

Patient Safety Review Committee 2012 Annual Report

Office of the Chief Coroner for Ontario

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Patient Safety Review Committee 2012 Annual Report

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Message from the Chair



It is my privilege to present the 2012 annual report of the Patient Safety Review Committee of the Office of the Chief Coroner for Ontario.

This year, the committee reviewed 11 deaths in which systemic issues related to medical care were identified. In the 10 cases for which the review is complete, the committee made a total of 46 recommendations aimed at preventing

future deaths in similar circumstances. (One case is still under review by the committee and will be included in the 2013 annual report.)

Four themes emerged from these reviews: clinical administration (three cases), clinical processes/procedures (five cases), medications/IV fluids (five cases), and healthcare associated infections (one case). Some cases involved more than one theme; hence the total number of themes identified is greater than the number of cases. Of the cases involving medications, two involved wrong doses of opiates, two involved adverse reactions to non-opiate medications, and one involved administration of medications to the wrong patient.

In addition to these individual case reviews, in 2012 the Patient Safety Review Committee initiated a special review of deaths in which operational issues related to air ambulance transport may have caused or contributed to death. This review was conducted by an expert panel under the auspices of the Patient

Safety Review Committee. While the final report was released in July 2013, a summary of the review and its recommendations is included in this annual report to ensure timely dissemination of the findings.

Towards the end of 2012, Margaret Keatings stepped down from the committee. Margaret has been an active member of the committee since its inception in 2005, and has contributed a great deal towards advancing patient safety through her work both on the Patient Safety Review Committee and at the Hospital for Sick Children. The Office of the Chief Coroner and the people of Ontario have greatly benefited from her efforts, and I would like to add my personal thanks for her work.

In late 2012, the committee welcomed two new members. Dr. Madelyn Law completed a PhD at the Department of Health Policy, Management and Education at the University of Toronto, and is an assistant professor in Community Health Sciences at Brock University in St. Catherine's. Patti Cochrane, a registered nurse, is the Vice-President, Patient Services, Quality and Practice and Chief Nursing Executive at Trillium Health Partners in Mississauga. The committee is stronger for their involvement, and we look forward to working with Madelyn and Patti in 2013 and beyond.

On behalf of the committee, thank you for your interest in patient safety, and in the work of the Patient Safety Review Committee.

Dr. Dan Cass
Committee Chair and
Deputy Chief Coroner - Investigations

Committee Membership

Dr. Dan Cass
Committee Chair
Deputy Chief Coroner - Investigations
Core Member, Centre for Quality Improvement
and Patient Safety
University of Toronto

Dr. Glenn Brown
Family Physician and Head
Department of Family Medicine
Queen's University

Ms. Patti Cochrane
Vice-President, Patient Services, Quality and Practice
and Chief Nursing Executive
Trillium Health Partners, Mississauga

Dr. Kris Cunningham
Forensic Pathologist & Medical Director
Kingston Regional Forensic Pathology Unit
(formerly Medical Director – Provincial Forensic
Pathology Unit, Toronto)
Ontario Forensic Pathology Service

Dr. Jonathan Dreyer
Emergency Physician and Research Director
Division of Emergency Medicine
University of Western Ontario

Ms. Julie Greenall
Interim Operations Leader
Institute for Safe Medication Practices (ISMP) Canada

Dr. Ian Herrick
Anesthetist and Co-Director, Continuing Medical Education
Department of Anaesthesia and Perioperative Medicine
University of Western Ontario

Ms. Margaret Keatings
Chief Nurse Executive and
Chief, Interprofessional Practice
Hospital for Sick Children

Dr. Madelyn Law
Assistant Professor
Dept. of Community Health Sciences
Brock University

Dr. Ann Matlow
Vice-President, Education
Women's College Hospital
Associate Director, Centre for Patient Safety
University of Toronto

Dr. David Musson
Academic Leader
Centre for Simulation-Based Learning
McMaster University

Dr. Michael Szul
Medical Advisor, Associate Registrar
College of Physicians and Surgeons of Ontario
(Ex-Officio)

Mr. David U
President and CEO
Institute for Safe Medication Practices (ISMP) Canada

Ms. Kathy Kerr
Executive Lead – Committee Management
Office of the Chief Coroner

History

Historically, issues or concerns relating to patient safety that were identified during a coroner's investigation may have led to individual recommendations being generated by the investigating coroner, or to a public review of the circumstances surrounding the death through a coroner's inquest. The complexity of cases involving patient safety issues, however, often requires specialized knowledge and expertise in order to fully understand the intricacies of the circumstances of the death. Inquests may take place several years after a death and it may be challenging for a jury comprised of member of the public to fully grasp the complex medical details in order to make practical recommendations aimed at preventing similar deaths in the future.

The Patient Safety Review Committee (PSRC) was established in 2005 in order to address the need for specialized knowledge and expertise and to help expedite the review of coroners' cases with actual or perceived systemic patient safety implications, and where possible, to make recommendations to prevent future similar deaths. information.

Note: The above described objectives and attendant committee activities are subject to limitations imposed by the Coroners Act of Ontario Section 18(2) and the Freedom of Information and Protection of Privacy Act.

Purpose

The purpose of the PSRC is to assist the Office of the Chief Coroner in the investigation and review of healthcare-related deaths where system-based errors or issues appear to be a major factor. The PSRC develops recommendations aimed at preventing similar future deaths, which are sent to the relevant agencies and organizations by the Chief Coroner for Ontario. The patient and public safety mandate of the Office of the Chief Coroner is derived from the Coroners Act:

Chief Coroner and duties

4. (1) The Lieutenant Governor in Council may appoint a coroner to be Chief Coroner for Ontario who shall,

(d) bring the findings and recommendations of coroners' investigations and coroners' juries to the attention of appropriate persons, agencies and ministries of government;

Disclosure to the public

18. (3) The Chief Coroner shall bring the findings and recommendations of a coroner's investigation, which may include personal information as defined in the Freedom of Information and Protection of Privacy Act, to the attention of the public, or any segment of the public, if the Chief Coroner reasonably believes that it is necessary in the interests of public safety to do so. 2009, c. 15, s. 10.

In the context of the PSRC, the use of the word "error" does not imply blame or responsibility on the part of any individual or organization. For the purposes of this committee, "error" is defined as a system design characteristic that either permits unintended adverse events to occur (latent error) or does not detect deviations from the intended path of care (active error). System design would include not only the design of care

Structure and Size

processes, but also access to care management (such as delays in receiving care). The presence of such errors does not mean that an individual or organization should be assigned blame or responsibility for an unintended outcome. The mandate of the PSRC, like that of the Office of the Chief Coroner, is one of fact-finding, not fault-finding.

The aims and objectives of the PSRC are:

1. To provide expert opinion about the cause and manner of death in healthcare-related cases where systems-based errors appear to be a major factor.
2. To assist coroners to improve the investigation of deaths within, or arising from, the health care system in which systems-based errors appear to have occurred.
3. To stimulate educational activities for professionals through identification of systemic problems, referral to appropriate agencies for action, collaboration with professional regulatory bodies and the dissemination of an annual report. Emphasis will be placed on speedy dissemination of information.
4. To provide expert evidence at inquests on request.
5. To conduct or promote research, where appropriate.
6. To undertake random or directed reviews when requested by the chairperson.
7. To help identify the presence or absence of systemic issues, problems, gaps, or shortcomings of each case to facilitate appropriate recommendations for prevention.

The committee membership consists of respected practitioners from various disciplines related to health care. The membership is balanced to reflect wide and practicable geographical representation and representation from all levels of institutions, including teaching centres, to the extent possible. Other individuals with specialized knowledge or expertise are invited to participate in committee reviews when required and at the discretion of the chairperson.

In 2012, the PSRC was comprised of 13 members, including the chairperson and executive lead. The committee membership, and its balance, is reviewed regularly by the chairperson and by the Chief Coroner, as requested. While one member of the committee resigned in 2012, two new members with expertise in patient safety and systems analysis joined.

Limitations

The PSRC is advisory in nature and makes recommendations through the chairperson. While the committee's consensus report is limited by the data provided, efforts are made to obtain all available, relevant information. It is not within the mandate of the committee to re-open other investigations (e.g. criminal proceedings) that may have already occurred.

Information collected and examined by the PSRC, as well as its final report, are for the sole purpose of a coroner's investigation pursuant to section 15(4) of the Coroners Act, R.S.O. 1990 Chapter C.37, as amended.

All information obtained as a result of coroners' investigations and provided to the PSRC is subject to confidentiality and privacy limitations imposed by the Coroners Act of Ontario and the Freedom of Information and Protection of Privacy Act. Unless and until an inquest is called with respect to a specific death or deaths, the confidentiality and privacy interests of the decedents, as well as those involved in the circumstances of the death, will prevail. Accordingly, individual reports, review meetings, and any other documents or reports produced by the PSRC, are private and will not be released publicly.

Each committee member has entered into, and is bound by the terms of a confidentiality agreement that recognizes these interests and limitations.

Members of the committee do not give opinions outside the coroners' system about cases reviewed. In particular, members do not act as experts at civil trials for cases that the PSRC has reviewed.

Members do not participate in discussions or prepare reports of clinical cases where they have (or may have) a conflict of interest, or perceived conflict of interest, whether personal or professional.

Medical records, draft and consensus reports and the minutes of committee meetings are confidential documents.

Summary of Cases Reviewed in 2012

In 2012, the PSRC completed reviews of ten cases which resulted in 46 recommendations; all of the deaths reviewed occurred in 2011 or 2012. Due to the vast experience and expertise present on the PSRC, the committee was asked to assist the Yukon coroner's office with a complex investigation pertaining to patient safety in one case. The Yukon case review resulted in two recommendations specifically addressed to that jurisdiction.

All other recommendations were distributed to agencies and organizations which were felt to be able to impact or affect implementation. These organizations were asked to respond within one year of the time the recommendations were received and indicate what action they had taken on these recommendations.

Case 2012-01

Date of Death: March 21, 2011

Age: 62 years

OCC File number: 2011-3624

History

The decedent was a 62-year-old male with a history of a myocardial infarction (MI) in 1999, hypertension and hypercholesterolemia. He was prescribed metoprolol, atorvastatin and ASA, but was non-compliant. He complained of sudden onset of left sided chest pain and profuse sweating while at home with his family at 1900 hours on March 20, 2011. His daughter called 911 at 1910 hours and an ambulance arrived at the patient's home at 1920 hours. He was assessed by an advanced care paramedic. He was described as having 10/10 chest pain radiating to his left arm. He was also noted to have consumed 10 alcoholic beverages during the day. He was profusely diaphoretic and pale.

Initial BP was 102/70, pulse 65 and oxygen (O₂) saturation 100% on high flow O₂. A 12 lead electrocardiogram (ECG) was performed at 1927 hours by paramedics while on scene. This was not indicative of an ST-elevation myocardial infarction (STEMI). Such a finding would have dictated that the paramedics transport the patient directly to the regional cardiac centre. In the absence of a STEMI, protocol determined that they should transport the patient to the nearest emergency department.

An intravenous (IV) was started and chewable aspirin was administered, but the patient spat it out because he did not have his dentures. At 1941 hours, a second ECG showed signs of anterior ischemia, but no STEMI. A first dose of sublingual nitroglycerine was administered at 1945 hours and transport was initiated. The paramedics assigned a Canadian Triage Acuity Score (CTAS) of 2 (Emergent). At 1954 hours, a third ECG was performed en route to the nearest emergency department (Hospital A); this was diagnostic for acute inferior STEMI. The ambulance arrived at Hospital A at 1957 hours.

The emergency department at Hospital A was extremely busy when the patient arrived and the paramedic crew was placed on off-load delay. Emergency department nursing staff drew blood for investigation of chest pain including cardiac enzymes,

and performed a 12 lead ECG at 2027 hours. Another ECG was performed at 2043 hours. Both of these ECGs were diagnostic for an inferior STEMI. These ECGs were shown to a physician at 2050 hours who expressed no concern about them, and no additional actions were taken. Serum CK and Troponin I drawn at 2036 hours were normal.

Between 1958 and 2058 hours, paramedics administered six doses of sublingual nitroglycerine which did not result in a change in the patient's symptoms. They were unable to give further nitroglycerine after this as the patient's blood pressure (BP) fell to 99 mm Hg, making it too low for them to administer this medication according to their medical directives. Between 2100 and 2240 hours, paramedics repeatedly asked the off-load delay nurse to move their patient to an emergency department stretcher. His BP during this time remained in the range of 100/70. With the patient's pain worsening and as he became more and more restless, paramedics performed a fifth ECG at 2234 hours. This ECG showed clear evidence of an inferior STEMI with lateral extension. BP was 104/74. After the ECG was shown to the emergency department off-load nurse in conjunction with earlier ECGs, the patient was moved to an emergency department stretcher at 2310 hours.

At 2311 hours, the patient's BP was 81/62, and pulse was 130. At 2315 hours, the patient was given diazepam 10 mg orally (PO). At 2335 hours, he was given dimenhydrinate 50 mg intravenously (IV) and morphine 5 mg intravenous push. At 2337 hours, he received oral viscous lidocaine with liquid antacid. At 2340 hours, the patient was given ASA 160 mg PO, clopidogrel 300 mg PO, enoxaparin 30 mg IV, tenecteplase 35 mg IV and enoxaparin 62 mg subcutaneous (SC) in rapid succession.

At 2350 hours, BP was 73/45 and pulse was 79. At 0001 hours, BP was 51/39 and pulse was 52. A norepinephrine infusion was started at 0006 hours and titrated to effect an improved BP. At the same time, the patient was receiving an IV bolus of three litres normal saline.

At 0001 hours, the Central Ambulance Communications Centre (CACC) was contacted with a request to transfer the patient to the Cardiac Catheterization Lab at Hospital B. The ambulance departed Hospital A at 0026 hours on March 21, 2011 with the patient and registered nurse (RN) on board with the paramedics

for the 18 minute transfer to Hospital B. At that time, the patient's BP was 71/54 with a pulse of 44. On arrival at Hospital B at 0044 hours, his BP was 147/99 and subsequently rose to 158/128. At 0045 hours, the norepinephrine infusion was decreased from 20 mcg/min to 8.5 mcg/min by the transport nurse.

