

Medication Safety Learning from Ontario Coroners' Cases – Focus on Opioids

Julie Greenall ISMP Canada

March 6, 2013

ISMP Canada

ISMP Canada is an independent not-forprofit 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



Canadian Medication Incident Reporting and Prevention System (CMIRPS)

ISMP Canada is a key partner in CMIRPS with Health Canada and 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.





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

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.





Medication Reconciliation



Reporting and Prevention Systems

REPORT a Medication incident (1)

Medication Incident and Near Miss Reporting Programs for:

- Practitioners
- General Public SafeMedicationUse ca.

MOHLTC Supported Initiatives

- · 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
- Multiple IV Infusions Safety Webinar
- Medication Reconciliation
- SHRTN Communities of Practice on. Medication Safety in LTC webinars

Multi-Stakeholder Projects



Canadian Pharmaceutical Bar-Coding Project



MyMedRec App- Keep track of your medicines and vaccines



Safer Medication Use in Older Persons



ISMP International Medication Safety Self Assessment® for Oncology

ISMP Canada Roles in Ontario Critical Incident Reporting

- Qualitative analysis of incidents reported to CIHI NSIR program
- Timely response to "concerned" reports received from individual practitioners
- Development and dissemination of safety strategies



Safety Bulletins for Practitioners

The Institute for Safe Medication



The Healthcare Insurance Reciprocal owned expert provider of professiona

Volume 12, Number 7

ISMP Canada Safety Bulletin

June 27, 2012

Identifying Knowledge Deficits Related to HYDROmorphone

Earlier this year, ISMP Canada undertook a survey to better understand the extent of healthcare professionals' knowledge deficits or gaps that could contribute to medication incidents with HYDROmorphone. The response to the survey was tremendous, with a total of 4399 respondents completing all or part of the survey, and 3476 respondents completing the knowledge assessment questions. Responses were received from every province and territory and represented healthcare disciplines involved in the prescribing, dispensing, preparation, administration, and/or monitoring of HYDROmorphone. This bulletin describes the context for the HYDROmorphone survey and provides an overview of the key findings

Why a Survey about HYDROmorphone?

HYDROmorphone is 1 of the top 3 medications involved in incidents associated with harm that have been voluntarily reported to ISMP Canada.1 As of June 30, 2011, the number of reported incidents involving HYDROmorphone with an outcome of harm or death totalled 160. Although the actual incident rate cannot be determined from voluntary reports, the number of harmful medication incidents involving HYDROmorphone warrants additional focus on this medication.

HYDROmorphone is a potent, centrally acting analgesic drug of the opioid class that is used to relieve moderate to severe pain.^{2,3} Its adverse effects are similar to those of other potent opioid analgesics, such as morphine and fentanyl. Respiratory depression is the primary concern with these medications

Available in oral and injectable forms, HYDROmorphone is about 4-7 times stronger than morphine; 2,3 therefore, any confusion between these 2 drugs can have devastating consequences for the patient, including death. A review of

HYDROmorphone incidents that have been reported to ISMP Canada, including mix-ups between HYDROmorphone and morphine, suggested to ISMP Canada analysts that the difference in potency between these 2 drugs may not be well understood by all healthcare professionals.

Background to the Survey

It was determined that an assessment of physicians', nurses', and pharmacists' knowledge related to the use and administration of HYDROmorphone was needed to identify potential knowledge gaps. Furthermore, it was felt that the types and magnitude of any gaps identified would assist in planning future interventions to decrease the notential for harm with this medication. An electronic survey format was selected as the approach that would support the widest dissemination of the survey and hence allow for the broadest reach across disciplines. Several expert advisors guided development of the survey, which was then field-tested by nurses in a regional health authority. The final survey consisted of 10 demographic questions, 19 knowledge assessment questions, and 1 question about how frequently HYDROmorphone was used in the respondent's practice setting. The survey questions covered the pharmacologic properties of HYDROmorphone, indications for use, adverse effects, usual dosage, dosing calculations, and difference in potency between HYDROmorphone and morphine.

