



Patient Safety Review Committee

2010 Annual Report

**Office of the Chief Coroner
Province of Ontario
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Message from the Chair

“We Speak for the Dead to Protect the Living”

The motto of the Office of the Chief Coroner for Ontario speaks to the importance of learning from each and every death to try to prevent similar deaths in the future. This is particularly important in situations where a person's own health care treatment has inadvertently caused or contributed to his or her death.

Health care has advanced dramatically in recent years. With such progress comes increasing complexity of treatments and therefore increasing opportunity for adverse events¹. The Canadian Adverse Events Study², published in 2004, examined adverse events that took place in Canadian hospitals in the year 2000. This landmark study found that 7.5% of people admitted to hospitals in Canada experienced at least one adverse event and that almost 21% of such adverse events are fatal.

While these numbers are sobering, the study also identified that 37% of all adverse events are potentially preventable. When put into the context of 2.5 million annual hospital admissions in Canada, this means that some 14,000 deaths that result from adverse events every year in Canadian hospitals could be prevented.

One way to prevent such deaths is to study fatal adverse events and to ensure that the lessons learned are understood by everyone in the health care system so that continuous improvements can be made in the way care is delivered. In this way, the processes of care are improved, and care becomes progressively safer. It is this philosophy upon which the mandate of the Patient Safety Review Committee (PSRC) of the Office of the Chief Coroner is based.

In this, the PSRC's first Annual Report, we summarize the cases reviewed by the PSRC in 2010 and the recommendations that have been generated. In coming years, we will track the response to these recommendations and report on their implementation. While the PSRC was established in 2005, for administrative reasons, an annual report was not published until this year. Appendix A is a summary of cases reviewed by the PSRC dating back to its creation in 2005, and the recommendations that have been generated from these cases.



Dan Cass, B.Sc., MD, FRCP(C)
Committee Chair
Regional Supervising Coroner

¹ An adverse event is defined as “an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process”.

² Baker GR et al. The Canadian Adverse Events Study. CMAJ 2004;170(11):1678-86.

Committee Membership

Dr. Dan Cass Committee Chair Regional Supervising Coroner	
Dr. Glenn Brown Queen's University Department of Family Medicine	
Dr. Ian Herrick London Health Sciences Centre-University Hospital Department of Anaesthesia and Perioperative Medicine	
Mr. David U President and CEO Institute for Safe Medication Practices (ISMP) Canada	
Dr. David Musson Director, Centre for Simulation-Based Learning McMaster University.	
Dr. Michael Szul Medical Advisor, Associate Registrar College of Physicians and Surgeons of Ontario	
Ms. Margaret Keatings Chief Nurse Executive and Chief, Interprofessional Practice Hospital for Sick Children	

Dr. Edward Etchells Director, Patient Safety Improvement Research Platform Sunnybrook Health Sciences Centre	
Ms. Kathy Kerr Executive Lead – Committee Management Office of the Chief Coroner	

History

In Ontario, the traditional means of disseminating information critical to patient safety that comes to light via coroners' investigations has been through the coroners' inquest process. Due to the complexity of such investigations however, an inquest (if held) may take place several years after the death in question. Further, it may be challenging for an inquest jury comprised of members of the lay public to fully grasp the complex medical details in such cases in order to make practical recommendations aimed at preventing a similar death in future.

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 through more immediate actions, the Office of the Chief Coroner established the Patient Safety Review Committee in 2005.

Purpose

The purpose of the Patient Safety Review Committee (PSRC) is to assist the Office of the Chief Coroner in the investigation, review and development of recommendations towards the prevention of deaths relating to healthcare-related cases where system-based errors appear to be a major factor. The PSRC also assists coroners in improving the investigation of deaths within, or arising from, the healthcare system in which system-based errors appear to have occurred.

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 processes, but also the management of access to care (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 aims and objectives of the Patient Safety Review Committee are to:

1. To provide expert opinion about the cause and manner of death in health care-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 inquest on request.
5. To do, 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.

Structure and Size

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 2010, the Patient Safety Review Committee was comprised of nine 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.