Based on information conveyed from staff at Hospital A, the receiving cardiologist at Hospital B made plans to perform a cardiac catheterization at 0230 hours. At 0107 hours, the receiving cardiologist was notified by telephone by the critical care unit (CCU) nurse that the patient's BP was 57/48 with respirations of 25. The norepinephrine drip was increased. At 0120 hours, the attending cardiologist was again paged and further orders were given to start a dopamine drip in addition to the norepinephrine infusion already running. At 0120 hours, the BP had improved somewhat to 81/49, but the respiratory rate was now 32. At 0130 hours, the attending anaesthesiologist decided to intubate the patient. This was done without difficulty following administration of midazolam 2 mg IV, propofol 50 mg IV, phenylephrine 50 mcg IV and succinylcholine 100 mg IV.

At 0150 hours, with the receiving physician in attendance, the patient became asystolic. Despite resuscitation with atropine, epinephrine, sodium bicarbonate and vasopressin, the patient remained in asystole. Resuscitation was discontinued at 0205 hours. The cause of death was felt to be cardiogenic shock secondary to acute myocardial infarction.

Post mortem

Cause of death was reported as acute and intermediate (at least one to two weeks in age) myocardial infarction as a consequence of atherosclerotic coronary artery disease. Autopsy findings included severe four vessel atherosclerotic coronary artery disease. There was 95% calcific atherosclerotic stenosis of the left main coronary artery; 90-95% calcific atherosclerotic stenosis with hemorrhage in plaque of the left anterior descending artery; 99-100% calcific atherosclerotic stenosis with hemorrhage in plaque in the left circumflex artery, and 40% focal calcific atherosclerotic stenosis, with a narrow lumen distally.

Discussion

1. Initial response and care provided by paramedics appears to have been appropriate, and their decision to transport

the patient to the nearest hospital was consistent with their base hospital medical directives for patients with presumed ischemic chest pain, who have a non-diagnostic ECG in the field. Reviews conducted by base hospital staff and Emergency Medical Services (EMS) supervisory staff came to the same conclusion.

2. A third ECG done three minutes from the doors of Hospital A was diagnostic for an acute STEMI. Paramedics decided to continue to Hospital A, rather than diverting to the regional cardiac centre at Hospital B. To do so would have added another 18-20 minutes to the out-of-hospital time. Base hospital and EMS supervisory staff supported this decision. However, with the benefit of hindsight, a diversion to Hospital B at this point would likely have obviated the three hours on off-load delay that was subsequently experienced at Hospital A.
3. The records from Hospital A note that 53 minutes after the patient arrived, the first two ECGs done in the emergency department were shown to the emergency physician. However there is no evidence that the patient was seen by a physician while he was waiting for a bed. These two ECGs are diagnostic for acute STEMI. Seeing the patient might have aided in the identification of this diagnosis. If the diagnosis had been made at this time, it would likely have resulted in earlier administration of thrombolytic therapy and transfer to the regional cardiac centre at Hospital B.
4. The investigation and treatment of the patient in the emergency department did not include administration of ASA. It was however, noted that the patient could not take ASA. A second attempt to administer ASA at this time may have been therapeutically helpful, and is part of the 2010 Emergency Cardiac Care Guidelines promulgated by the Heart and Stroke Foundation.
5. Paramedics who cared for the patient continued to advocate for him and repeated an ECG 2 hours 37 minutes after their arrival in the emergency department. This ECG confirmed the diagnosis of acute STEMI and resulted in the patient receiving thrombolytic therapy shortly thereafter.
6. There are no records of the communication between emergency department staff and the cardiologist at Hospital B. It would appear, however, that the cardiologist

was unaware that the patient was in cardiogenic shock when the patient left Hospital A. The cardiologist was therefore not in attendance when the patient arrived in the CCU at Hospital B. The patient was therefore not taken immediately to the catheterization lab for possible percutaneous coronary intervention (PCI).

Themes Identified: Clinical Administration; Clinical Processes/ Procedures

Recommendations

To Base Hospitals:

1. STEMI bypass medical directives should permit paramedics to reroute to a primary coronary intervention site at any time prior to arrival in an emergency department, provided total time from patient contact to arrival at the PCI centre will be ≤ 60 minutes.

To EMS and hospital emergency departments:

2. When there is an ambulance off-load delay and there is a disagreement about patient care between the EMS crew and the triage nurse in an emergency department, the Charge Nurse and the EMS Duty Supervisor should intervene in an attempt to expeditiously resolve the dispute in the interest of patient care.

To Hospital A:

3. A Quality of Care Review should be conducted with respect to this case, with particular attention to:
 - Communication process between the paramedics, triage nurse and emergency physician.
 - Recognition and management of acute coronary syndrome and STEMI.
 - Titration of inotropic medications and dangers of rapid increases / decreases in dose.

To All Hospitals:

4. It is recommended that when transferring a patient to another facility, details of the patients' most recent vital signs and general condition, be communicated to the receiving physician and that a written record and the time of such communication be kept in the patient care record.

Case 2012-02

Date of Death: November 13, 2011

Age: 86 years

OCC File number: 2011-14129

History

The decedent was admitted to a long-term care home in January 2010 after being admitted to hospital for stroke (right middle cerebral artery territory) with subsequent dependence for activities of daily living and feeding. Her medical history included

chronic obstructive pulmonary disease, cerebrovascular disease, trigeminal neuralgia, hypertension, hyperlipidaemia, congestive heart failure, and recurrent aspiration pneumonia.

The day prior to her death, she was ordered a hydromorphone infusion at a rate of 0.2 mg/hr. She was inadvertently administered hydromorphone at a rate of 2 mg/hr for approximately two hours. The patient died the following day, approximately eight hours after the infusion was stopped.

Detailed timeline (based on information contained in the health record):

Date/Time	Information Item
1 Oct 2011	Patient's warfarin had been discontinued on 15 Sept 2011 but had not been removed from medication administration record (MAR) and was given until 30 Sept 2011. It was noticed when the new monthly MAR was printed. She had bruises, a small amount of bleeding from the nose (resolved when nasal prongs removed), and some bleeding from the urethra.
2 Oct 2011	Continued hematuria. Patient was given 5 mg of oral vitamin K and had INR ordered which was reported as greater than 6.6. A repeat dose of vitamin K 5 mg was given by the SUBCUT route.
3 Oct 2011 to 5 Oct 2011	Slight hematuria reported on 3 October 2011. Catheter was reported to be draining clear on 5 October 2011.
5 Oct 2011	Loose, foul smelling stool reported. Stool sent for C. difficile testing, positive result reported on 8 Oct 2011.
11 Oct 2011	Metronidazole ordered then discontinued on the same day.
16 Oct 2011 to 22 Oct 2011	Diagnosis of pneumonia on 16 Oct 2011. Prescribed levofloxacin 500 mg IV daily for 7 days.
18 Oct 2011 to 25 Oct 2011	Given metronidazole 500 mg by G-TUBE q8h.
1 Nov 2011 to 8 Nov 2011	Given fluconazole 100 mg G-TUBE daily. Interaction with clopidogrel (decreased clopidogrel clearance) and fluoxetine (potential for QT prolongation) identified.
4 Nov 2011	Fever and aspiration noted. Started on vancomycin 1g IV q24h and metronidazole 500 mg IV q12h.
7 Nov 2011	Antibiotics changed to ceftriaxone 1g q24h. Only 1 dose documented on MARs available for review – duration of treatment unclear.
9 Nov 2011	Patient transferred to more acute unit.
10 Nov 2011	Status changed to DNR.
11 Nov 2011	Treatment goals changed to palliative. Given a 0.2 mg hydromorphone dose (route unspecified- assumed SC) at 0845 hours and patient experienced a decrease in respiratory rate at 1000 hours.

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Date/Time	Information Item
12 Nov 2011 at 2100 hours	Hydromorphone infusion ordered via computerized physician order entry (CPOE) system: 5 mg in 50 mL to run at 0.2 mg/hr. Additional note in comment field indicated concentration was to be 1 mg/mL. The computer calculated the rate of administration as 2 mL/hr based on the information entered. The nurse prepared the infusion as 50 mg/50 mL (1 mg/mL) as specified in the comment field and ran it at 2 mL/hr per the rate field in the printed order. An independent double check was conducted prior to starting infusion. (Note that the route was not specified in the documentation and the order was not available for review. Based on the intended concentration of 1 mg/mL, it is suspected that the intended route was subcutaneous, but the patient was ordered other medications intravenously so it may have been administered IV.)
12 Nov 2011 at 2245 hours	Nurse noticed discrepancies between the dosage and the concentration. The hydromorphone infusion was stopped at 2250 hours and the physician was contacted. In consultation with the family, decision made not to administer naloxone given the patient condition and goals of care – “did not want her to be in distress when the narcotic was reversed”. Plan to continue to monitor and restart infusion at 0.2 mg/hr when the patient started to show agitation again. (Unknown if infusion restarted based on available documentation).
13 Nov 2011 at 0650 hours	Death pronounced.

Post mortem

A post mortem examination was not conducted.

Discussion

Two clinically significant medication errors were identified in the case review. The first took place approximately two months prior to her death and involved repeated administration of warfarin for 15 days after an order to discontinue it. This was clinically significant but is an incidental finding and not considered to be a factor in her death. The second error occurred 10 hours before her death and involved a ten-fold overdose of hydromorphone.

A computerized prescriber order entry (CPOE) system was in place in the organization. It appears that electronic orders were printed for transcription and implementation by nurses. The process for transmitting orders to pharmacy is not known.

Warfarin Error

Warfarin was to be discontinued on September 15, 2011, but continued to be given to the patient from September 15 until September 30 without INR monitoring. The error was noticed on October 1, which coincided with the printing of a new MAR (presumably generated from the pharmacy profile). An INR ordered at the time of discovery was reported as greater than 6.6.

Based on available information, possible contributing factors include:

- MARs for this unit are printed once a month only.
- Availability of warfarin to be given to the patient once the medication was discontinued.

Hydromorphone Error

Hydromorphone was infused at a rate 10 times greater than the intended rate (2 mg/hr instead of 0.2 mg/hr).

Based on available information, possible contributing factors include:

- CPOE system order entry process

Failure to recognize that the selected product already had a pre-specified concentration and that the free text comment field would conflict with pre-populated data.

In most order entry systems there are pre-built medication files. For infusions, it is typical that these medication selections include both total amount of medication and volume in data fields. In this case, it appears that in entering the order into the computer system, the physician selected an order for a hydromorphone infusion bag that had a concentration of 0.1 mg/mL (5 mg of hydromorphone in 50 mL of 0.9% sodium chloride) and then entered the desired dose of 0.2 mg/hr. The physician wished to use a concentration of 1 mg/mL and entered this desired concentration in the comments field of the order as supplementary information. The printout of this order was not available for review, but from the progress notes it appears that it contained conflicting information.

The computer system automatically calculated the infusion rate of 2 mL/hr based on the pre-specified information (concentration 0.1 mg/mL; dose 0.2 mg/hr). The nurse referenced the requested concentration of 1 mg/mL in the comment line and mixed 50 mg hydromorphone in 50 mL and then set the infusion rate at 2 mL/hr based on the calculated rate in the order; thus delivering 2 mg/hr of hydromorphone, rather than the intended 0.2 mg/hr.

- Availability of sufficient hydromorphone in unit stock to prepare a 50 mg bag for this patient

If the nurse had been unable to obtain sufficient hydromorphone to prepare an infusion of this concentration, the error might have been caught when

pharmacy was contacted to obtain additional medication.

- Failed independent double check process

The prepared bag was checked by a second nurse prior to administration. It is not known if the process for conducting the verification was fully independent.

- No pharmacist review of order

The order was written in the evening when presumably there would not have been a pharmacist available to review the order prior to implementation.

- Knowledge Gaps

The implications of an order with conflicting information were not evident to the physician or the nurse. The fact that the dose administered would represent an overdose was not evident to the nurse.

Theme Identified: Medications/IV Fluids

Recommendations

To the Ontario Hospital Association, the College of Nurses of Ontario, and the Registered Nurses Association of Ontario:

1. Ensure there is a process to review electronic charts for new orders that may have been missed (i.e. reduce reliance on paper copies of orders that could be misplaced).
2. Ensure a regular review process of the MAR and patient medication profile to detect discrepancies.
3. Ensure that patient-specific medications are returned to pharmacy when discontinued to prevent inadvertent continued administration.
4. Dispense warfarin individually for patients for whom it is prescribed; do not provide in ward stock.
5. Review optimal MAR printing frequency based on order changes.

6. Identify standard concentrations for opioid infusions and discourage the use of non-standard concentrations.
7. If the available selections in the CPOE system do not meet patient requirements, require physicians to enter a free text order, rather than attempting to modify a selection through the use of the comment field.
8. Ensure that pre-defined orders (e.g. intravenous infusions vs subcutaneous) are clearly distinguishable in the CPOE system.
9. Assess the ability for pharmacy to provide opioid infusion solutions to avoid the need for nurses to mix infusions.
10. Consider the use of morphine as the drug of first choice in patients with low opioid needs and no contraindications.
11. Review the mechanism for pharmacy order review for new orders for high alert medications.
12. Review the need for hydromorphone and other opioids in ward stock. Refer to ISMP Canada priority recommendations for opioid management in hospitals (Appendix 1) and Accreditation Canada Required Organizational Practices ¹.
13. Provide education for practitioners on how to optimize independent checks ².
14. Provide education for nurses as to the potency differences between hydromorphone and morphine.

¹ Accreditation Canada Required Organizational Practices. Medication Use: Narcotics Safety. ROP Handbook, p. 36; available from: <http://www.accreditation.ca/sites/default/files/rop-handbook-2014-en.pdf>

² Accreditation Canada Required Organizational Practices. Communication: Verification Processes for High-Risk Activities. ROP Handbook, p. 31; available from: <http://www.accreditation.ca/sites/default/files/rop-handbook-2014-en.pdf>

Case 2012-03

Date of Death: March 25, 2011

Age: 46 years

OCC File number: 2011-3639

History

The decedent was a 46-year-old woman who presented with dysfunctional uterine bleeding. A pelvic ultrasound revealed a 5cm X 3cm X 3cm submucosal fibroid. She chose to undergo a hysteroscopic myomectomy.