The HYDROmorphone Knowledge Assessment Survey was launched via 2 national webinars presented in February 2012, one in English (February 9, 2012) and one in French (February 16, 2012). The online survey was open until March 4, 2012. After the survey closed, a link to the survey questions and answers was posted on the ISMP Canada website (available from http://www.ismp-canada.org/ education/webinars/20120209 Hydromorphone/Answers.pdf).

Table 1: HYDROmorphone Knowledge Assessment Survey Results, by Discipline

Discipline	Number (%) of respondents	Average score on knowledge assessment questions (%)
Nursing	2169 (62.4)	72.5
Pharmacy	968 (27.8)	78.8
Medicine	299 (8.6)	81.7
Other	40 (1.2)	65.6
Total	3476 (100)	75

CRITICAL Incident Learning

October 2012 Distributed to:

- · Chief executive officers
- · Chiefs of staff
- Board chairs

Issue 1

- · Quality/patient safety leads
- Directors of pharmacy

Suggested circulation:

- Hospital and
- organizational leadership · Quality, risk, and patient
- safety personnel · Clinical leadership
- Medical directors
- Medical advisory committees

I/MP

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- Hospital safety and quality committees
- · Drugs and therapeutics committees
- · Physicians, pharmacists, nurses, and other front-line staff

· To advance the patient safety agenda, in August 2011 the Ontario Ministry of Health and Long-Term Care (MOHLTC) issued a directive that hospitals must report critical incidents involving medications and intravenous (IV) fluids to the Canadian Institute for Health Information (CIHI) National System for Incident Reporting (NSIR).1

Mandatory Reporting—Can We Do Better?

Improving quality in patient safety

- Anonymous data from the NSIR are analyzed by the Institute for Safe Medication Practices Canada (ISMP Canada) to identify medication system vulnerabilities, to share strategies for mitigating risks, and to inform medication safety efforts in Ontario.
- 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.
- Accreditation Canada focuses a number of its Required Organizational Practices on medication safety. Reporting incidents through the NSIR supports Accreditation Canada's guidelines on adverse event reporting and client safety quarterly reports.²

Learning from Analysis

- In the first year of mandatory reporting, from October 1, 2011, to October 1, 2012, a total of 15 critical incidents were submitted, including 5 that resulted in death.34 This likely represents under-reporting of the true number of critical incidents.
- · Many of the reports of critical incidents received through the NSIR did not include sufficient detail to allow for meaningful analysis or to allow sharing of quality improvement strategies.
- To date, the NSIR has an underutilized message system that could be used to solicit further details on a submitted report.

Call to Action for Hospitals

- Promote detailed reporting to the NSIR of all critical incidents within 30 days, including a detailed description that elaborates on specific circumstances and variables that led
- · Perform effective analysis of incidents from your facility to identify vulnerabilities in
- Report any recommendations or strategies that you develop to the NSIR within 60 days. · Ensure that your hospital NSIR administrator responds to emails from CIHI for ISMP Canada follow-up with your hospital.
- · Use the learning from these analyses to improve systems and procedures related to patient safety
- Share learning from your facility through ISMP Canada and other organizations, so that all patients, healthcare workers, and facilities can benefit.

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SHARE STEEL

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

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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.



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- Resolving Concerns About the Safety of Your Care
- Frequently Asked Questions (FAQs).
- Your privacy.

Sign up to receive the latest Alerts and Newsletters:





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- Health Canada Endorsed Important Safety Information about potential device failure with Pulmicort Turbuhaler 2012-07-28
- Take Care with Medicine Patches | 2012-07-04
- Health Canada Endorsed Important Safety Information on the Dangers Associated with the Use of Counterfeit Drugs 2012-06-22
- Preventing Harm from Drug Interactions: Consumers Can Play an Important Role 2012-06-14
- Check Labels Carefully When Selecting Gravol Products! 2012-05-04
- Consumer Catches Error Involving Similar Medicine Names 2012-05-01

Safety Bulletins for Consumers





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

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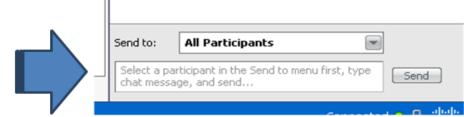
Questions

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





Type your question in the chat box



ISMP Canada (Host)

Audio

Participants

Name △

Panelists: 1

Attendees: 0

Make Presenter

Chat

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



1 of 1 ready Feedback

+2 -

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.