Limitations

The Patient Safety Review Committee reviews coroners' cases that are referred by a Regional Supervising Coroner. These cases, and the issues arising from them, may be brought to the attention of the Regional Supervising Coroner through the investigating coroner, family of the deceased, or other organizations, agencies or individuals.

The Patient Safety Review Committee is advisory to the coroners' system and may make recommendations to the Chief Coroner through the Chairperson.

The consensus report of the Committee is limited by the data provided. Efforts are made to obtain all relevant data relating to the death.

The Committee's opinion is subject to the limits imposed on coroners' investigations and inquests by the *Coroner's Act*.

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

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

Medical records, draft and consensus reports and the minutes of the meetings are confidential documents. Meetings of the Committee are not open to the public.

Summary of Cases Reviewed in 2010

In 2010, the Patient Safety Review Committee reviewed nine cases which resulted in 26 recommendations. Three external physicians with expertise in the following fields were consulted for specific case reviews: methadone prescription (2010-03), plastic surgery (2010-05) and otolaryngology (2010-06).

Case Reviews

Case 2010-01

Date of Death: October 26, 2008.

Age: 77 years

Sex: Male

File number: 2008-15274

History:

The deceased had a history of prostate cancer and was treated with hormone therapy. He presented to his local community hospital with dizziness, nausea and vomiting and decreased appetite following a day of investigations at the regional cancer centre.

At the time of presentation, the patient was noted to be somewhat confused. He was admitted with a provisional diagnosis of some type of reaction as a consequence of investigations conducted earlier that day. The question of early sepsis was raised and he was started on intravenous fluids, levofloxacin (presumably for possible urinary sepsis) and amlodipine for blood pressure control.

Due to the patient's persistent confusional state, arrangements were made to transfer him to the local referral hospital for computerized tomography (CT) imaging of his head. Transfer to the regional hospital took place via ambulance with a Registered Practical Nurse (RPN) in attendance. Note is made of a verbal report from the radiologist confirming a massive intracranial hemorrhage involving the right frontal lobe and including an intracerebral and subarachnoid component. It is noted that the bleeding pattern was suspicious for a ruptured aneurysm.

Contact was made with several hospitals. The response varied between a lack of an available neurosurgical bed, or willingness to accept the patient in transfer due to the abysmal prospects or recovery. After three hours, a bed was eventually identified by CitiCall³ in a geographically distant hospital. Transfer was made by air ambulance.

³ **CitiCall Ontario** is a 24-hour-a-day 'medical 9-1-1' emergency referral service for hospital-based Ontario physicians. It provides a capacity management system that documents the 'status of' and 'access to' Ontario's acute care beds and provides implementation, training and problem solving assistance for the Critical Care Information System (CCIS) to Ontario hospital critical care units.

Following his arrival at the receiving hospital, the patient was assessed by the neurosurgical service and underwent a CT angiogram of the head and neck. No cerebral flow was documented and he was pronounced brain dead.

Post Mortem:

A post mortem examination was not performed.

Cause and Manner of Death:

Cause of Death:

1. Subarachnoid hemorrhage, due to
2. Probable ruptured cerebral aneurysm

Manner of Death: Natural

Discussion:

In its deliberations, the Patient Safety Review Committee (PSRC) recognized that the deceased suffered a devastating neurological insult as a consequence of a massive intracranial hemorrhage - an injury from which he was unlikely to have recovered irrespective of whether he received emergent neurosurgical care. These circumstances notwithstanding, the PSRC was of the opinion that there were opportunities to improve the process of care to potentially benefit future patients and healthcare providers faced with similar circumstances. These opportunities included:

1. The deceased was transferred for urgent diagnostic imaging from a small community hospital to a "full-service" community referral hospital with 24-hour emergency services and an intensive care unit. Management decisions for critically ill patients, including provisions for safe transfer, should be informed by the results of emergent/urgent investigations whenever possible. In this case, once it was determined that a neurological emergency existed, it may have been prudent for the patient to have remained at the "full-service" community hospital rather than being transferred back to the sending facility.
2. Several neurosurgical centres were contacted despite an initial neurosurgical consultation that deemed the patient suitable for transfer. A delay in transfer was experienced due to lack of resources (critical care beds) or disagreement as to whether the patient was a candidate for specialized care.
3. The deceased was not well served by the emergency transfer process that was available for neurosurgical services at the time of his presentation. Improvements can be realized by having suitability for transfer determined by the neurosurgical specialist initially contacted and subsequent efforts directed to identifying the most appropriate destination to ensure timely access to emergent care.