She was admitted to Hospital A on March 23, 2011 at 0800 hours. Her BP was elevated on admission at 153/100. In 2008, she had an episode of hypertension which resolved without treatment. She was noted to be somewhat anxious.

The patient was taken to the operating room at 1007 hours. Under general anaesthesia, she underwent a hysteroscopic myomectomy. The procedure commenced at 1018 hours. The operative report indicates that the procedure went as planned and there were no recognized intra-operative complications. Specifically, estimated blood loss was less than 100cc, there were no concerns of uterine perforation and there was adequate hemostasis at the completion of the procedure. The distending fluid balance was -470 cc which was within normal limits. Her blood pressure during the procedure was 110-120/60 and heart rate was 60-70 bpm. The procedure was completed at 1120 hours.

The patient was transferred to the post-anaesthetic care unit. Her vital signs were stable at 1125 hours with a BP of 172/79 and pulse 101 bpm. She initially denied having any pain, but subsequently required 5 mg of oxycodone at 1140 hours. At 1150 hours, she was awake and alert. Vaginal blood loss was small and she was fit for discharge to the outpatient unit. BP at that time was 160/78.

On arrival to the outpatient unit at 1155 hours, her vital signs were stable with a BP of 140/100. Her pain (i.e. cramps) was noted to be 3/10. She got up to void at 1320 hours and was quite dizzy and nauseous. At 1440 hours, she was noted to be pale. Her BP was lower at 100/50. At 1545 hours, her BP went as

low as 85/45. She was attended by her physician and the IV rate was increased. Thereafter, her BP at 100/50 and pulse remained around 65 bpm until discharge. She was able to ambulate to the washroom at 1630 hours. The cramping settled and vaginal blood loss remained small. She was discharged home at 1730 hours under the care of her husband and with a prescription for oxycodone IR 5-10 mg every four hours (20 tabs) and naproxen 500 mg every six hours (15 tabs).

Upon returning home, the patient spent most of the time in bed, except for occasional trips to the washroom. She did not complain of excessive pain. She took the naproxen as prescribed, but substituted Tylenol #3® for oxycodone IR due to concerns that the latter medication might cause a repeat of the dizziness, nausea and vomiting she experienced in hospital. Her husband checked on her at around 2200 hours on March 24 and she appeared to be resting. He did not disturb her. He next checked on her early in the morning of March 25 and again thought she was sleeping. Later that morning when he went in to check on her, he noticed dark fluid around her face. She was cold to touch and he realized she had no vital signs. Paramedics were called and upon arrival, confirmed her death.

Post mortem

The significant finding at the postmortem examination was the presence of 950 mL of blood and clot in the peritoneal cavity. Examination of the uterus disclosed the presence of two transmural uterine perforations and a third area of penetration through 80% of the myometrium. The two transmural perforations were in the superior aspect of the uterine fundus. These measured 0.3 and 0.4 cm and the margins were hemorrhagic. Histologic findings were consistent with cauterization effects in these areas. Focally there was recent hemorrhage dissecting through the substance of the myometrium. Multiple mid-sized, muscular arteries were observed in the immediate vicinity of the transmural defects.

The cause of death was given as acute hemoperitoneum due to instrumental transmural punctures of the uterine corpus complicating hysteroscopic myomectomy for the treatment of menorrhagia as the result of uterine leiomyomata.

Discussion

This patient died from hemorrhagic shock resulting from intraperitoneal bleeding caused by uterine perforations resulting from a hysteroscopic myomectomy.

Uterine perforation is a recognized complication of hysteroscopic myomectomy. The rate of reported incidence ranges from 0.4 -1.6%. Risk factors for uterine perforation include the size and location of the fibroid and operator experience. Leiomyomas greater than 3 cm and greater degrees of penetration into the myometrium, require advanced surgical skills to reduce the risk of perforation. The medical records provided for this review indicated that the fibroid was 5 cm X 3 cm X 3 cm, but the location (i.e. the percentage of the fibroid extending into the myometrium), was not described. The surgical skill level of the operator cannot be determined from this review.

Uterine perforation occurring at the time of hysteroscopy may result in excessive bleeding, sudden loss of visualization, sudden loss of uterine distension and an abrupt increase in the distending fluid deficit. None of these were observed during the performance of this procedure. Severe or persistent pelvic or abdominal pain and heavy or persistent vaginal bleeding may occur if a perforation occurred and was not recognized. There may be abdominal distension, shoulder tip pain and hemodynamic instability.

The deceased did experience a drop in BP during the in-hospital recovery period. She was assessed by her physician although no note of this assessment was in the records provided. No laboratory investigations were ordered. Her blood pressure stabilized, albeit at a lower level than at the time of admission, and she was alert and ambulatory at the time of discharge. If there was significant intraperitoneal bleeding at the time of discharge, she would likely have been more symptomatic and the time course of the events that subsequently unfolded would likely have been much shorter. The finding of 950 mL of blood in the peritoneal cavity at autopsy may have been due to slow and persistent bleeding or more acute and massive bleeding from thermal injury in the perforation sites eventually affecting the integrity of the muscular arteries in the area identified on histology.

Discussion by Committee

The PSRC reviewed the case and discussed the sequence of events and the post mortem findings. There was concern expressed by some committee members that the amount of intra-abdominal bleeding found at post mortem seemed insufficient to cause death in an otherwise healthy woman. A question was raised as to whether there were additional contributing factors involved, such as a low pre-operative hemoglobin, excessive vaginal blood loss post-operatively, or a toxicological contributor. Further discussion centred around the discharge instructions provided to the decedent and/or her husband, and whether the hospital conducted any type of telephone follow-up following the procedure.

Additional information was obtained in order to clarify the above questions, and the case was discussed again at the next PSRC meeting. This information included:

1. Hemoglobin – the pre-op hemoglobin was 116 (March 4); there was no post-op hemoglobin obtained.
2. In speaking with the forensic pathologist who performed the post mortem, while there was only 950 mL of blood in the peritoneal cavity, he noted that the organs and tissues looked very pale, consistent with a greater degree of blood loss than was seen in the abdomen at post mortem.
3. Toxicology testing was done; it showed only a therapeutic concentration of codeine (consistent with the reported use of Tylenol #3®) and a trace of morphine (likely the result of metabolism of codeine to morphine).
4. The coroner followed up with the decedent's husband. He indicated that:
 - The decedent had not complained of / noted excessive vaginal bleeding or pain post operatively (he felt she would have indicated this to him if she had experienced either).
 - He did not recall them being given detailed instructions re: when to call / return to the hospital.
 - He did not recall any phone call or other contact from the hospital in the post-operative period.

5. Hospital A was contacted regarding their discharge instructions and follow-up processes. Copies of the typical patient information and discharge instruction materials were provided for the committee to examine. These consisted of a dilation and curettage (D&C)/hysteroscopy booklet and follow up instruction sheet. The decedent's surgeon was confident that the decedent had received these.
6. Hospital A indicated that they do not routinely call patients in follow-up, but acknowledge that this is "a practice that we should aspire to achieve." The committee did not feel that such telephone follow-up would likely have had any effect on the outcome in this case.
7. Hospital A was unaware that the patient had died until they were contacted by the Office of the Chief Coroner. The Hospital has since conducted a Quality of Care Review of this case.

Theme Identified: Clinical Processes/Procedures

Recommendations

No recommendations.

Case 2012-04

Date of Death: January 12, 2012

Age: 33 years

OCC File number: 2012-236

Reason for review

The Regional Supervising Coroner referred this case to the PSRC because of concerns involving the care provided to the patient. In particular, the patient had been partially worked-up for sarcoidosis and had a computerized tomography (CT) scan that supported this finding. The CT scan was not followed-up by the patient's healthcare providers.

History

The decedent was a 33-year-old male who was found face down and unresponsive by his roommate in his basement apartment. Paramedics were called, but the patient was obviously deceased and resuscitation was not attempted.

The decedent had recurrent idiopathic chronic iritis and was followed by a specialist in ophthalmology. A note from the ophthalmologist to the family physician on September 15, 2010, indicated that the patient required a work-up for granulomatous diseases including blood work, tuberculosis testing, and chest X-ray. It was clear in the note that this was to be arranged by the family doctor and that the ophthalmologist would follow the ocular issues.

The complete blood count (CBC), rheumatoid factor, anti-nuclear antibodies (ANA), VDRL (serological testing for evidence of syphilis infection) and Lyme Disease screening was reported to the family physician on September 22, 2010. The only abnormality was minor elevation of alkaline phosphatase.

A chest X-ray from September 23, 2010, showed a discrete 3.5 cm mass in the right pulmonary hilus, with a smaller nodular mass immediately below it. Left pulmonary hilum was thought to be prominent, and other non-specific changes were suggestive of lymphadenopathy. The radiologist concluded that the examination was suggestive of sarcoidosis. A CT scan and ultrasound were suggested.

An abdominal ultrasound done on September 30, 2010 was reported as normal.

A CT scan from October 23, 2010 found perilymphatic nodules and bulky lymphadenopathy suggestive of sarcoid. Other non-specific nodules were identified and reassessment by CT was suggested in three to six months time. A small liver hypodensity was identified, but was non-specific.

The CT scan report arrived while the family physician was on extended leave. The replacement physician apparently reviewed and initialed the report, but did not contact the patient to arrange for follow-up. The notes of the primary family physician were felt to be scanty and did not readily provide the replacement physician with a clear understanding of the active issues for the patient.

There was no additional follow-up by any healthcare providers prior to the patient's sudden death in January 2012.

Post mortem

At autopsy, marked enlargement of lymph nodes above and below the diaphragm and concentrated in the hilar and paratracheal regions was noted. The papillary muscles in the heart showed well-circumscribed diffuse replacement by a non-necrotizing granulomatous inflammatory process.

Cause of death: Sarcoidosis with Cardiac Involvement

Theme Identified: Clinical Administration

Recommendations

To Ontario Medical Association and Ministry of Health and Long-Term Care:

1. Urgently complete the implementation of electronic medical records (EMRs) in primary care settings in order to:
 - Facilitate organization of the patient's medical record in a manner that ensures that all members of the healthcare team have a shared understanding of the active issues and medical plan.

- Include “alert” systems, accessible to all members of the healthcare team, to ensure appropriate response to critical issues.
- Facilitate patients’ access to their own test results.
- The need for physicians’ notes to be comprehensive enough to facilitate a replacement physician being able to quickly identify ongoing issues.
- Who is responsible for follow-up of investigative procedures.

To the College of Physicians and Surgeons of Ontario:

2. Consider publication of this case in an upcoming issue of Dialogue to highlight issues identified, including:

Case 2012-05

Date of Death: October 1, 2011

Age: 82 years

OCC File number: 2011-13099

History

The decedent was an 82-year-old male who had been a resident of a long-term care home since June 16, 2011. His past medical history was significant for oxygen-dependent chronic obstructive pulmonary disease, sleep apnea, coronary artery disease, hypercholesterolaemia, hypertension, cardiac defibrillator insertion, trans-urethral resection of the prostate, diabetes and peripheral vascular disease with a left above-knee amputation; he was bed and wheelchair-bound. In July 2011, he had a hospital admission for a fall that resulted in a fractured right lower tibia and fibula and subsequent osteomyelitis requiring a course of IV cloxacillin therapy.

He was admitted to hospital on August 31, 2011 for failure to thrive. In hospital, he was managed for his multiple medical problems, including debridement of his right leg ulceration and management of an associated wound infection, hypokalemia, hypotension, and an episode of gross hematuria. He was stepped down to alternate level of care (ALC) status on September 13, 2011. With general overall deterioration and loss of appetite, he was deemed palliative on September 22, 2011 and transferred to the palliative care unit on September 29, 2011. He died on October 1, 30 minutes after an apparent medication error where he was given 4 mg of hydromorphone subcutaneously instead of the prescribed 0.2-0.4 mg dose.

Detailed timeline around time of incident:

On September 29 at 1900 hours, the patient was transferred to the palliative care unit and continued on a number of medications for treatment of the above conditions.

New palliative care medication orders were also prescribed:

29/9/11 Dilaudid 0.2-0.4 subcut q 15pr prn
Midazolam 1.0-2.0 subcut q 15pr prn
Addol 0.5-1.0 subcut q 15pr prn

The physician dictated note with explanation of above medication orders indicated:

In addition, in case of pain, I added a low dose of opioid in the form of Dilaudid 0.2 to .4 mb subcu if needed for pain, Midazolam 1 to 2 mg subcu if needed for anxiety, and Haldol 0.5 to 1 mg subcu if needed for nausea or agitation.

Three significant events followed:

- September 30 at 1930 hours acetaminophen 650 mg x 1
at 2330 hours haloperidol 1 mg sc x 1

October 1 at 0320 hours haloperidol 1 mg sc x 1
at 0320 hours hydromorphone 0.4 mg sc x 1

A late entry on October 1 at 2310 hours was written by a registered practical nurse (RPN) in the progress notes which stated the patient was anxious and yelling. The registered nurse (RN) gave haloperidol without effect. The patient continued to call out, but denied pain. The RPN gave another dose of haloperidol without effect. The patient was confused and calling out continued. The patient was restless and uncomfortable, and subsequently hydromorphone was given with good effect.

- On October 1 at 1116 hours, the RPN noted that all morning medications were held since the patient refused and was drowsy, lethargic, confused, and hypotensive. When awakened, he was agitated. The RN and doctor were notified. An order to hold bisoprolol was written and the plan was for close observation.
- On October 1 at 1900 hours, hydromorphone 0.4 mg was documented as given; however the Coroner's Investigation Statement indicated that a 4 mg subcutaneously dose was inadvertently administered. The dose had been drawn from a vial containing a 10 mg/mL concentration and resulted in a ten-fold error. Death was pronounced at 1930 hours. The file did not include documentation as to why this dose was administered or when and how the error was discovered.

Post mortem

A post mortem examination was not conducted as the patient had been embalmed before the coroner was notified.