Speaker



Julie Greenall, RPh, BScPhm, MHSc (Bioethics), FISMPC



Presentation Outline

- Describe ISMP Canada's role in the Patient Safety Review Committee (PSRC) of the Office of the Chief Coroner for Ontario
- Highlight PSRC cases involving medications with a focus on opioids
- Describe how a detailed incident analysis can assist in identifying underlying contributing factors
- Review recommended actions for Ontario hospitals to decrease potential medication errors involving opioids



ISMP Canada Collaborative Work with the Office of the Chief Coroner for Ontario

- Collaborative work began in 2004 with retrospective review of medication incident associated deaths investigated by coroners (1999-2003)
- Membership on Patient Safety Review Committee (PSRC), initiated 2005



PSRC Cases Involving Medications 2005-2012

2005: Heparin; warfarin + macrolide; lithium + hypokalemia; morphine

2006: No medication-related cases

2007: Hydromorphone; fentanyl; fluconazole + ciprofloxacin and olanzepine; morphine; warfarin + antibiotics; unspecified narcotics; morphine/ hydromorphone; clozapine

2008: Insulin; warfarin; hydromorphone; diphenhydramine

2009: Low molecular weight heparin; morphine/ hydromorphone

2010: Methadone/ oxycodone; epoprostenol; hydromorphone/ fentanyl

2011: Morphine + hydromorphone; hydromorphone; morphine/ hydromorphone; amsacrine; morphine/ hydromorphone; morphine SR; docetaxel

2012: Hydromorphone + warfarin; hydromorphone



"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



Examples of High-Alert Medications

- narcotics (opioids)
- insulin
- anticoagulants
- chemotherapy
- concentrated electrolytes
- neuromuscular blocking agents
- adrenergic agonists and antagonists

From: ISMP's List of High-Alert Medications; http://www.ismp.org/Tools/highalertmedications.pdf



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2011: Morphine + hydromorphone; hydromorphone; morphine/ hydromorphone; amsacrine; morphine/ hydromorphone; morphine SR; docetaxel

2012: Hydromorphone + warfarin; hydromorphone



Case Example # 1

Elderly LTC resident admitted to hospital with symptoms of aspiration pneumonia. After further deterioration, the family opted for comfort care.

- Ordered morphine 4 mg SC q4h and morphine 2 mg SC q1h prn for pain.
- Two prn doses of morphine 2 mg were documented as given at 4:15 pm and 8:30 pm, with positive effect
 - Scheduled doses of q4h morphine 4 mg for 6 pm and 10 pm were documented as not given, noting that prn doses had been given
- Assessment note at 10:30 pm indicates BP low, 02 sats low, patient totally lethargic
- The 2 am scheduled dose of morphine 4 mg documented as given at 1:45 am
- Patient found vital signs absent at 4 am



Case Example # 2

Elderly male resident of a LTC home admitted to hospital. Current issues included infected leg ulcer, hypokalemia, hypotension, hematuria. Deemed palliative.

Order for hydromorphone 0.2-0.4 mg SC q1h prn pain.

Patient died 30 minutes after first dose administered.



Which of these circumstances suggests a potential medication error?

- Case 1
- Case 2
- Both Case 1 and Case 2
- Neither Case 1 nor Case 2



What were the factors that led to these incidents occurring?

What can be done to reduce the likelihood of recurrence?