To: Diagnostic Imaging section of Ontario Medical Association; Ontario Hospital Association and College of Physicians and Surgeons:

Recommendation 1:

“When a patient is transferred from one institution to another for an urgent / emergent imaging study for a potentially life/limb threatening condition, the imaging study should be interpreted and the result communicated to the Most Responsible Physician (MRP) at the sending hospital before the patient is transferred back to the sending facility.”

Rationale: Patients are often transferred on an urgent or emergent basis between hospital facilities for imaging studies (such as CT or MRI), with a plan for the patient to return to the sending facility after the imaging is completed. In some cases, findings on imaging will dictate the need for a change in management as new information regarding the patient’s condition may no longer conform to existing arrangements for safe return transfer or may dictate the need for urgent care at a facility with more specialized services than can be provided at the sending hospital.

Communicating the result of the imaging study to the MRP before the patient leaves the imaging facility would allow the MRP to decide whether the patient should be returned to the sending hospital, or whether it is necessary, and more appropriate for the patient’s continuing care, to arrange for transfer to a facility that can provide a higher level of care (e.g., admission to the imaging hospital or transfer to another regional or tertiary care centre, as appropriate).

To: Critical Care Secretariat; Ministry of Health and Long Term Care; Local Health Integration Networks (LHINs); Ontario Hospital Association:

Recommendation 2

The Patient Safety Review Committee of the Office of the Chief Coroner supports the efforts underway by a working group, facilitated by the Office of the Chief Coroner and comprised of the above-named stakeholders, aimed at facilitating access to “critical health services” for patients with life and limb-threatening conditions.

Specifically, the Committee supports the working group’s recommendations that:

- a. the Critical Care Secretariat, in collaboration with the provincial LHINs, advance their commitment to addressing critical care access and capacity issues to include definition of a menu of life and limb threatening critical health services — examples included neurosurgery, vascular surgery, trauma care, dialysis, and cardiac surgery.
- b. the LHINs develop and implement a “no refusal” policy, for patients who require one of these services to ensure acceptance of the patient for treatment first, with bed logistics addressed secondarily.

- c. within each LHIN, there should be a defined process to ensure patient access to each of the services defined on the life and limb threatening critical health services menu.
- d. when services are not available within a LHIN, clustering and partnerships between LHINs should be developed to produce corridors of service supported by service level agreements.

To: CritiCall Ontario; Critical Care Secretariat:

Recommendation 3

Community physicians contacting CritiCall for assistance with the transfer of a patient requiring emergent neurosurgical care should be able to arrange transfer based on a single source of neurosurgical consultation, assessment and review of appropriate imaging. A process should be developed in collaboration with the province's neurosurgical centres to ensure that timely, coordinated access to neurosurgical critical care is available to patients following neurosurgical consultation that deems the patient appropriate for transfer.

Rationale: Notwithstanding significant advances with respect to refining the consultation process and implementation of the Emergency Neurosurgical Image Transfer System (ENITS), referring physicians should not need to engage in multiple contacts with neurosurgical centres with the potential for conflicting opinions and advice. The Neurosurgery Expert Panel Report (2007)⁴ endorsed the adoption of a provincial referral model and on-call system for neurosurgical services. Such a system should include a process that enables access to neurosurgical critical care, if appropriate, following contact with the initial neurosurgical specialist.

Case 2010-02

Date of Death: October 13, 2008.