Discussion

This incident was identified as a drug dosing error by the hospital and investigated internally. A copy of the hospital's recommendations are reprinted below (with permission from the hospital), along with the comments of the PSRC case reviewer from the Institute for Safe Medication Practices (ISMP) Canada. Based on available information, possible contributing factors included:

- Availability of high concentration hydromorphone in unit stock
The ten-fold dosing error may have been more readily recognized if the nurse was using a lower (2 mg/mL) concentration of hydromorphone since the volume calculated for administration (4 mg would equal 2 mL) would be larger than a usual subcutaneous injection.
- Failed independent double check process

Year <u>2011</u>	Month <u>09/10</u>	Date <u>24</u>	Time <u>20</u>	Out
Medication <u>Dilaudid</u>				
Dose <u>0.2 mg - 0.4 mg</u>	Route <u>SC</u>	Frequency <u>Q4h</u>		
Comments <u>PRN (in 10 mg concentration)</u>				
Order Date <u>9/30</u>	Reorder Date	Stop Date		

- There was no documentation of an independent double check in this file although the hospital states that there is an existing policy in place.
- Knowledge Gaps

A comment on the MAR stated "use 10 mg concentration"; however there was no information included on how to

obtain a 0.4 mg dose from a 10 mL vial. It appeared that it was not evident to the nurse that the prescribed dose could not be obtained from that specific product unless further dilution was carried out. A 0.4 mg dose would equal a volume of 0.04 mL of the undiluted product.

A similar case involving a ten-fold dosing error with hydromorphone was the subject of a recent public inquiry regarding a fatality, in Alberta. In the Alberta case, a 5 mg dose of hydromorphone was inadvertently administered into a patient who had an active order for hydromorphone 0.25 - 0.5 mg SC q3h PRN. The 0.5 mL overdose was drawn from a vial containing a 10 mg/mL concentration. The report can be accessed at:

http://justice.alberta.ca/programs_services/fatality/Documents/fatality-report-Lecavalier.pdf

Theme Identified: Medications/IV Fluids

Hospital's Recommendations

The hospital's Quality Coordinating Committee made 13 recommendations following this fatal incident. When sorted based on the hierarchy of effectiveness, there are four recommendations that would be considered high leverage.

High Leverage

Forcing functions and constraints

- That the high concentration of hydromorphone be removed from the unit immediately as there currently is no patient requiring this medication in this patient care area.

ISMP Comment: Conduct ongoing reviews of the need for hydromorphone and other opioids in ward stock, to prevent ward stock "creep." Refer to ISMP Canada priority recommendations for opioid management in hospitals (Appendix 1) and Accreditation Canada Required Organizational Practices³.

³ Accreditation Canada Required Organizational Practices. Medication Use: Narcotics Safety. ROP Handbook, p. 36; available from: <http://www.accreditation.ca/sites/default/files/rop-handbook-2014-en.pdf>

2. That the pharmacy explore mechanisms to physically separate morphine from hydromorphone (sic).

ISMP Comment: While this may be helpful, it is not clear from the documentation provided how this recommendation is related to this case. Note misspelling of hydromorphone.

Automation/ computerization

3. That the computerized electronic medication record (CMAR) is implemented.

ISMP Comment: Consider that careful design decisions will need to be implemented to minimize the potential for new technology-driven misinterpretations.

In reviewing the case documentation, it was noted that the hydromorphone order had been incorrectly entered into the pharmacy profile and then "discontinued" rather than "cancelled" or "voided." This is incidental to this case, but an incorrect entry such as this could be misinterpreted as a valid part of the patient's medication history (see excerpt from electronic patient medication profile below).

DISCONTINUED THERAPIES			
PRN			
Medications, IT, IV's Therapies			
HYDROMORPHONE INJ 2 mg/mL	0.2 - 0.04 MG=0.1 - 0.02 mL	SUBCUT	Q1H PRN
[HYDROMORPHONE HYDROCHLORIDE]			

4. Finalize time frame for roll out of automated dispensing cabinets and consider prioritization of placement of cabinets in areas that administer high concentration narcotics.

Mid Leverage

Reminders, checklists, double checks

5. That additional warning is highlighted on the CMAR with regard to high risk medications.

ISMP Comment: Consider that this additional warning would be most helpful when attached to a requirement for an independent double check.

6. That the medication administration safety committee explores other means of adding patient labels to high risk medications that are available in multiple concentrations.

ISMP Comment: Consider dispensing high concentration hydromorphone only on a patient-specific basis (individually labeled) so it can be easily removed when no longer required.

7. That professional practice and medication administration safety committee review the current policy on independent double checks.

ISMP Comment: Consider resources available to provide education for practitioners on how to optimize independent checks^{4,5}.

8. That pharmacy routinely audit narcotic drawers in patient care areas to remove high risk medications that are not being used, grant pharmacy technician access to medication narcotic drawers.

ISMP Comment: Would need to clarify the process and accountability between pharmacy technicians and nursing staff to implement this recommendation. Consider incorporating required documentation of "no removal needed" at such time.

Low Leverage

Rules & Policies

9. That pharmacy reviews the current practice of 'borrowing' medications between patient care areas.

ISMP Comment: While this is a good idea, it is not clear from the documentation provided how this recommendation is related to this case.

⁴ Accreditation Canada Required Organizational Practices. Communication: Verification Processes for High-Risk Activities. ROP Handbook, p. 31; available from: <http://www.accreditation.ca/sites/default/files/rop-handbook-2014-en.pdf>

⁵ Lowering the Risk of Medication Errors: Independent Double Checks. ISMP Can Saf Bull. 2005 Jan [cited 2012 Jun 12];5(1):1-2. Available from: <http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2005-01.pdf>

Education and Information

10. The nurse involved is to complete medication administration module through the College of Nurses of Ontario and reflective practice. The nurse manager and the chief practice officer to follow up with regard to any additional actions.

ISMP Comment: Consider education and training for all staff; knowledge deficits are likely not limited to one individual.

11. That emotional support is offered to the staff.
12. That this incident be used in safety huddles within complex continuing care to discuss high risk drugs and mitigating strategies.
13. That risk management ensures that for any critical incident resulting in death the coroner has been notified.

The PSRC reviewed and endorsed the recommendations that arose from the hospital's review of the incident. In addition, the PSRC made additional recommendations.

Recommendations

To the Ontario Hospital Association, Ontario College of Pharmacists; Ontario Branch of Canadian Society of Hospital Pharmacists; Ontario Long-Term Care Association; Ontario Association of Long-Term Care Physicians:

1. Consider pharmacy preparation of small doses of hydromorphone in the absence of a commercially available product.
2. Provide a readily available standard dilution chart for usual doses of HYDROMORPHONE using the standard concentration available (usually 2 mg/mL).
3. Consider the use of morphine as the drug of first choice in patients with low opioid needs and no contraindications.

4. Review prescribing practices related to the use of dangerous abbreviations and dose designations. Refer to ISMP Canada's Do Not Use list available at: <http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf>
5. Review prescribing practices related to range dosing.
6. Consider implementation of standardized palliative care admission orders.
7. For palliative care areas in which higher concentration preparations of hydromorphone may be necessary, mechanisms must be in place to maintain a physical separation from lower-concentration preparations, and ideally to limit access to these preparations to prevent inadvertent administration.
8. Consider using ISMP Canada's HYDROMORPHONE knowledge assessment survey as an education tool. It is available at http://www.ismp-canada.org/education/webinars/20120209_Hydromorphone/
9. Periodic checks / audits should be conducted to ensure compliance with existing policies, such as independent double-checks.

To Canadian manufacturers of hydromorphone (Sandoz Canada and Hospira Canada); the Pharmaceutical Manufacturers Association of Canada:

10. Lower concentration preparations of hydromorphone should be produced, including pre-filled syringes (0.5 mg/ml and 1 mg/mL) such as are being marketed in other jurisdictions.

To Office of the Chief Coroner for Ontario:

11. For future incidents investigated by coroners, encourage documentation of how the incident was discovered as this can provide valuable insight into system-based strategies to decrease risk and mitigate harm.

Case 2012-06

Date of Death: October 17, 2011

Age: 87 years

OCC File number: 2011-12791

History

The decedent was an 87-year-old man with a history of cardiac disease. He was inadvertently given his roommate's medications (ramipril, diltiazem and metformin) resulting in clinical deterioration and death. His cause of death was determined to be the "hypotensive effects of ramipril and diltiazem in the setting of ischemic heart disease."

The decedent was admitted to hospital on September 28, 2011 after presenting to the emergency department with congestive heart failure (CHF) and *Clostridium difficile* (C. difficile) diarrhea. He received antibiotic and diuretic therapy, and improved. Otherwise, his hospital stay was uneventful. On October 17, 2011, he was stable and scheduled for discharge later that day.

His past medical history included a right ventricular myocardial infarction in 2004. He had Grade 2 left ventricular function and a history of congestive heart failure. He had a dual pacemaker, hypertension, hypothyroidism and chronic renal failure. In 1994 he had a lobectomy for lung cancer.

The decedent was on the following medications: furosemide 120 mg in the morning and 80 mg in the evening; atorvastatin 20 mg once daily; bisoprolol 2.5 mg once daily; levothyroxin 0.05 mg once daily; acetylsalicylic acid; warfarin; potassium chloride and laxatives.

On the morning of his death, the decedent's lab results were: blood glucose 5.8, urea 21.5 and creatinine 224.

Prior to admission to hospital, the decedent lived at home with his wife and son with relatively good function. His son called at approximately 1000 hours on October 17, 2011. During the conversation, the decedent told his son that he had been given different pills and more than he expected. He indicated that one was a black and white capsule and that he had also been given four containers of orange juice (even though his fluids were restricted). His son told him to check with the nurse to ensure

these were correct before taking them. The decedent told his son that he had checked and was informed they were correct and that his medications had been changed.

His son called again around 1200 hours and was told by his father that his vision was blurry. He was assessed at that time and found to be borderline hypotensive.

When the son called again shortly thereafter, his father's roommate answered the phone and told him that his father was not doing well and was being attended to by the healthcare team. The son rushed to the hospital where he was informed by the nurse practitioner (NP) that they were concerned that his father was having a stroke.

The deceased had diminished level of consciousness and his blood glucose was 2.7. By 1500 hours, his blood pressure had dropped to 50 mm Hg systolic and he was transferred to the CCU.

When the son arrived, he informed the NP that he was concerned his father had received the wrong medication. The decedent rallied briefly and confirmed this to the NP. The NP said she would follow up, but returned to say that the roommate was not diabetic and that there was no evidence of a medication error.

The decedent was managed for his low blood glucose and given inotropes for his blood pressure. At 1655 hours, he had a cardiac arrest and following unsuccessful resuscitation attempts, was pronounced dead at 1735 hours.

Because of the circumstances of the decedent's sudden deterioration and death, the death was reported to the coroner. The attending nurse was interviewed by the coroner and denied the potential for a medication error. Pharmacy records indicated that these medications were only dispensed once that day.

The decedent's roommate was determined to have been taking several medications including: ramipril 10 mg once daily, metformin 1 g twice daily, and long-acting diltiazem 120 mg once daily (this was to have been discontinued).

Post mortem

Toxicology results indicated the presence of ramipril, diltiazem and a level of metformin above the therapeutic range (decedent's level was 2.7 mcg/ml; the therapeutic range is 1 – 2

mcg/ml.). [In discussions with a toxicologist, it was determined that metformin has been noted to demonstrate significant post mortem redistribution, which could account for the observed level in the post mortem blood sample following a single dose.]

An expert opinion provided by an internist suggested that ramipril and diltiazem given together to an intravascular volume depleted patient (CHF), and augmented by pseudomembranous colitis, could have caused severe refractory hypotension. It was determined that the degree of hypoglycemia observed was not significant enough to cause death, and this was, in fact, treated in the CCU.

The conclusion was that cause of death was related to the "hypotensive effects of ramipril and diltiazem in the setting of ischemic heart disease."

Discussion

During his admission, the decedent appeared to have been treated appropriately and successfully for his CHF and his *C. difficile* infection. He was ready for discharge on October 17, 2011 when he received medications intended for another patient. The effects of these medications resulted in significant hypotension, and initiated a series of events which led to his death later that day. The PSRC felt it noteworthy that the decedent had identified what he believed to be incorrect medications being administered to him that morning, but was told that these were indeed correct and represented a change to his medications.

The hospital has conducted a quality of care review of this case. However, the PSRC felt that there were additional opportunities for learning from this case that had not been completely addressed through the hospital's review.

Theme Identified: Medications/IV Fluids

Recommendations

To College of Nurses of Ontario (CNO), the College of Physicians and Surgeons of Ontario (CPSO), and the Ontario Hospital Association (OHA):

1. The CNO, CPSO and OHA should consider using this case as an illustrative example for their respective memberships to reinforce a number of principles:
 - The importance of listening to patients and their families when they voice concerns related to a potential medication error.
 - To consider the possibility that a medication error may have occurred when a patient's condition deteriorates unexpectedly or there is an unusual change to a laboratory finding (such as lowering of blood glucose).
 - That if the possibility of a medication error is felt to exist, it may be prudent for clinicians to contact the Ontario Poison Centre for guidance regarding potential mitigating actions.

To the Regional Supervising Coroner (RSC):

2. The RSC should conduct a Regional Coroner's Review with the hospital. This review should focus on elucidating a clear understanding of the sequence of events in this case, and on exploring the principles of patient safety in the context of patient and family-centered care.

Case 2012-07

Date of Death: August 18, 2011

Age: 73 years

OCC File number: 2011-10123

History

The decedent was a 73-year-old male who died as a consequence of complications arising during an elective colonoscopy procedure performed under monitored anesthetic care with sedation at Hospital A on August 18, 2011.

The decedent had a history of anemia of unknown etiology and had also been experiencing dysphagia prior to the procedure. He was scheduled to undergo elective colonoscopy for the investigation of anemia as well as gastroscopy and dilation of an esophageal stricture. The procedure was scheduled for 30 minutes in duration and was planned as an outpatient procedure. It was performed in the operating room of a community general hospital by a general surgeon under intravenous sedation provided by a family practice anesthesiologist.

Premorbid conditions included chronic obstructive pulmonary disease, benign prostatic hypertrophy, gastroesophageal reflux disease, and lumbar spinal stenosis. These conditions were considered stable at the time of the procedure and therefore no preadmission investigations were arranged in advance. There was no history of cardiac or neurovascular disease. Medications included pantoprazole, ketoprofen, pregabalin, dutasteride, budesonide/formoterol inhaler, tiotropium bromide inhaler, acetaminophen and triamcinolone nasal spray.

