suicide Prevention Program**
  - implemented in Toronto Catholic District School Board.
- **Flu Prevention and Immunization**
  - mandatory flu shots for health care workers, flu awareness programs.
- **Hospital procedures**
  - emergency room management and triage procedures; hospital funding; education. documentation and charting
- **Wandering patients**
  - amendments to policies and procedures for facilities housing patients prone to wandering

Positive Changes Resulting from Inquests

- **Safety of Residents in Seniors Facilities**
- **Communication protocols for emergency responders**
- **Mental Health issues regarding the use of physical restraints of patients while being detained in a psychiatric facility**
  - Amendment to the Coroners Act, July 2009, Section 10 (4.7) requiring mandatory inquest
- **EMS Policies / Procedures**

King / Bertrand Inquest

- Donna Bertrand, 41
  - Prescribed OxyContin for back injury
    - Receiving up to 1440 mg / day
- Dustin King, 19
  - Chronic oxycodone abuse
    - Snorting OxyContin
    - Overdosed on OxyContin Rx to Bertrand
- 11 days after King's death, Bertrand died of intentional overdose of paroxitine and venlafaxine

King / Bertrand Inquest

- Focus of inquest was the prescribing, dispensing, and diversion of prescription narcotics
- Concept of upper dosing limits for narcotics in non-cancer pain
  - 100 mg morphine equivalents / dose
  - 200 mg morphine equivalents / day
  - Oxycodone = 2x potency of morphine p.o.

King / Bertrand Inquest

- Jury made 48 recommendations
  - Withdrawal of CR products above threshold dose
  - Removal of above-threshold doses from ODB formulary
    - Restrict to Exceptional Access Program
  - Enhanced monitoring of opiate prescribing /dispensing
  - Education, Research
  - Comprehensive strategy for pain / addiction

BMJ 2011;343:d4371 doi: 10.1136/bmj.d4371

NEWS

Inquest jury seeks to take prescription opioids off Ontario's streets

Following the Inquest…

- Purdue Pharma withdraws OxyContin from market
  - Replacement = OxyNEO
  - Tamper-resistant
- OxyNEO will not be on ODB formulary
  - Exceptional Access Program

March 5, 2012

Fatal overdose sparks warning about switch from OxyContin

By ANNA MEHLER PAPERNY
From Tuesday's Globe and Mail

Physicians and pharmacists urged to work closely to ensure correct dosages of alternative opiods are prescribed and dispensed

A Northern Ontario coroner says the province's doctors and pharmacists need to take extra care in switching patients from OxyContin to other opioids, following the death of a man whose doctor changed his prescription and gave him an incorrect dose.

Purdue Pharmaceutical is discontinuing its popular painkiller OxyContin in favour of OxyNEO, which is harder to crush and, in theory, tougher to snort and inject. Several jurisdictions are going further to stem the problem: Starting this month, seven provinces and the federal government's health benefits program will pay for OxyNEO only in exceptional circumstances. This means a sudden shift in treatment for patients across the country.

Michael Wilson, regional supervising coroner for Northwestern Ontario, says the man who died lived in the Kenora-Rainy River-Thunder Bay area, and had been prescribed OxyContin for years to treat his chronic pain. He was covered by a federal government program for first nations and Inuit that ended its previous coverage of OxyContin on Feb. 15.

How Does the Death Investigation System Help Improve Patient Safety?

- Preventative Role
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  - Inquests
  - **Special death reviews**

Special Death Reviews

- Drowning Review
- Youth Suicides on Pikangikum First Nation
- Pedestrian Death Review
- Cycling Death Review
- ORNGE Air Ambulance Review

Assembly of First Nations National Chief Commends all Parties for Supporting Suicide Prevention, Calls on Government to Work with First Nations

CNW
2011-10-05
Byline: ASSEMBLY OF FIRST NATIONS
OTTAWA, Oct. 5, 2011 /CNW/ - Assembly of First Nations (AFN) National Chief Shawn A-in-chut Atleo today commended all Parties for making suicide prevention a national priority.

In the House of Commons yesterday, all Parties showed support for a National Suicide Prevention Strategy that would "promote a comprehensive and evidence-driven approach."

"On behalf of all First Nations, I commend all Parliamentarians for coming together to support the calls for a national suicide prevention strategy and approaching the tragic issue of suicide collectively," said AFN National Chief Shawn Atleo.

On September 2 of this year, National Chief Atleo called on all levels of government to work with First Nations to implement key recommendations of a report by the Ontario Chief Coroner regarding youth suicides in Pikangikum First Nation. The report included a total of 100 recommendations in the areas of education, policing, child welfare and health care, with a particular focus on the development of suicide prevention strategies.

Motto of the OCCO

"We speak for the dead to protect the living"


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