Age: 58

Sex: Female

File number: 2008-12560

History:

The deceased was a 58 year old female with an extensive medical history that included: coronary artery disease with previous coronary artery bypass grafting; aneurysm of the descending aorta, managed conservatively; peripheral vascular disease; left subclavian artery stenosis; hypertension; vertebral-basilar artery calcification and possible prior

⁴Rutka J (Chair), Report of the Neurosurgery Expert Panel, December 2007. http://www.health.gov.on.ca/transformation/wait_times/providers/reports/neuro_rep_20071201.pdf

brainstem transient ischemic attacks; and chronic obstructive pulmonary disease believed to be on the basis of cigarette smoking.

The deceased presented to the Emergency Department (ED) of the hospital with a chief complaint of headache. An initial set of vital signs appeared to be normal and the deceased was assigned a Canadian Triage Acuity Scale (CTAS) score of 2 (based on a 5-point scale, with 1 being most acute and 5 being least acute). According to documentation, the deceased was placed in the waiting room in a wheelchair. There is no documentation of any reassessment of the deceased from the time of triage at 1304 hours until shortly after 1900 hours. At that time, the patient complained of left-sided chest pain and worsening headache. An electrocardiogram did not reveal any acute changes. The patient's headache was recorded as 9/10. Metoclopramide 10 mg intramuscularly and acetaminophen 1 g orally were given on verbal order from a physician, and the patient was returned to the waiting room.

No further documentation took place until 2055 hours when it was noted that the patient was called in the waiting room and there was no answer. The patient was noted to have "left without being seen" (LWBS). The official time of discharge was given as 2055 hours, although the exact time that she left the ED is not known. There is no indication that the deceased was assessed by a physician during the time she was in the Emergency Department.

Two days later, paramedics were called to the home of the deceased. The deceased was transported to the same hospital she had been to previously. The presenting complaint in the Emergency Department was given as, "coma / altered level of consciousness" with an initial Glasgow Coma Scale (GCS) that had decreased to 6/15. A computerized tomography (CT) scan was performed and an extensive subarachnoid hemorrhage, felt to be arising from the area of the anterior cerebral or anterior communicating artery, was identified. The deceased was transferred to the Intensive Care Unit for further care.

A neurosurgical consultation was obtained, but it was felt that there was no role for surgical intervention due to the poor neurological condition of the deceased. The deceased's condition deteriorated further over the next 12 hours and a formal determination of neurological death was made three days after the initial presentation to the Emergency Department and one day after the second admission.

Post Mortem:

A post mortem examination was performed. This confirmed the presence of a subarachnoid hemorrhage, most likely due to a ruptured cerebral aneurysm.

Cause and Manner of Death:

Cause of Death:

- a. Subarachnoid hemorrhage, due to
- b. Ruptured cerebral aneurysm

Contributing factors:

- a. Diabetes mellitus; Coronary artery disease

Manner of Death: Natural

Discussion:

The following issues were examined:

- a. The deceased presented to the Emergency Department with a severe headache and nausea. Two days later, she presented with an acute worsening of her headache and an abrupt neurological deterioration on the basis of a subarachnoid hemorrhage. The initial presentation likely represented a “sentinel headache” or “warning headache” that commonly occurs in cases of subarachnoid hemorrhage. Correctly diagnosing and managing patients at the point of presentation with a sentinel headache and intact neurological status can result in favourable neurological outcomes if a treatable lesion is identified.
- b. The deceased appeared to have been triaged promptly and was assigned a CTAS score of 2. Despite the urgency identified by the CTAS score, the deceased was placed in the waiting room, presumably due to the lack of an available treatment area in the Emergency Department. In the event that a patient who is triaged waits for a prolonged period of time in the waiting room, it is important to have a process in place to facilitate the reassessment of the patient and to revisit and update their triage score if their condition changes.
- c. Emergency Department crowding is a ubiquitous problem locally, nationally and internationally. It is not clear from the documentation provided what circumstances led to the prolonged wait experienced by the deceased at the time of her presentation. It is likely that Emergency Department crowding contributed to the situation and led to the decision by the deceased to leave the Emergency Department without seeing a physician after waiting almost eight hours.