The decedent proceeded to endoscopy uneventfully. Preoperative automated blood pressure was reported at 109/91 mmHg, heart rate was 63 bpm and oxygen saturation was 93% on room air. The intravenous was started in the operating room apparently with some difficulty. Intraoperative monitors included noninvasive blood pressure, five-lead electrocardiogram, and (based on the anesthetic record) a pulse oximeter. Oxygen was delivered via nasal prongs at a rate of 5 L/min. The initial systolic blood pressure in the operating room was recorded at 200 mmHg; a level that was attributed to anxiety.

Sedation was started with the administration of midazolam 1.5

mg, ketamine 10 mg and a bolus of a mixture of propofol (5 mg/ml) and remifentanyl (5 mcg/ml). The amount delivered by bolus is not recorded although it is indicated in the anesthesiologist's note that the size of the bolus was based on weight and was delivered by an infusion pump followed by an infusion of the same mixture. The anesthetic record reported that 10 ml of this mixture was infused over approximately 30 minutes (i.e. propofol dose of 50 mg and remifentanyl dose of 50 mcg).

Following the induction of sedation, both the surgeon and anesthesiologist reported that colonoscopy commenced without incident. Subsequent events were not as clear, but at some point during the colonoscopy procedure the decedent was noted to be "ashen." Apparently, at this time it was noted that the pulse oximeter was not in place. The pulse oximeter was placed on a finger and the record indicated that the initial oxygen saturation value was documented by the anesthesiologist as 100%; however, the decedent's colour at that time was described as being "not good." The operative note indicated an initial oxygen saturation of 95%. Initially, ventilation was assisted manually and subsequently a laryngeal mask was inserted. It was noted that these maneuvers resulted in resolution of the "ashen" colour. The precise timing of these events was difficult to determine. The anesthetic note indicated that these events occurred "minutes into the scope." The surgical note suggested approximately five minutes had elapsed and that the ashen colour was noted when the scope was withdrawn to reposition the patient. The colonoscopy was apparently completed while the anesthesiologist responded to the patient and the subsequent gastroscopy was aborted. The care team appeared to be convinced that a respiratory event occurred during this period.

The decedent did not awaken following the termination of anesthesia. He was intubated in the operating room and subsequently transferred to the Intensive Care Unit (ICU). Despite the absence of focal neurological signs and no evidence of acute neurologic injury on CT imaging, the decedent remained unconscious and unresponsive to physical stimulation. Post-procedural laboratory investigations were essentially normal with the exception of a low hemoglobin level of 83 g/L and a mildly elevated serum glucose level at 8.6 mmol/L. One unit of packed red blood cells was transfused. Myoclonic seizure activity was noted approximately one hour following the termination of anesthesia and propofol sedation was started and phenytoin was administered. Showing no evidence of improvement, the

deceased was transferred to the ICU at Hospital B later that evening.

In the face of a persistent neurologically unresponsive state, continuous generalized seizure activity on electroencephalogram (EEG) treated with benzodiazepines, propofol, anticonvulsants and neuromuscular blocking drugs and an abysmal prospect of functional recovery, the deceased's family decided to provide compassionate care and withdraw ventilatory support. Death was pronounced at 1902 hours on August 18, 2011.

Post mortem

Microscopic findings consistent with hypoxic / anoxic brain injury were noted in the absence of frank cerebral infarction or hemorrhage. The cause of death was attributed to anoxic brain injury complicating colonoscopy under anesthesia.

Secondary findings included emphysematous changes in the lungs with early focal bronchopneumonia, cardiac and renal changes consistent with chronic poorly controlled hypertension and normal coronary arteries.

Discussion

The decedent appeared to have received appropriate pre-operative and post-operative care. Pre-operative evaluation and documentation appeared appropriate given his stable co-morbid conditions and the short duration and minimally invasive nature of the planned procedure. He received appropriate attention immediately following the procedure in Hospital A and arrangements were made for timely transfer to a tertiary care facility with the resources and experience for managing acutely brain injured patients. The clinical course of this devastating event appears to have been determined at the time of the procedure.

The decedent experienced a hypoxic neurologic injury that was most likely a consequence of an intraoperative hypoxic episode. A cyanotic episode occurred early in the course of the colonoscopy procedure and resolved with the initiation of manual ventilation. The degree of hypoxemia cannot be definitively ascertained as pulse oximetry inadvertently had not been applied at the time sedation was administered. He was reported to be anemic preoperatively although the hemoglobin

level was not identified in the pre-operative documentation available for review. The hemoglobin level measured following the procedure was 83 g/L. It is unclear to what extent, if any, perioperative anemia contributed to his neurologic injury.

The pulse oximeter is a noninvasive monitor that supports the detection and recognition of hypoxemia (oxyhemoglobin saturation). The 2011 Guidelines to the Practice of Anesthesia - revised edition¹, prepared by the Canadian Anesthesiologist Society (CAS) classifies pulse oximetry as a 'required' monitor (i.e., must be in continuous use throughout the administration of all anesthetics) for all patients undergoing procedures under general anesthesia, regional anesthesia or intravenous sedation. While the CAS recommendations are classified as guidelines, they are widely accepted by the profession. It appears from all accounts of the intraoperative events that failure to use pulse oximetry during the procedure was inadvertent.

Although the etiology of the decedent's hypoxemic event was not definitively established, it appeared to have developed within minutes of commencing the administration of sedation. As such, the event was most likely related to ventilatory depression that may accompany the administration of a number of medications used for procedural sedation. The decedent received ketamine, midazolam, propofol and remifentanyl. The latter three drugs have pharmacologic profiles that prominently include ventilatory depression at appropriate doses, particularly in combination. The decedent received propofol and remifentanyl as the primary sedation drugs administered in fixed combination. The anesthetic record and the anesthesiologist's note did not identify the dose administered as a bolus although a bolus of the combination was noted to have been administered. The record suggested that 10 millilitres of solution was administered over approximately 30 minutes during the procedure. This would represent a dose of remifentanyl of 50 micrograms and 50 mg of propofol. It is not clear whether this dose included the bolus. In view of the fact that the decedent was noted to be cyanosed within a few minutes of commencing the procedure and sedation was noted to have been terminated at that point, it is most likely that he received this dose over five-six minutes rather than 30 minutes. Brief ventilatory depression would not be uncommon with remifentanyl / propofol doses in this range, particularly in elderly patients.

No standard approach to the provision of sedation for

colonoscopy / gastroscopy procedures has been established although there is extensive literature on the topic. As a result, the choice of drugs, drug combinations and administration protocols are largely at the discretion of individual practitioners and reflect individual experience and preference, patient demographics, co-morbidities and surgeon-specific preferences and practices. Nevertheless, some features of the choice of sedation technique for this case are felt to merit comment.

1. The addition of remifentanyl to any sedation protocol, while not an uncommon practice, is widely reported to be associated with an increased risk of ventilatory depression and apnea. While this is typically readily managed by an experienced anesthesiologist, it requires a heightened level of vigilance and potential need for intervention.^{2,3}
2. This risk is heightened further when remifentanyl is administered as a bolus prior to establishing a continuous infusion.^{4,5}

The CAS Guidelines to the Practice of Anesthesia explicitly note that, "Mechanical and electronic monitors are, at best, aids to vigilance. Such devices assist the anesthesiologist to ensure the integrity of the vital organs and, in particular, the adequacy of tissue perfusion and oxygenation." Endoscopic procedures are typically busy procedures for the operative team given the fast pace and short duration; achieving adequate sedation and comfort can be challenging.

In this case, the deceased was undergoing two procedures during the 30 minute booking. A standard monitor - the pulse oximeter - was not applied prior to commencing sedation and its absence was not recognized for at least five-six minutes. These circumstances raise the question whether the anesthesiologist's attention was diverted during this time.

It is not clear from the anesthetic record or the anesthesiologist's notes whether ventilation was monitored following the induction of sedation. The anesthesiologist commented that ventilation was assisted with the recognition of cyanosis without determining if spontaneous ventilation was present. While this critical condition appeared to have been managed appropriately when it was recognized, it was not clear that stable spontaneous ventilation was confirmed following the commencement of sedation at the start of the procedure. Capnography, which

would have been available in the operating room, may have provided additional confirmation of the presence of ventilation (supplementing observation).

Sensitive to the benefit of hindsight, the PSRC suggests that the addition of capnography might have been prudent in the context of a multiple drug sedation regimen but recognizes that capnography was not classified as a 'required' monitor for procedures performed under intravenous sedation in the 2011 version of the CAS Guidelines to the Practice of Anesthesia. As such, its use would have been at the discretion of the attending anesthesiologist.

The PSRC notes however, that the 2012 edition of these Guidelines⁶ now lists capnography as a required monitor for procedures performed under deeper levels of intravenous sedation (Ramsay Sedation Scale levels 4-6)⁷ administered by an anesthesiologist. The PSRC was of the impression that the inclusion of capnography in this context was a substantive change from the 2011 document and suggested that the position of the CAS should be disseminated not only to the anesthesia community but also to other groups involved in the administration of procedural sedation.

In summary, it is the view of the PSRC that three key issues appear to have contributed to this tragic sequence of events (and a fourth that may be contributory):

1. The use of a multi-drug sedation protocol that included remifentanyl and propofol, while potentially a legitimate clinical choice, carried the need for heightened vigilance due to the risk of transient ventilatory depression.
2. Inadvertent failure to apply a standard monitor (and recognize its absence) that may have hastened the identification of hypoxemia if it had been used.
3. Questions concerning vigilance and factors that may have diverted the anesthesiologist's attention to the patient's response to the administration of sedation.
4. Reported pre-operative anemia (hemoglobin level not identified in material available for review) that could have compounded the clinical consequence of hypoxemia.

Theme Identified: Clinical Processes/Procedures

Recommendations

To the Chief of Anesthesia, Hospital A:

1. Conduct a thorough review of the circumstances surrounding this patient's death including factors, if any, which may have contributed to a decline in vigilance or diverted the attention of the anesthesiologist during the procedure.

To the Canadian Anesthesiologists Society:

2. The anesthesia community is reminded of changes to the 2012 edition of the CAS Guidelines to the Practice of Anesthesia that includes the use of capnography as a 'required' monitor for patients undergoing procedures under deeper levels of intravenous sedation.
3. To the Canadian Anaesthesiologists Society; Ontario Medical Association Sections on Anaesthesia, Emergency Medicine, Gastroenterology and General Surgery; the Out-of-Hospitals Premises Inspection Committee of the College of Physicians and Surgeons of Ontario; Canadian Association of Gastroenterology Clinics and Ontario Association of Gastroenterology Clinics:
4. Healthcare practitioners who provide procedural sedation and organizations where these procedures are performed should recognize that the current CAS Guidelines for the Practice of Anesthesia require anesthesiologists to use capnography during procedures performed under deeper levels of intravenous sedation.

References

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Case 2012-08

Date of Death: September 19 2011

Age: 73 years

OCC File number: 2011-11766

History

The decedent was a 73-year-old male who presented to Hospital A on August 2, 2011 complaining of worsening lower body weakness and incontinence following a game of golf the previous day. Imaging conducted at Hospital A demonstrated spinal stenosis and possible spinal cord compression at the L3/L4 vertebrae level.

He was transferred that day to the emergency department at Hospital B, a major teaching hospital located approximately one hour away. He was assessed by the neurosurgical service at Hospital B and it was decided that urgent laminectomy was the most appropriate course of action. A laminectomy was performed on August 3, 2011. Dexamethasone therapy was also initiated pre-operatively and continued post-operatively (4 mg intravenously every six hours) throughout his stay at Hospital B (August 2 to August 14, 2011).

Although the decedent's past medical history included hypertension and hyperlipidemia, no history of diabetes was identified at the time of admission. The decedent's post-operative course was largely uneventful, though he regained little function in his legs as a result of the surgery. He was transferred to Hospital C on August 14, 2011 to undergo a rehabilitation program.

Upon arrival at Hospital C, the admitting physician noted the ongoing administration of dexamethasone and indicated in a note that a plan would be made to address how long this should continue. It was noted that the dexamethasone was "presumably started to minimize the risk of further cord compression." In consultation with the neurosurgical service at Hospital B, a tapering schedule for dexamethasone was developed and begun on August 19, 2011 with the plan to end all dexamethasone therapy on September 2, 2011.

On August 21, 2011, the decedent was noted to be polyuric, and nursing staff performed dipstick testing which was positive for glucose. Subsequent measurement of serum glucose showed a serum level of 47.3mmol/L. The patient was sent that evening to the emergency department at Hospital B due to this very high

blood sugar, and also because he was febrile with a temperature of 39.2°C. No clear point of fever origin was identified at the time of transfer.

At the Hospital B emergency department, the decedent was diagnosed with elevated blood sugar secondary to dexamethasone administration (with or without underlying diabetes mellitus) and treatment with insulin was initiated. No clear source of infection was noted, but a urinary tract infection was identified as a possible source and multiple blood and urine cultures were obtained. He was transferred back to Hospital C early in the morning of August 22, 2011 on a sliding-scale insulin dosing regimen. He was subsequently afebrile during his stay in the emergency department and he was not placed on antibiotics at the time of transfer. Of note, the neurosurgical service at Hospital B does not appear to have been informed or consulted during this emergency department visit.

When the decedent was returned to Hospital C he was started on ciprofloxacin, consistent with urine cultures obtained during the emergency department visit on August 21, 2011. There was some reference in the chart to *Klebsiella pneumoniae* also being diagnosed based on blood cultures, and the ciprofloxacin was changed to cefazolin IV.

Over the next few days, he continued to do poorly, with dropping levels of both hemoglobin and platelets, and continued high blood glucose levels. He was transferred back to Hospital B on August 27, 2011 for admission and treatment of his worsening state.

When the decedent was transferred from Hospital C back to Hospital B on August 27, 2011, he was transferred to a medical service, not to the original neurosurgical service that performed his surgery. He was found to be suffering from urosepsis, with *Klebsiella* and *E. coli* growing in his blood, and subsequently levofloxacin therapy was started. *Staphylococcus epidermidis* was also isolated in both his blood and his spinal surgical site drainage, and vancomycin was started to treat this organism.