Foundational Principles

Errors occur at all levels of healthcare

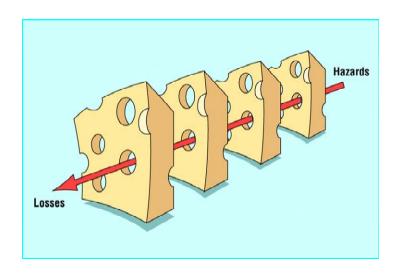
 All staff, even the most experienced and dedicated professionals can be involved in preventable adverse events

 Incidents result from a sequence of events and tend to fall in recurrent patterns regardless of the personnel involved



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 (HFE) 101

HFE: a discipline concerned with design of systems, tools, processes, machines that takes into account human capabilities, limitations, and characteristics





Clinical evidence for optimal care

Clinical practice level 1 – "Doing the right things"

Clinical practice level 2 – "Doing things right"

High quality patient care

Gap # 1:

Clinical evidence not incorporated in clinical practice

Example: VTE prophylaxis

Evidence:

Establishing the problem:

- Clinical studies
 Characterization of the problem:
- Clinical studies, qualitative research

Gap # 2:

Patient's care plan not carried out properly

Examples: Medication error--wrong medication or dose prescribed/dispensed/administered, medication omitted, wrong patient, etc

Evidence:

Establishing the problem:

E.g., IOM reports, Canadian Adverse Event Study, IHI Trigger Tools

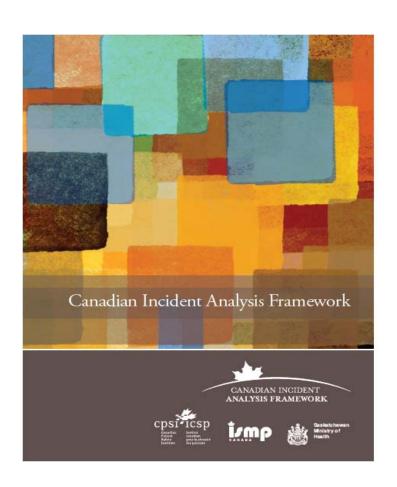
Characterization of the problem:

E.g., ISMP Canada Medication Incident Analyses

How can we analyze incidents effectively?

Canadian Incident Analysis Framework (CIAF) 2012

- Updated from Canadian Root Cause Analysis (RCA) Framework (2006)
- Developed collaboratively by CPSI, ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), and with assistance from Paula Beard, Carolyn Hoffman and Micheline St. Marie





Key Enhancements in the CIAF

- Increased discussion of and support for the role of patients and families in incident analysis
- Models for analysis of single and multiple incidents
- Innovative diagramming process
- Expanded section on developing and managing recommended actions



What happened?

Case #1:

- Hydromorphone/ morphine mix-up
- Identified from narcotic count that the patient had received hydromorphone 4 mg instead of morphine 4 mg

Contributing factor:

Look-alike/ sound-alike drug names



What happened?

Case # 2:

- Ten-fold overdose
- Patient had received 4 mg hydromorphone instead of 0.4 mg
 - 10 mg/mL vial used to prepare dose
 - 0.4 mL instead of 0.04 mL

Contributing factor:

 Availability of hydromorphone 10 mg/mL vials in patient care area



Case #3

- Young adult admitted with upper back pain and ?sepsis
- Prescribed antibiotics and morphine
 - Initially Morphine 1-5 mg IV q2h prn
 - Increased to Morphine 5-10 mg IV q2h prn
- Next day, pain not controlled
 - Switched to hydromorphone 5-10 mg IV q4h prn
- Next morning found vital signs absent in bed
- Cause of death mixed opioid toxicity



Case # 4

- Young adult requiring opioid treatment for management of severe pain
- Day 1: single dose hydromorphone 2 mg SC, then morphine 4 mg SC x 3 doses, followed by hydromorphone 1 mg IV x 4 doses total: morphine 12 mg/ hydromorphone 6.5 mg
- Day 2: hydromorphone IV 22 mg
- Day 3: hydromorphone IV ~ 22.5 mg + Tylenol #3 x 4 tablets
- Day 4: 6 am found vital signs absent



Toxicology

- Toxicology testing post-mortem revealed hydromorphone level greater than 200 ng/mL
 - While potential tolerance needs to be considered, levels greater than 77 ng/mL potentially fatal



Clinical notes

- Patient slept most of the day on Day 3
- Shallow breathing questioned by physician; no complaints of pleuritic pain or cough; 02 saturation described as "excellent with minimal 02 supplementation throughout the day"
- Drowsy for much of the evening anti-nauseant not given for this reason
- Evening vitals: temp 38.2C, HR 156/min, BP 109/66; RR 20/min; pain described as 10/10
- Scheduled midnight dose of hydromorphone refused by patient; given water shortly after midnight
- 1 am dose of dimenhydrinate
- 2 am able to get out of bed to use commode
 - Indicated nausea improved; wanted to sleep
 - Given scheduled dose of hydromorphone 4 mg IV
- 4:30 am "sleeping comfortably"
- 6 am vital signs absent



What happened?