To: Hospital

Recommendation 1

A Quality of Care review should be conducted (if not already done) by the Hospital regarding this case, and any recommendations generated from the review provided to the Office of the Chief Coroner and the Patient Safety Review Committee.

Rationale: This case highlighted some perceived process issues related to the reassessment of patients in the Emergency Department waiting room. The review should therefore include (but not be limited to) the frequency and documentation of reassessment of patients in the waiting room for prolonged periods as per the revised

Canadian Triage Acuity Scale Implementation Guidelines (*Can J Emerg Med* 2004;6(6):421-7).

To: Hospital and relevant Local Health Integration Network

Recommendation 2

The Hospital, in collaboration with the relevant Local Health Integration Network, should continue efforts to mitigate the impact of Emergency Department (ED) crowding on access to emergency department care, particularly for high-risk patients.

Rationale: Access to Emergency Department care is a focus of the Provincial Ministry of Health and Long Term Care Wait Time strategy. We recommend that efforts and resources, including those under this strategy, be targeted towards initiatives to ensure that wait times to physician assessment are minimized, and that appropriate resources (such as waiting room nurses in the ED) are directed towards the management of patients presenting with high-acuity problems for whom a longer than ideal wait to see a physician is unavoidable.

To: The Regional Supervising Coroner

Recommendation 3

The family of the deceased should be informed as to the potential for an inherited cause leading to the deceased's subarachnoid hemorrhage so that they may seek appropriate follow up care.

Case 2010-03

Date of Death: December 28, 2008.

Age: 28 years

Sex: Male

File number: 2008-16249

History:

The deceased, age 28, had a history of sleep apnea, obesity, hypertension, bipolar illness, anxiety disorder, migraines, back problems, alcoholism and narcotic abuse. On December 12, 2008, the deceased entered a methadone maintenance treatment program for treatment of Oxycontin® abuse. He was assessed by a physician and provided with documentation regarding methadone safety. He also agreed, in writing, to adhere to various undertakings (i.e. General Agreement, Carry Agreement, Release to Share Information, Treatment Contract).

The deceased was placed on 20 mg of methadone daily, starting on December 12 with the dose to increase by 10 mg daily every few days. On December 23, the dose of

methadone was increased from 40 mg to 50 mg daily, and he was placed on doxepin. The deceased complained of anxiety. He was assessed twice a week by physicians. No take home (or “carry”) doses of methadone were given and no adverse effects were documented.

On December 25, 2008, the deceased was brought to the Emergency Department (ED) of a major hospital because of what the family state were signs of increased sedation, fluid retention, difficulty breathing and change in behaviour. The ED chart, however, indicates that the deceased had presented for assessment of leg redness and swelling following a cat scratch or bite. There is no documentation in the chart to indicate that the family’s concerns regarding the deceased’s physical and behavioral changes were relayed to the clinical staff in the ED. The deceased was assessed with clinical examination, oxygen saturation determination, ECG and blood work. He was diagnosed with leg cellulitis, and discharged with a prescription for antibiotics (amoxicillin/clavulinate) and instructions to follow up with his family physician.

On December 28, 2008, the deceased was found on the floor of his locked apartment. A 911 call was made, and he was pronounced dead at the scene.

Post Mortem:

A post mortem examination with toxicological testing revealed a higher than therapeutic level of oxycodone; a methadone level which alternatively could cause death in a non-tolerant individual or could be therapeutic in a patient in a methadone maintenance program; therapeutic levels of chlorthalidone and citalopram; and the presence of 7-aminoclonazepam (a metabolite of clonazepam).

Cause and Manner of Death:

Cause of Death:

- a. Acute Mixed Drug Toxicity

Contributing factors:

- a. Bipolar affective disorder; Obesity

Manner of Death: Accident

The ability of the deceased to continue to get multiple prescriptions of narcotics and tranquilizers that remained unmonitored while on the methadone, along with on-going illicit oxycodone use, had a high probability of contributing to his death. This was compounded by the lack of communication between the various physicians involved in the deceased’s care, all of whom were prescribing sedating drugs. This may be in part due to lack of disclosure from the patient of the various medical doctors involved and remains a problematic safety issue for methadone practices in Ontario.