On September 3, 2011, the decedent was febrile and was assessed by house staff. The laminectomy site was found to be draining a purulent discharge. [Of note, September 3, 2011 was the Saturday of the Labour Day long weekend.] The apparent abscess was drained four days later on September 7, 2011 and a drain was left in place.

Discharge summaries in the chart suggested that at some point, Infectious Disease (ID) recommended treatment be reduced to the single antibiotic, vancomycin. The discharge summary dated September 8, 2011 however, specifically stated that levofloxacin be continued and vancomycin be discontinued. Although the original ID consult that recommended vancomycin and levofloxacin can be located in the chart (dated September 3, 2011), the subsequent consult recommending the discontinuation of levofloxacin only, could not be located. A note does appear in the "Patient Care Orders" section of the chart on September 9, 2011 stating that "ID suggests D/C vancomycin, levofloxacin 750mg po daily x 12 weeks" which appears to be the point at which vancomycin was discontinued. The duration of the antibiotic therapy contemplated would suggest that the intent of this was for treatment of the surgical site infection. Given this, the order as written would appear to be the opposite of what should have been ordered according to the cultured microbial sensitivities of the Staphylococcus epidermidis isolated from the wound drainage. A spinal abscess fluid sample ordered/collected on September 7, 2011 and reported on September 12, 2011, showed Staphylococcus epidermidis that was vancomycin-sensitive, suggesting that the recommendation to discontinue vancomycin was not correct or appropriate, and that therapy should have been restarted. Progress notes on September 10, 2011 indicated that the decedent was awaiting transfer to Hospital A. It should be noted that September 10 and 11, 2011 were a Saturday and Sunday.

The decedent was transferred to Hospital A on September 13, 2011. Upon arrival, levofloxacin was continued as per the discharge orders from Hospital B. There was a thorough note by the on-call resident (dated September 13, 2011, at 2354 hours) that detailed the decedent's history, treatment and plan. This note was clear in that the infection, and more specifically, the Staphylococcus epidermidis, was sensitive to levofloxacin, and the vancomycin was intentionally discontinued at this time. There was also a note on the following day (September 14, 2011) that the attending physician reiterated the medical history, including a note to clarify antibiotic dose and duration with Hospital B.

It is also significant that the decedent's renal function apparently declined between September 6 and September 13, 2011. This information was not likely available to the receiving physician at Hospital A.

The decedent continued to do poorly and on September 15, 2011, was started on metronidazole to treat a Clostridium

difficile infection. It appears that this is the point in time that the attending physicians realized the erroneous cessation of vancomycin during the previous week at Hospital B. This was verified by communication with ID at Hospital B. Radiologic examination at this time demonstrated a large abscess and osteomyelitis at the site of the original surgery.

On September 17, 2011, the decedent was doing so poorly that a consultation was made for consideration of transferring him to the ICU. A CT scan of his abdomen was ordered, and showed an infectious pancolitis, small and large bowel ascites, and a large paraspinal abscess. He was transferred to the ICU and despite aggressive treatment, he deteriorated significantly and developed worsening pulmonary edema.

On September 19, 2011, after consultation with the decedent and his family, aggressive interventions were abandoned and the patient died that evening.

The family and investigating coroner identified several significant concerns about the quality of care received.

Post mortem

At autopsy, it was found that, "the cause of death was Clostridium difficile colitis which was probably secondary to the prior antibiotic therapy. The colon showed a pancolitis with thick pseudomembrane formations consistent with a pseudomembranous colitis due to Clostridium difficile. A section of the lumbar spine in the region of the prior back surgery showed features suggestive of chronic osteomyelitis."

Cause of death:

- 1a) Clostridium difficile colitis, due to
- 1b) Prior antibiotic therapy

Discussion

There were a number of significant concerns arising from this review of the decedent's medical record. The care received by the decedent was no doubt complicated by the fragmented nature of his care – treatment at three different hospitals, admission under two separate services at one hospital, and challenges in communication and information transfer between institutions.

There were also concerns about specific medication decisions,

erroneous cessation of required medications, and the timeliness of interventions performed. A number of these specific concerns are detailed below:

1. The use of high dose and prolonged steroids.

While there is some debate regarding the efficacy of steroid use in spinal cord injury, a recent Cochrane review (2009) supports the use of steroids administration in general for spinal trauma. However, evidence for this recommendation is scant and the risks are not insignificant. The specific evidence-based recommendations from the 2009 review indicate:

High-dose methylprednisolone steroid therapy is the only pharmacologic therapy shown to have efficacy in a phase three randomized trial when administered within eight hours of injury. One trial indicates additional benefit by extending the maintenance dose from 24 to 48 hours, if start of treatment must be delayed to between three and eight hours after injury. There is an urgent need for more randomized trials of pharmacologic therapy for acute spinal cord injury.

(Source: Cochrane review, Steroids for acute spinal cord injury (Review), Bracken MB, 2009)

In this decedent, dexamethasone was prescribed. Dosing was continued post-surgery (6mg, four times daily), and was continued at this dose throughout his 13-day stay at Hospital B (as opposed to 24-48 hours). Tapering of this dose began after the decedent was transferred to Hospital C (tapering began on August 19, 2011 – four days after transfer). The tapering was finished and the medication was fully discontinued on September 1, 2011.

High dose dexamethasone therapy almost certainly contributed to the hyperglycemia and suppression of the decedent's immune response during this period. There is no discussion found in the hospital record explaining the decision to continue this medication for the duration of this period, assuming such dosing schedule was intended. There is the possibility that this was ordered post-operatively as an ongoing medication without a plan to discontinue. It would have been reasonable to revisit, comment upon or monitor the use of this medication on daily patient rounds; however,

no evidence of this is indicated in the patient record.

2. Issues related to high blood sugar and possible latent diabetes mellitus.

The decedent may have had impaired glucose tolerance prior to admission. There is a note that initial blood work at Hospital A showed an elevated blood glucose ("Serum random blood sugar at the time of original admission of 15.5"), though two subsequent arterial samples taken early in the admission to Hospital B showed high-normal levels (August 2, 2011: 9.8 mmol/L (3.5-10.0); August 3, 2011: 9.5 mmol/L (3.5-10.0)). There was no clear evidence identified that the decedent's blood sugars were assessed during his initial 13 day stay at Hospital B. In particular, given the prolonged treatment with dexamethasone, periodic blood sugar assessment would have been prudent.

3. Lack of neurosurgical consultation during emergency department visit at Hospital B.

There was some concern about the lack of review or consultation with the originating neurosurgical service at the time of the decedent's brief return to Hospital B on August 21-22, 2011.

In reviewing the case file, it is not possible to appreciate the workload in the emergency department, the availability of beds at Hospital B, or the culture surrounding consultations between the emergency department and the various services - all of which may have been factors that night.

Regardless, the return of the decedent to the originating hospital within a week of being transferred to a rehabilitation hospital is an occurrence of which the initial referring service should likely have been made aware. There was no evidence that the neurosurgical service was consulted or otherwise knew that their patient was in the emergency department that night, with evidence of sepsis and polyuria. Particularly, given that this decedent's issues were likely caused by treatments prescribed by that service, and the potential for significant complications associated with those issues, it would seem reasonable to involve them in, or at least inform them of, the treatment plan at such a time.

4. Cessation of medication.

The cessation of the incorrect antibiotic (vancomycin) on September 9, 2011 was identified as a concern. It is unclear from the record if ID made the wrong recommendation, or if the recommendation was made correctly, but was incorrectly understood by the receiving physician. It is possible that the resident on call who made the brief note inadvertently transposed the antibiotic recommendations. It is unclear if the communication of these recommendations was that of a face-to-face discussion, a phone discussion, or some other means of communication. Regardless, the resulting course of incorrect antibiotic therapy impacted the patient's outcome. This error was continued on transfer back to Hospital A the following week. There was not enough information in the chart to analyze and identify the nature of this failure, but there is little doubt that this error contributed to the demise of the patient. On September 12, 2011, final culture sensitivities confirmed that vancomycin would have been the effective treatment, but no notes reflecting this appear on the chart.

5. Delays in assessment.

The apparent delay between identifying the purulent drainage from the surgical site on September 3, 2011 and the percutaneous drainage of the underlying abscess on September 7, 2011 is concerning. There was a progress note dated September 6, 2011 to consult interventional radiology to drain the abscess, but it is unclear why this did not occur earlier. It may be significant that September 3-5, 2011 fell on the Labour Day long weekend.

6. Identification of *Clostridium difficile*.

There seems to have been little consideration given to the possibility of *Clostridium difficile* infection in this decedent prior to September 17, 2011, despite many days of treatment with a number of powerful antibiotics.

7. Assessment of renal function.

There appears to have been little appreciation of the changing renal function from September 7-14, 2011. No clear measures of renal function were obtained during this time period and there were no adjustments in the dosages

of diuretic (hydrochlorothiazide) and angiotensin receptor blocker (ibersartan) made when the decedent's creatinine was noted to have risen to 131 on September 14, 2011 (which was a significant rise over previous values). This likely contributed to a period of hypotension that was noted on September 15, 2011, at which time the decedent's creatinine was found to have risen to 200.

8. Documentation regarding supervision of residents.

It is unclear whether the supervision provided to the neurosurgical resident was adequate and appropriate. Due to illegibility of the chart notes and signatures, it was not possible to determine whether, or to what degree, the staff surgeon was actively engaged in the decedent's care. This made it challenging to determine the root cause of some of the issues which arose in this case.

Themes Identified: Clinical Processes/Procedures; Medications/ IV Fluids; Healthcare Associated Infections

Recommendations

To Hospital B:

1. The Division of Neurosurgery, including the original neurosurgeon and house staff involved in this case, review the most current recommendations regarding high dose steroid use in spinal injury, including drug selection, dosage, and duration as well as the risks and complications of high dose steroids, including their effects on blood sugar and immune function. Consideration should be given to the development of appropriate protocols to guide the use of steroids in spinal cord injury, including periodic review of ongoing treatment orders, and monitoring for and management of side effects of this therapy.
2. A review of the infectious disease consultation and treatment recommendation process at Hospital B should be conducted. This may include consideration of Infectious Disease (ID) participation in multidisciplinary patient rounds, or the development of mechanisms to ensure that recommendations are understood and followed through a closed loop or chart-review process.

3. Consideration be given to automatic consultation of discharging surgical and medical services when a recently discharged patient presents to the Emergency Department.
4. Documentation should clearly reflect the degree of supervision provided to residents and medical students by staff physicians.

To the Regional Supervising Coroner and Hospitals A, B and C:

5. Given that there were multiple points of failure throughout the care of this individual, it is recommended that a Regional Coroner's Review, involving all three hospitals, be conducted

with a view to identifying failures in the provision of best care to this individual. It is strongly recommended that external parties, including the family of the decedent, be engaged to inform this process. Areas of particular focus for such a review should include:

- Medication reconciliation processes at points of transition of care.
- Processes to ensure that *C. difficile* infection is considered in any deteriorating patient receiving prolonged antibiotic therapy
- Mitigation of the risks associated with management of acute conditions and issues over weekends and holidays.

Case 2012-09

Date of Death: August 9, 2012

Age: 60 years

OCC File number: Yukon Case

History

The decedent was a 60-year-old woman with a history of chronic alcohol misuse, hypothyroidism, back/hip pain from a previous motor vehicle collision, and arthritis.

The woman attended at a medical clinic in a small (approximate population: 1500) community in the Yukon Territory on August 3, 2012. She presented with symptoms of nausea, vomiting, and severe dehydration. Her last bowel movement was noted to be three to four days previously, and she had intermittent lower abdominal pain.

She was transferred by ambulance from the clinic to Hospital A (a six-bed hospital in the same community) on the same day and was admitted to the hospital. It was noted on her admission that she was "extremely dehydrated and had severe diarrhea and vomiting."

Notes from Hospital A included a very brief admitting history and physical exam by the most responsible physician. There were no progress notes by the most responsible physician in the chart. There appeared to be a paucity of investigations and no documentation of response to concerns raised by the nursing staff.

During the six days as an inpatient at Hospital A, it would appear that the decedent never became stable. At no time were vital signs found to be normal. The decedent continued to complain of abdominal pain, nausea and vomiting despite attempted interventions.

No radiological examinations were performed until August 6, 2012, three days after they were ordered. Those X-rays revealed small bilateral pleural effusions as well as multiple loops of moderately dilated small bowel. It was thought these were related to bowel obstruction or ileus. A repeat chest X-ray was ordered on August 8, 2012 and it showed persistent small bowel dilation.

The decedent's condition in hospital had deteriorated with grossly unstable vital signs and deteriorating mental status. Oxygen saturation was difficult to maintain. Arrangements were made for the decedent to be transferred to Hospital B (a regional hospital) by plane. Interventions at the time of transport were appropriate with intubation, ventilation, and good vascular access.

Upon arrival at Hospital B, the decedent was noted to be in severe shock with multi-organ failure. A CT scan confirmed the diagnosis of small bowel obstruction. Despite appropriate intervention, the decedent succumbed to the severe shock and was declared dead on August 9, 2012. The diagnosis at the time of death was hypovolemic shock secondary to dehydration from small bowel obstruction.

Post mortem

Post mortem examination was not conducted.

Discussion

The decedent was admitted to Hospital A and it would appear that the presumptive diagnosis was alcohol withdrawal. The notes suggested that delirium tremens was also entertained as a diagnosis. The differential diagnosis did include small bowel obstruction; however, X-rays were not done for three days. The diagnosis was "alcoholism" despite the abnormal vital signs, and the decedent's persistent complaint of lower abdominal pain which was associated with nausea, vomiting, apparent melena, and vomitus which smelled of stool. Although initial hydration resulted in slight improvement, normal vital signs were never achieved nor did the decedent become asymptomatic. The decedent's condition steadily deteriorated during the time in hospital and it would appear that her abdominal pain was not investigated with blood work or X-rays until the third day after admission. Even then, the finding of dilated loops of small bowel did not result in any further investigation or intervention.

There was a lack of documentation by the attending doctor with only a superficial history and physical exam and no daily progress notes. Review of the nurse's notes suggested that the doctor did attend from time to time, or that the nurses did notify the doctor, but the physician response to these concerns is quite unclear.