Case # 3:

 Inappropriate dose conversion from morphine to hydromorphone

Case # 4:

Increasing sedation not identified as early sign of opioid toxicity

Nighttime is critical for monitoring of opioids - Periods of reduced external stimuli enhance sensitivity to opioid effects and are critical periods for toxic effects to become apparent



Larger Context

- Development of a Model to Translate Learning from Fatal Medication Incidents into Evidence-Based Interventions
 - Collaborative project with provincial/ territorial Coroners Offices funded by Health Canada
- Ontario: January 2007 December 2012
 - 53 closed cases with medication error as a death or involvement factor
 - Top 3 classes: opioids (21); anticoagulants (12); insulin (6)



Larger Context: ISMP Canada Medication Incident Data

Reports from hospitals/ long-term care homes and other organizations submitting reports via AnalyzeERR™:

Top 6 HARM Drugs:

Hydromorphone 223

Insulin 220

Morphine 200

heparin 126

Warfarin 108

Fentanyl 97

Drug Class:

Opioids 520 Anticoagulants 328 Insulin 220

ISMP Canada database 30Dec2012



Why so many problems with Hydromorphone??

- Look-alike/ sound-alike names
- High potency relative to morphine
 - 4-7 times more potent than morphine
- Available dosage forms don't reflect doses ordered for opioid-naïve individuals
 - 0.2-0.6 mg initial dose
 - 2 mg/mL and 10 mg/mL vials available
- Beyond PCA protocols, monitoring of patients receiving opioids for acute pain is inconsistent



Hydromorphone Knowledge Deficit Survey 2012

- 4399 respondents across Canada; 3476 (79%) completed the knowledge assessment questions
- 87.9% correctly identified hydromorphone 1 mg as approximately equal to 5 mg morphine
- Lowest scores related to pharmacologic properties, especially sustained release vs. immediate release
- Second lowest scores related to dose calculations
- Other areas of concern:
 - Ability to identify opioid tolerance
 - Co-morbidities requiring lower doses
 - Distinction between side effects and allergies
 - Recognition and management of overdose



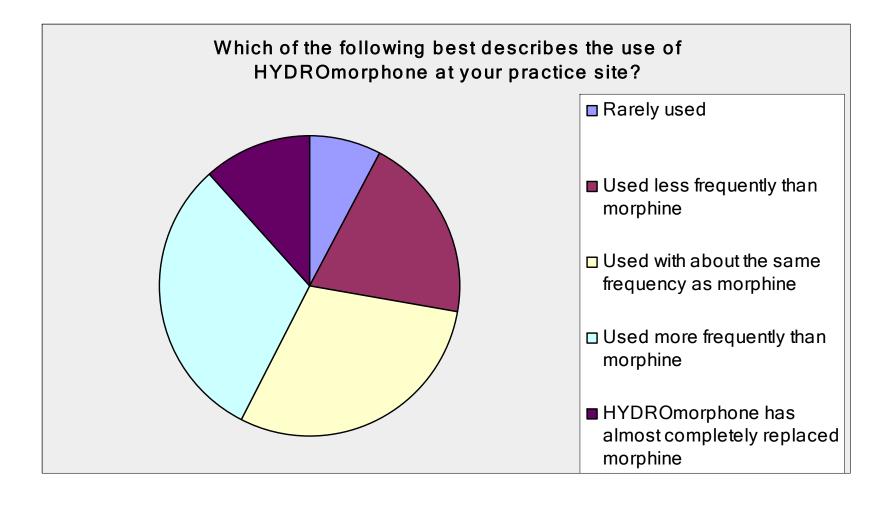
Which of the following best describes the use of HYDROmorphone at your practice site?