To: College of Physicians and Surgeons of Ontario (CPSO):

Recommendation 1

The Committee recommends that the CPSO remind all methadone prescribers in Ontario of the established best practice of communicating with all other physicians known to be providing care to patients who enroll in a methadone treatment program.

Rationale: A consent form allowing such communication between prescribers is included as part of the sample Patient Treatment Agreement appended to the Methadone Maintenance Treatment guidelines. The CPSO should remind all methadone prescribers that obtaining this consent should be part of the enrolment of a patient in a methadone treatment program, and of the importance of communicating with all other physicians involved in that patient's care so that they are aware of the patient's enrolment in a program and can assist in providing care to the patient effectively.

Recommendation 2

The Committee recommends that the current CPSO task force, the "Opiate Public Policy Project", include as part of its mandate, recommendations to support the ability for all prescribers to be aware of all prescriptions issued for a given patient.

Rationale: In this case, the deceased had used oxycodone in addition to methadone. It is not clear how this oxycodone was obtained, and indeed whether it had been prescribed for him (and if so, when) or obtained illicitly. There are, however, circumstances where a prescriber may not be aware of other opiate medications which have been prescribed for their patient and may inadvertently contribute to over-prescribing of opiates which are either used in excessive amounts or diverted to other users. Ideally, a system which would allow a given prescriber access to information about other opiate prescriptions issued for a given patient by other physicians could decrease the likelihood of such over-prescribing.

Case 2010-04

Date of Death: August 22, 2008

Age: 88

Sex: Male

File number: 2008-17140

History:

The decedent was assessed at home by Emergency Medical Services on August 3, 2008. He was admitted to the Emergency Department (ED) of Hospital A, a 20-bed primary care hospital, with presenting complaints of fever, cough and congestion for two days. The provisional diagnosis was pneumonia and the health system's standard pneumonia order set was initiated. Doctor notes indicate that the patient was feeling

better with more strength and better appetite on August 4 and 5. A chest x-ray was done and radiological diagnosis was heart failure or early interstitial pneumonia. Nursing notes from August 5 indicate that the patient was confused, shaky and short of breath on exertion.

On the evening of August 5, 2008, the decedent's nurse called the on-call physician due to severe hypoxemia. There were coarse breath sounds bilaterally. The decedent was transferred back to the ED for resuscitation. He was treated with intravenous furosemide, topical nitroglycerine, and intravenous morphine. He did not improve, so he was given paralytic medications, intubated, and ventilated. After intubation, his blood pressure fell to 50 mm Hg systolic so he was started on intravenous dopamine.

On August 6, 2008 at 0015 hours, the decedent was transferred to the Intensive Care Unit (ICU) at Hospital B (regional referral hospital for Hospital A) with constant physician attendance. The provisional diagnosis was acute coronary syndrome/non ST-segment elevation myocardial infarction (NSTEMI) with cardiogenic pulmonary edema, with possible superimposed pneumonia.

The patient had a long stay in the Hospital B Intensive Care Unit. The patient had problems with recurrent ICU associated/ventilator associated pneumonia which was identified and treated. He reverted to sinus rhythm around 1535 hours on August 7. There were no further significant arrhythmias. The nasogastric tube from August 6 was inserted into the left mainstem bronchus. This was identified by routine radiology, and repositioned without incident in a timely fashion. On August 11, there was one episode of hypoglycemia related to intensive insulin therapy and a temporary disruption of his feeding, which was identified and treated. An echocardiogram on August 11, 2008 showed normal left ventricular (LV) systolic function, impaired LV relaxation (diastolic dysfunction), and no other significant findings.

Over the next 11 days, the decedent developed acute respiratory distress syndrome (ARDS), persistent atrial fibrillation, myocardial ischemia, shock (cardiogenic / septic), and renal failure. A bronchoscopy was performed on August 20, 2008. Attempts at ventilator weaning and extubation were unsuccessful. A tracheostomy was performed at the bedside in the ICU on August 22, with no complications. The decedent died later in the day on August 22, 2008.