The only blood work was from August 8 - approximately 11 hours before death. There was evidence of pre-renal failure with a BUN of 14.6, creatinine of 316 and severe electrolyte disturbance with a potassium of 2.1. By August 8, 2012 the decedent was clearly in severe shock. She was appropriately prepared for transport and effectively transferred to Hospital B where care was appropriate and decisive. A CT scan confirmed the small bowel obstruction and blood gases confirmed that the patient was in severe metabolic acidosis and renal failure.

Following discussion with the family, comfort measures were instituted and the decedent died on August 9, 2012.

Themes Identified: Clinical Administration; Clinical Processes/ Procedures

Recommendations

To the Yukon Hospital Association:

1. Peer assessment of the care provided and documentation by the most responsible physician at Hospital A should be considered.

Committee comments:

It would appear that a misdiagnosis of alcohol withdrawal/delirium tremens was made. However, assessment of the physician's decision-making was not clear because of the lack

of documentation. Steps should be taken to address why the documentation was incomplete and, as appropriate, to provide the physician with peer feedback with respect to the care provided in this case.

The Committee understands that there is no process for physician peer assessment through the Yukon Medical Council. This recommendation is therefore directed to the Yukon Hospital Association, which the Committee understands is the body responsible for granting hospital privileges to physicians in the Yukon.

To Hospital A:

2. A review should be conducted of the policies and procedures for transfer of patients from Hospital A to regional / tertiary care centres (including, but not limited to, Hospital B). This review should include the indications for transfer (including the need for timely investigations not available at Hospital A).

Committee's comments:

It was not clear why radiologic investigations in this case took three days to complete. If radiology was truly not available at Hospital A, consideration should have been given to urgent transfer of this acutely ill patient to a regional or tertiary care centre so that appropriate investigations could be completed in a timely way to guide further treatment.

Case 2012-10

Review ongoing at time of report; to be completed in 2013.

Case 2012-11

Date of Death: February 16, 2012

Age: 47 years

OCC File number: 2012-1853

History

The decedent was a 47-year-old male with three significant illnesses: schizophrenia, panic disorder and Type 2 diabetes mellitus (T2DM). After an incident that resulted in criminal charges and subsequent institutionalization in 2007, his schizophrenia was treated with olanzepine. The T2DM was diagnosed in January 2009 and treated with metformin 500 mg (twice to three times daily) and glyburide 2.5 mg (twice daily) over time.

In November 2009, the decedent lived in a supportive housing-type environment with daily dispensing and monitoring of medications. In November–December 2009, he was re-admitted to hospital with panic disorder; clonazepam was started and the olanzepine was switched to risperidone.

During this admission, the decedent continued on his diabetes medications and received further monitoring and therapy for T2DM and its complications. This included:

- Education (he saw a dietitian November 2009, and attended diabetes education in January 2010);
- Monitoring for glycemic control –(this showed suboptimal control with hemoglobin A1C 7.6% (ideal < 7%) on December 3, 2009);
- Screening for complications (he had undetectable urinary microalbumin levels and eyes screened in February 2010);
- Treatment of additional cardiovascular risk factors (he was started on rosuvastatin in December 2009 for hypercholesterolemia).

Reports from December 2009 indicate that the decedent blamed the symptoms of his panic attacks (i.e. abnormal pacing, panic, fear that he was having a heart attack) on his diabetes medications.

He was readmitted to hospital from May 11 - June 28, 2010 with worsening psychosis. His risperidone was switched to clozapine and he was taking metformin and glyburide with well-

controlled DM (A1C 6.8%). An elevated insulin level confirmed the diagnosis was Type 2 DM and not Type 1 DM.

After discharge from hospital in late June 2010, the decedent was again living in the community and was seen two to three times weekly by the nurse or social worker. On September 27, 2010 he is noted to have been assessed by a psychiatry resident.

Glycemic control deteriorated dramatically by November 22, 2010 when the decedent's general practitioner noted that his A1C was now 14.3% and plasma glucose was 32 (normal random < 11 mMol/L). Electrolytes and anion gap were not mentioned. At the time, the decedent indicated that he had stopped taking the diabetes medications because he was following a better diet at home (and said that he hadn't stopped them for that long). His weight had decreased to 75 kg.

Subsequent nurse and physician notes indicated that the decedent would not allow monitoring of his diabetes laboratory values or take diabetes medication despite many warnings and offers of assistance. These notes indicated:

- January 25, 2011 - invited to attend diabetes education.
- February 24, 2011- refused to do fasting glucose.
- May 2, 2011 - stopped clonazepam on his own as the panic attacks were much better - doctor (psychiatry) reduced hospital visits to three times a week - acknowledged that he was not having sugar testing and had not seen his family doctor for over six months.
- The decedent had no panic attacks since 2010 when he went off diabetes medications. He indicated that, 'he hasn't had BG [blood glucose] testing or seen GP in greater than six months.' Said he is aware DM can affect multiple organs with potentially severe consequences (including death) and indicated 'I'm willing to take that risk' because he feels OK now, and noted his father had also told him that he could die if he didn't take his diabetes medication. He appears to be most worried about the medications causing panic attacks.
- Last blood work noted was a random glucose in June 2011 that indicated a level of 32 mMol/L; (date written in notes, this may have been an earlier sample).

- October 11, 2011 - February 3, 2012 - the psychiatry resident saw the decedent seven times in this period and each time, the resident documented that the decedent was refusing to take diabetes medications, to have blood testing and/or to see his general practitioner about his very poor glycemic control. The resident used psycho-education with the hope that it would change the decedent's mind about allowing treatment of the diabetes. The decedent stated that he had stopped following his diabetes diet and was eating unhealthy food.
- February 13, 2012 - Did not show up for his medication check-up and was subsequently found deceased in his rooming house February 16, 2012 after healthcare workers called the home concerned about the man's absence a few days earlier. One of the other residents in the house indicated that on the evening of February 15, the decedent had joked about consuming pop, despite his diabetes.

Post mortem

Post mortem examination revealed classic findings of diabetic ketoacidosis (DKA). There was also terminal esophageal hemorrhage secondary to Mallory-Weiss tears.

Discussion

The decedent had multiple risk factors for T2DM including a strong family history of T2DM, schizophrenia, and use of atypical anti-psychotic agents. He was modestly overweight at the time of his diagnosis (i.e. maximum BMI 26 in the record, normal being 20-25). The decedent refused diabetes therapy and had poorly controlled diabetes in the year preceding his death despite ongoing warnings and encouragement from his physicians. It is not clear from the records whether or not the decedent was specifically offered insulin therapy as opposed to oral hypoglycemic agents. However, the decedent was aware of the use of insulin for the treatment of some patients with diabetes, as his sibling was being treated with insulin. Further, there are numerous references in the medical records to the decedent refusing "all DM medications."

The decedent ultimately died from acute DKA. DKA typically occurs in patients with T1DM who both lack insulin and have a precipitating factor, usually another acute illness. Atypical antipsychotics have been associated with DKA in patients with

T2DM. In this case however, the decedent had already been on an antipsychotic for three years. His glycemic control deteriorated with the switch to clozapine, in addition to stopping his diabetes medications.

It is not clear what precipitated the decedent's DKA, or how he died from it. There was no opportunity for physicians to intervene to treat the DKA and acute event as there was no warning that an acute event was imminent, and when did occur, it appears to have been rapid.

Although neither the expert reviewer or the Committee found the care in this case to be lacking, it was felt that this death represented an opportunity to educate care providers of the need to consider DKA, even in patients with T2DM, especially in those receiving atypical antipsychotic agents.

Theme Identified: Medications/IV Fluids

Recommendations

To College of Physicians and Surgeons, Ontario College of Family Physicians, Ontario Psychiatric Association, Canadian Mental Health Association, Canadian Association of Emergency Physicians:

1. Physicians are reminded that in patients with schizophrenia, particularly those on atypical antipsychotics, it is important to:
 - Screen for, and diagnose diabetes mellitus.
 - Treat the diabetes with oral agents +/- insulin to achieve adequate glycemic control, and monitor and treat complications and other cardiovascular risk factors.
 - Discuss and document ongoing conversations with patients who are competent and who refuse monitoring and/or therapy.
 - Have a low threshold to involve an Endocrinologist in the care of diabetic patients with severe mental health disorders.
2. Physicians should be aware that atypical antipsychotics have been associated with diabetic ketoacidosis. This typically occurs early in therapy with the anti-psychotic agent.¹

3. Patients who have very poor glycemic control should be assessed for ketoacidosis even if they have T2DM. While this is most relevant to those patients receiving an atypical antipsychotic, it should be a consideration for any patient with T2DM who appears unwell, especially in the setting of high capillary blood glucose readings.

References

1. Nihalani ND et al Diabetic ketoacidosis among patients receiving clozapine: a case series and review of socio-demographic risk factors. Ann Clin Psychiatry 2007; 19(2): 105-12.

Special Review of Ornge Air Ambulance Transport Related Deaths

NB: While this review was released in July, 2013, the results are included in the 2012 PSRC Annual Report to facilitate timely dissemination of the findings and recommendations. The full report may be accessed online at:

http://www.mcscs.jus.gov.on.ca/english/DeathInvestigations/office_coroner/PublicationsandReports/OrngeReview/Ornge_Air_Review.html

Background

In late 2011, concerns began to arise regarding Ornge (Ontario's provincial air ambulance service provider) and, in particular, its management and oversight. In addition to allegations of fiscal mismanagement, questions were raised by politicians and members of the public as to whether the issues at Ornge were affecting care provided to patients.

Around the same time, the Ministry of Health and Long-Term Care Emergency Health Services (EHS) Branch notified the Office of the Chief Coroner of a number of cases in which a death had occurred during or after air ambulance transport, and in which there were concerns that operational issues (such as delays in launch, or configuration of the cabin of the aircraft) may have had a negative impact on the care provided.

Ornge became the subject of greater public scrutiny after the release of the Auditor General's Report in March, 2012. Subsequently, a legislative review committee was struck and a criminal investigation by the Ontario Provincial Police into financial concerns at Ornge was announced.

The Office of the Chief Coroner issued a news release in June, 2012, stating that it had commenced investigations into approximately 10 deaths identified by EHS Branch where air ambulance services had been considered of potential relevance. Preliminary conclusions at that time revealed that the air transport service performance had not materially affected the outcome in any of the cases for which our investigation was complete.

Following this, concerns regarding the role of Ornge in a number of additional deaths were brought to the attention of the Office of the Chief Coroner. In response to these private and public concerns, the decision to conduct a more comprehensive review was announced on August 15, 2012. The review was initiated by the Chair of the Patient Safety Review Committee (PSRC).

Investigation

The review examined deaths in Ontario involving air ambulance transport from January 1, 2006 to December 21, 2012 to systematically identify and review all known cases in which operational issues related to the air ambulance transport may have caused or contributed to the death.

An Expert Panel was formed under the auspices of the PSRC. The PSRC provided input to the Expert Panel throughout the process, including the findings and recommendations.

After screening hundreds of cases in which a death occurred following a request for air ambulance transport, the Expert Panel identified 40 cases which met the criteria for this review. A full review of these cases was conducted independently by each member of the Expert Panel. For each case, the panel members were asked to provide their opinions on two separate questions:

- To what degree did the identified operational issue(s) impact the outcome of the case (No Impact; Possible Impact; Probable Impact; or Definite Impact)?
- Notwithstanding whether the operational issue(s) in the case impacted the outcome, are there recommendations that arise from the case which might improve care and prevent deaths in similar circumstances in the future?

Of the 40 cases reviewed, the Expert Panel concluded that in 32 cases there was No Impact on the outcome. In five cases there was a Possible Impact; in one case there was Probable Impact; and in two cases there was a Definite Impact on outcome.

The Expert Panel identified eight themes into which the operational issues were categorized, each of which gave rise to one or more recommendations:

- Decision-Making (five recommendations)
- Response Process (five recommendations)
- International Transports (one recommendation)
- Communications (four recommendations)
- Aircraft/Equipment (five recommendations)
- Staffing (one recommendation)
- Paramedic Training/Education/Certification (one recommendation)
- Investigation/Quality Assurance (three recommendations)

In all, the Expert Panel made 25 recommendations directed to Ornge and/or the Ministry of Health and Long-Term Care. These recommendations, along with the rationale for each, are reproduced below.

Recommendations – Decision-Making

To Ornge:

1. Decision-making around mode of transport (air versus land) for inter-facility transfers should be coordinated between the Ornge Transport Medicine Physician, Ornge operations staff, and, where possible, the sending and receiving physician(s). This should include a consideration of the various options available, including the expected transfer times via each route.

Rationale: When a sending facility makes a request for air ambulance transport, there is no formal process to review the circumstances and determine if air is, in fact, the most appropriate option. In some situations, land transport may be quicker than air.

2. Decision-making by Transport Medicine Physicians should primarily focus on three areas: (i) the medical urgency of the call; (ii) the level of paramedic care required for the patient, and; (iii) the triaging of two or more calls of equal priority within a given response area. Transport Medicine Physicians should not make operational decisions, such as which aircraft is assigned to a call or when the aircraft is to launch.

Rationale: In some cases, the Transport Medicine Physicians strayed outside their area of expertise, and were making decisions of an operational nature. Such decisions should

be made by staff in the Ornge Communications Centre who have the appropriate knowledge and expertise, and greater awareness of competing call priorities and pressures.

3. Decision-making with respect to assigning fixed-wing versus rotary-wing aircraft to a call should be based on patient-related factors (such as level of paramedic staffing and transport time), and not on relative cost of one mode versus the other at the expense of the timely provision of best possible care.

Rationale: In at least one case, the relative cost of transport between fixed and rotary-wing was factored into the decision-making process. This ultimately resulted in a delayed response and a possible impact on outcome.

4. If, in the course of a transport, it appears that an unanticipated delay will occur (due to weather or mechanical issues), the Transport Medicine Physician should be consulted so that a decision can be made whether or not to proceed with air versus land transport. Whenever possible, decision-making in such situations should involve input from the sending and receiving physicians.