- a) Used less frequently than morphine
- b) Used about the same frequency as morphine
- c) Used more frequently than morphine
- d) It has almost completely replaced morphine
- e) Don't know



Results from ISMP Canada Survey

(n = 3447)





PSRC Recommendations re Opioids

- Use standard protocols for parenteral opioids that include guidelines and practices for assessment, monitoring and documentation for opioids
 - Consider: initial period of opioid therapy;
 nighttime; use of concomitant CNS depressants,
 manner in which patients are assessed
- Ensure processes are in place to consider the need for naloxone infusions subsequent to bolus doses



Specific Recommendations for Pharmacists

- Review opioid orders prior to administration whenever possible
- Confirm if patients are receiving opiates from any other source with each prescription
- For all new narcotic prescriptions, ensure dosing is appropriate given prior narcotic use
- Identify high dose narcotics as medications requiring additional review prior to dispensing



PSRC Recommendations re Hydromorphone

- Consider pharmacy preparation of small doses of hydromorphone in the absence of a commercially available product
 - Recommendation to manufacturers to provide appropriate lower dose formats (e.g., 0.5 mg, 1 mg pre-filled syringes available elsewhere)
- Provide a readily available standard dilution chart for usual doses of hydromorphone from a 2 mg/mL vial
- Consider auxiliary labels for hydromorphone to differentiate from morphine (e.g., "for Dilaudid")
- Encourage the use of TALLman lettering to enhance differentiation (e.g., HYDROmorphone)
- Educate practitioners about the differences between morphine and hydromorphone



Current ISMP Canada initiative: Hydromorphone Intervention Demonstration Project

- 5 interventions being piloted by a small number of hospitals
 - Interventions to address key issues:
 - 10-fold overdoses
 - Starting dose too high
 - Monitoring
 - Results will be available in Spring 2013



Additional PSRC Cases of Interest

Epoprostenol (Flolan):

- Cause of death: complication of primary pulmonary hypertension following blockage of Hickman line for pump
- Recommendations:
 - Provide emergency information directly on pumps
 - Write instructions in a clear and understandable way (for patients and providers)
 - Advise patients to take supplies with them whenever leaving home
 - Provide emergency information on hospital website
 - Proactively test emergency response processes



Additional PSRC Cases of Interest

Drug Interactions: Warfarin + antibiotics:

- Recommendations:
 - Education re: appropriate INR testing, common drug interactions with warfarin

Severe hypoglycemia with insulin regimen:

- Recommendation:
 - Adoption of tighter glucose control must be accompanied by review of educational and clinical management programs to ensure they reflect recommendations for the safe implementation of these practices



Investigating Coroner's Checklist for Medication Error Associated Deaths

- Incident details, including:
 - How incident discovered
 - Original order
 - MAR, narcotic record sheet
 - Actual packaging/ photos of medications involved

Supporting information:

- Physical environment
- Context for activities
- Redacted version of review conducted (if available/ possible (e.g., non-QCIPA)
- Recommended corrective actions identified/ taken by the facility



Summary

- Coroners' cases are a rich source of data pertaining to fatalities involving medication incidents
- In-depth analysis of information from these cases offers unique opportunities to:
 - identify underlying contributing factors
 - Direct recommendations to regulatory and professional associations and others to reduce the chances of similar incidents occurring in the future



Summary (cont'd)

- Ontario's critical medication incident reporting program, in tandem with coroner involvement in medication incident associated deaths, supports shared learning to prevent future incidents
- Learning from the Health Canada funded "Coroner's Project" will inform future medication safety initiatives





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ISMP Canada

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We encourage you to report medication incidents

ISMP Canada:



Practitioner Reporting

https://www.ismp-

canada.org/err_report.htm



Consumer Reporting

www.safemedicationuse.ca/

Canadian Institute for Health Information (CIHI) -- National System of Incident Reporting (NSIR)

http://www.cihi.ca/CIHI-extportal/pdf/internet/NSIR_PRO GRAM_OVERVIEW_EN



UPCOMING WORKSHOPS

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