Post Mortem:

A post mortem examination was not performed.

Cause and Manner of Death:

Cause of Death:

- a. Pneumonia

Contributing factor:

- a. Coronary ischemia

Manner of Death: Natural

Discussion:

A member of the patient's family has several concerns about the system and processes of care. In response to the family's concern, a Regional Coroner's Review was held on December 1, 2009, with representatives of the Health System encompassing Hospital A and Hospital B. The Regional Supervising Coroner was satisfied that any issues of concern raised by the investigating coroner and family were taken seriously and resulted in changes that met the Chief Coroner's mandate of death prevention.

This case was subsequently reviewed at the Patient Safety Review Committee, in order to determine if there were any systemic issues or concerns related to the death. The expert review concluded that there were no systemic or process of care issues identified at Hospital B. The expert identified some process issues at Hospital A, most of which had been identified through the Regional Coroner's Review process.

To: The Health Systems encompassing Hospitals A and B, The Ontario Hospital Association and the Open Source Order Sets group:

Recommendation 1

Pneumonia order sets should include triggers to prompt consideration for ordering ECG, CXR, blood and sputum cultures.

Recommendation 2

Order sets for adults that include salbutamol prn should include parameters for the indication to administer the medication (such as 'for wheezing and/or dyspnea') and when the medication should be held and/or the physician notified (such as, 'notify MD for HR greater than 'X' per minute').

Case 2010-05

Date of Death: January 9, 2009.

Age: 55 years

Sex: Female

File Number: 2009-2016

Synopsis of Case:

The deceased is a 55 year old female with a history of obesity (Body Mass Index (BMI) = 35.2), a sleep disorder and depression.

In August, 2008, she was assessed by a certified Plastic Surgeon (Dr. X) at Hospital A (an academic health science centre) for consideration of an elective body contouring procedure. Specifically, she expressed a desire for removal of pannus and adipose

tissue from her trunk and extremities. A consult note from that visit indicates Dr. X's decision not to combine panniculectomy and liposuction due to "increased risk of poor wound healing with two scars." In October, 2008, a further consult note by Dr. X indicates a decision to proceed with both procedures in the same surgery. The note states, in part, "Aware of risk of bleeding, blood clots and other complications." Surgery was booked for December, 2008.

The decedent's anesthetic risk was assessed as an American Society of Anesthesiologists (ASA) 3 in the nursing OR record. Following the donation and banking of two units of autologous blood, the decedent underwent an elective standard hypogastric excision abdominoplasty and rectus plication combined with a high volume (6.8 L) of liposuction of her thighs, flanks and upper arms. This was performed by Dr. X, under a general anesthetic administered by a certified Anesthetist (Dr. Y) in an accredited hospital (Hospital A) with plans for an overnight admission and autologous blood transfusion. The surgical procedure lasted nearly six hours and was associated with the loss, excision and aspiration of almost 9 kg of skin, subcutaneous tissue, blood, lipo-aspirate, infusate and urine, representing almost 10% of the patient's total body weight.

On post-operative day 1, the decedent complained of shortness of breath, and was found to have decreased oxygen saturation and opacities on chest radiograph. This was felt to be due to volume overload, and the decedent was admitted to the step-up unit at Hospital A where she was treated with diuresis and blood transfusions. Her condition continued to deteriorate, and on post-operative day 3 she was intubated and transferred to the Intensive Care Unit (ICU) at Hospital B (another academic health science centre in the same city). Despite continued aggressive treatment, the decedent developed multi-system organ failure. She required dialysis and insertion of a tracheostomy. After a protracted ICU stay, she died on post-operative day 29.

Post Mortem

A post mortem examination was performed. This revealed evidence of pulmonary fat embolism, as well as pneumonia and acute respiratory distress syndrome.