Rationale: Significant delays sometimes occur after the call is triaged and the sending facility is provided with an estimated time of arrival of the air ambulance. In some cases, the Transport Medicine Physician and/or the sending physician and/or receiving physician were not made aware of the delay. This prevented informed decision-making and reconsideration as to the best option to ensure timely and appropriate transport of the patient.

5. Ornge should re-examine its staffing and communications procedures in the Ornge Communications Centre. Specifically, all reasonable efforts should be made to minimize hand-offs of a given call between call-takers and other Ornge Communications Centre staff, and to ensure that all Ornge Communications Centre staff maintain situational awareness of calls in progress, assets available, and other critical operational information.

Rationale: In several cases, it was apparent that decision-making was hampered by a lack of complete awareness on

the part of the call-taker about both the call details and the options available for response. This problem was compounded when multiple calls were in progress simultaneously, and when multiple persons within the Ornge Communication Centre were managing the call.

Recommendations – Response Processes

To Ornge:

6. Responses to remote nursing stations should be treated as scene calls, and not inter-facility transfers, in terms of their prioritization and level of paramedic care assigned.

Rationale: Nursing stations in remote northern communities are not staffed or equipped like community hospitals, and therefore the response needs to proceed as quickly as possible using the most immediately available paramedics, irrespective of whether they have Advanced or Critical Care certifications. This will avoid unnecessary delays in response.

7. When a request for a potential scene response is received, the nearest available rotary-wing aircraft should be pre-alerted. The pilots and paramedics should immediately perform any necessary preparation, and the helicopter should be readied and “rotored up” while awaiting confirmation.

Rationale: In several cases in which a potential air ambulance scene response was contemplated, a significant delay in departure occurred. Preparation of the aircraft for departure did not begin until several minutes after a land paramedic crew had arrived at the scene and the need for an air scene response was confirmed.

8. Once a request for a scene response is received, the helicopter should be airborne within ten minutes of the request unless this is precluded by extenuating circumstances. In such cases, the launch should proceed as soon as possible after the ten minute target.

Rationale: The panel's understanding of the current protocol is that, when a request for a scene response is received, the crew is to prepare for launch. If a land paramedic crew is expected to be on scene within ten minutes, the launch is deferred until

confirmation is received from the land crew. However, in some of the cases reviewed, when the land paramedics arrived on scene, their priority was (appropriately) the care of those injured, and there was an additional delay before confirmation was received from the land paramedics and the launch was authorized. In order to avoid this delay, once a scene response is requested, the launch should occur within ten minutes whenever possible, unless specific information is received from the scene to indicate that the air ambulance response is not required.

9. In modified scene responses, transfer of care to the air paramedic crew and departure of the air ambulance from the hospital should occur without delay.

Rationale: Modified scene responses occur when a land paramedic crew transports an ill or injured patient from the scene of the incident to the nearest hospital where they are met by the air ambulance paramedics. In some of these cases, a lack of understanding of how care should proceed resulted in delays in departure from the local hospital while additional medical investigations and interventions were performed. This runs contrary to the intent of the modified scene response, that being to ensure timely transport to a definitive care centre such as a Trauma Lead Hospital. Paramedics and Transport Medicine Physicians are sometimes inconsistent in their approach to such situations. This has led to delays in transport to definitive care.

10. Ornge should review their current policy and procedures with respect to responding to calls for patients who are vital signs absent at the scene with ongoing cardiopulmonary resuscitation. Such patients rarely, if ever, benefit from air ambulance transport, and such responses divert air ambulance and paramedic resources away from other patients with potentially survivable illness or injuries.

Rationale: The panel reviewed cases in which an air ambulance response was initiated and/or continued when the patient was vital signs absent with ongoing cardiopulmonary resuscitation. When there is no response to initial resuscitation efforts by land paramedics, the survival rate for such patients is unfortunately essentially zero. Despite this, in some cases air ambulances were dispatched, and air paramedics were advised to continue cardiopulmonary resuscitation until arrival at the receiving

hospital. This resulted in the air ambulance and paramedic crew being unavailable to respond to other calls where they may have had a positive impact on outcome.

the documentation is often confusing and difficult to analyze. Reference to the time zone in question, or alternatively, documenting all times with reference to the Eastern time zone, would resolve this issue.

Recommendation – International Transports

To Ornge and Ministry of Health and Long-Term Care:

11. Ornge and the Ministry of Health and Long-Term Care should work with the Canada Border Services Agency and United States Customs and Border Protection to ensure that delays do not occur when patients are transported across the border for emergency medical care.

Rationale: In at least one case, a transport was delayed in order to obtain the necessary travel documents for a patient who required emergency transport to a facility in the United States. There needs to be clear and universally understood and accepted processes to allow such transports to proceed without delay, even in the absence of the usual documents.

Recommendations – Communication

To Ornge:

12. Ornge should review and upgrade its communications technology with a view to preventing loss of communication between paramedics and the Transport Medicine Physician.

Rationale: In a number of cases, there was a loss of communication between paramedics and the Transport Medicine Physician because of a failure of the satellite telephone technology. This resulted in paramedics being unable to obtain direction from the Transport Medicine Physician in a timely fashion.

13. For calls involving more than one time zone, times referenced in communication and documentation should clearly identify the time zone in which the event is taking place.

Rationale: While most of Ontario falls within the Eastern time zone, north-western Ontario and Manitoba are in the Central time zone. During the review, it was noted that with calls which involve transport from one time zone to another,

To the Ministry of Health and Long-Term Care:

14. Greater integration and linkages are required between CitiCall and the Ornge Communication Centre in order to provide sending facilities/physicians with simpler and more seamless access to both critical care resources and air transport.

Rationale: The Patient Safety Review Committee noted that the current system is confusing, fragmented and siloed, and requires the sending facility/physician to first access a receiving hospital via CitiCall, and then separately access air ambulance transport for the patient, all the while attempting to provide care to the patient. It should be possible to have one point of contact to access all necessary resources to facilitate the transfer of a critically-ill or injured patient.

15. The Ministry of Health and Long-Term Care should develop an education program and materials to support a simplified process for sending facilities/physicians to access critical care resources and air ambulance transport. Both the process and the materials should be easy to understand, even by an inexperienced care provider in a remote location.

Rationale: The Patient Safety Review Committee expressed concern that the current system has a steep "learning curve" for care providers in order to understand the various processes for accessing critical care resources and air ambulance transportation. As a simplified, integrated process is developed, educational materials to support sending facilities/physicians in accessing these resources more easily should be developed.

Recommendations – Aircraft / Equipment

To Ornge:

16. All air ambulance cabins must permit paramedics to perform critical resuscitation activities (including cardiopulmonary resuscitation, and care delivery with the patient in the head-up position) without interruption in all phases of flight.

Rationale: In several cases, concerns were identified by paramedic crews about their inability to perform cardiopulmonary resuscitation in the new AW139 helicopters during taxiing, take-off and landing. Due to the design of the cabin, the stretcher must be turned 90 degrees (from a position parallel to the long axis of the helicopter, to a perpendicular position) in order to lower the stretcher for cardiopulmonary resuscitation or to fully elevate the head of the stretcher. Transport Canada requires that the stretcher be secured in the long axis position for taxiing, take-off and landing. This means that these activities would have to cease for several minutes during these phases of flight.

17. The current mechanism for securing the stretcher in the AW139 aircraft should be reviewed to ensure that incidents of the stretcher becoming “jammed” are avoided.

Rationale: In one case, a delay of several minutes occurred when the stretcher became jammed while the patient was being removed from the helicopter.

18. A review of oxygen equipment should be conducted on all aircraft used as air ambulances in Ontario. This should be done to ensure that excessive oxygen flow rates cannot inadvertently be selected, resulting in premature depletion of the oxygen supply onboard the aircraft. If high flow rates (i.e., 25 L/min) are not medically necessary, they should be disabled. If they are required, processes should be implemented (such as engineering designs, checklists, warning labels, etc.) to decrease the likelihood that such rates will be selected in error. Notwithstanding these preventative measures, the possibility of a warning system should be explored in order to alert care providers before the patient oxygen supply reaches a critical level.

Rationale: In one case, the oxygen supply onboard the aircraft was depleted due to the inadvertent setting of the oxygen flow rate at 25 L/min instead of the intended 15 L/min. This resulted in the patient becoming hypoxic and suffering a fatal cardiac arrest.

19. Ornge should ensure that all equipment used by air paramedics is compatible with all aircraft used for air ambulance transports (both aircraft operated by Ornge and charter aircraft).

Rationale: In two cases, there was incompatibility between paramedic equipment (such as transport ventilators) and equipment on charter aircraft that are used on an occasional basis by Ornge. In one such case, this required the paramedics to manually ventilate an intubated patient throughout a long transport, potentially compromising the effective ventilation of the patient and hindering their ability to perform other patient care activities.

To the Ministry of Health and Long-Term Care:

20. The Ministry of Health and Long-Term Care should amend provincial ambulance equipment standards to mandate the minimum standards for equipment available on fixed-wing aircraft used for patient transport. This should include standards regarding the minimum supply of oxygen available for use in patient care.

Rationale: The reviewers learned that provincial ambulance equipment standards currently exist for rotary-wing, but not for fixed-wing aircraft.

Recommendation – Staffing

To Ornge:

21. Ornge should review its policies, procedures and practices with respect to paramedic staffing, with a particular focus on preventing down-staffing of air ambulance units when paramedics exceed their hours of work (“duty day”) on the previous shift.

Rationale: The current collective agreement with Ornge paramedics delineates maximum duty hours, and the minimum number of hours between shifts when paramedics exceed their usual shift duration. In a number of cases, air ambulances were either unstaffed or partially staffed for the first hours of the next scheduled shift, in order to allow for the minimum number of hours off between shifts. In other cases, paramedics who called in sick or who requested bereavement leave were not replaced. This resulted in air ambulances being unavailable to respond until full staffing was achieved. Greater efforts need to be made to ensure that, whenever possible, every shift is fully staffed for its entire duration with two paramedics.

Recommendation – Paramedic Education / Training / Certification

To Ornge:

22. Ornge should undertake a comprehensive review of the education, certification, and ongoing training of paramedics in advanced airway management, including management of the paediatric airway, with a view to ensuring that the highest standards are met and maintained.

Rationale: In a number of cases reviewed, issues or concerns were identified with respect to advanced airway management by paramedics (such as management of the difficult airway, and use of paralytic and sedative medications to facilitate intubation and/or safe transport). The way in which air paramedics are trained and certified, and the maintenance of their skills and knowledge, should be reviewed with the aim of ensuring the highest quality of airway management.

Recommendations – Investigation / Quality Assurance

To Ornge:

23. All discussions and conversations related to air ambulance response should be audiotaped for the purposes of quality assurance, improvement and case review.

Rationale: In some cases, the ability for Ornge, the Ministry of Health and Long-Term Care, and/or the Expert Review panel to understand the root causes of incidents was hampered by the lack of recorded communications. This required the reviewers to rely upon statements given after-the-fact by those involved. Such statements are subject to recollection bias.

To The Ministry of Health and Long-Term Care:

24. The Ministry of Health and Long-Term Care should review, and where necessary revise its policies with respect to which cases need to be reported by Ornge to the Ministry of Health and Long-Term Care for potential review. The aim would be to ensure that all cases involving a death, in which operational issues have been identified, are reported to the Ministry of Health and Long-Term Care Emergency Health Services Branch to facilitate independent review in a timely fashion.

Rationale: In the course of the review, it became apparent to the Expert Panel that some cases involving significant operational issues (such as preventable delays to launch) were not brought to the attention of the Ministry of Health and Long-Term Care by Ornge. There needs to be enhanced clarity brought to these reporting requirements.

To Ornge and the Ministry of Health and Long-Term Care:

25. Ornge and the Ministry of Health and Long-Term Care should institute a process to track and identify all deaths that occur within 24 hours of air ambulance transport. This would permit comprehensive and timely investigation of cases in which operational concerns are identified, and allow Ornge to benchmark its performance against other jurisdictions.

Rationale: Throughout the course of this review, the Expert Panel was aware that there is currently no process to flag deaths which occur within 24 hours of air ambulance transport. It is recognized that the majority of these deaths are the result of the severity of the patients' illness or injuries, and are not the result of operational issues. However, the ability to track such deaths would facilitate more timely review by Ornge and the Ministry of Health and Long-Term Care in cases in which such concerns are identified.

Appendix 1: Ontario Priority Recommendations for Management of Opioids in Hospitals (2005)



Priority Recommendations* for Ontario Hospital Narcotic (Opioid) Project

Culture and Communications

1. Educate staff regarding the system-based causes of medication error.
2. Educate staff about the hierarchy of effectiveness of error reduction strategies.
3. Include the patient/family in the narcotic medication-use process.

Storage and Standardization

1. Remove the following stock items from patient care areas:
 - Hydromorphone ampoules or vials with concentration greater than 2 mg/ml (exceptions may include palliative care).
 - Morphine ampoules or vials with concentration greater than 15 mg/ml.
 - Morphine ampoules or vials greater than 2 mg/ml in paediatric patient care areas.
 - Sufentanil (exceptions may include Operating Room and Labour and Delivery).
2. Assess risk associated with narcotic stock in patient care areas.
3. Restrict as much as possible the admixing of narcotic solutions outside of pharmacy.
4. Standardize infusion concentrations of parental narcotic medications and selection of medications for pain management.

Independent Double Check

1. Implement a policy of Independent Double Checks for PCA infusions.

The policy should include a clear process for an independent double check and documentation when the following occur:

- Initial pump programming
 - Changes in pump programming
 - Solution changes
 - Patient transfers
2. Consider a policy of Independent Double Checks for:
 - a. All opioid infusions (continuous or intermittent)
 - b. Epidural infusions

PCA and Epidural

1. For PCA, develop and follow patient selection criteria (inclusion and exclusion).
2. For epidural, identify and implement multiple error prevention strategies to enhance differentiation of epidural infusions from other infusions.

*for detailed recommendations, strategies and supporting material refer to the Narcotic Project binder.

ISMP Canada Narcotic (Opioid) Project supported by the Ontario Ministry of Health and Long-Term Care, January 2005, version 1



Questions and comments regarding this report may be directed to:

Patient Safety Review Committee
Office of the Chief Coroner
25 Morton Shulman Avenue
Toronto, ON
M3M 0B1