Cause and Manner of Death:

Cause of Death:

- a. Pneumonia and acute respiratory distress syndrome (ARDS), due to
- b. Fat embolism, due to
- c. Complications of liposuction and panniculectomy

Contributing factor:

- a. Obesity

Manner of Death: Natural

Expert review

Based on concerns identified by the family of the deceased that the risks of the surgery were not appropriately explained, as well as concerns identified by the investigating coroner and Regional Supervising Coroner, a review by an external expert was undertaken. The expert was a certified plastic surgeon with expertise in body sculpting procedures who practiced at an academic health science centre in a different city from that in which Hospitals A and B are located. At the direction of the Patient Safety Review Committee, the expert focused on three specific aspects of the case:

1. What is the incidence of fat emboli syndrome with liposuction and is this risk adequately reflected in the consent process?

Comments from Expert: Liposuction is one of the most commonly performed surgical procedures in North America which has shown itself to be very safe. It has progressed from a modality to treat simple contour irregularities to being applied to more extensive body contouring scenarios as well as for reversing the metabolic consequences of obesity. However, patients should be made aware that liposuction, just like any surgical procedure, does carry a risk of mortality. There is an overall mortality risk of approximately 0.002% that may rise by a factor of 10 when large volumes are aspirated and when the liposuction is combined with another surgical procedure (0.02%). These are frequently related to complications associated with wound infection, pulmonary emboli and surgical misadventure.

Fat embolus is one the least common entities associated with liposuction mortality; most instances, when they occur, are reported in the literature as individual case reports. By way of clarification, some authors make the distinction between mechanical fat embolism and fat embolism syndrome. The clinical course and the findings at autopsy in this case would suggest that the patient succumbed to complications of the former. Fat embolism syndrome is a complex of symptoms and pathologic findings classically involving not just the lungs, but the integument and central nervous systems - none of which were noted in the clinical record or at the time of autopsy. Whereas fat embolism syndrome is thought to be a biochemical inflammatory response to circulating hydrolyzed free fatty acids, mechanical fat embolism comprises the trapping of fat globules that have been traumatically introduced to the vascular system in the pulmonary capillaries.

While the incidence of mechanical fat embolism leading to ARDS and death in cases of liposuction is exceedingly rare, some feel that sub-clinical fat embolism is relatively common. There is animal research that suggests that there may be a cumulative process of the introduction of fat globules into the circulation that is directly related to the extent and volume of liposuction being performed. Nonetheless, in the course of outlining the complications and risks associated with liposuction, a normal consent process would not expect that patients be advised of the specific risk of fat embolism.

2. Is 6.8 litres of tissue removal during liposuction appropriate? Are there accepted clinical practice guidelines, and if so, (i) were they followed and (ii) are most practicing plastic surgeons aware of these guidelines?

Comments from Expert: Large volume liposuction is defined as the aspiration at one surgical procedure of greater than 5000 cc of lipo-aspirate. Although not generally considered a treatment for obesity, contour enhancement, as well as metabolic benefit from large volume liposuction, has been documented in the literature.

A number of practice surveys leading to practice advisories have been published in leading Plastic Surgery journals that support the following general recommendations to guide physicians who perform liposuction:

- The surgeon should be certified by a recognized surgical board having obtained training in body contouring surgery during accredited residency or fellowship.
- Large volume liposuction should be performed in an accredited acute care facility.
- The volume of aspirate removed should be proportional to the patient's overall size and medical condition.
- Fluid resuscitation guidelines for application to large and small volume aspiration.

In this particular case, there was general adherence to the first two of these guidelines. The decedent was carefully monitored post-operatively, with assessments and interventions being initiated soon after symptoms of respiratory difficulty were noted.

The decedent's care may have diverged from the recommendations in the latter two areas. Her surgical procedure lasted nearly 6 hours and was associated with the loss of almost 9 kg of skin, subcutaneous tissue, lipo-aspirate, blood, urine and infusate, representing nearly 10% of her total body weight. Some practice advisories suggest that no more than 5% of the patient's body weight be removed at any one surgical setting.

The operative record imprecisely and incompletely documents fluid losses and administration during the procedure. The best estimate from the available information suggests that less than 7 litres (this may be an over estimate) of infusate and intravenous fluid were administered throughout the course of the surgery, leaving the patient with a volume deficit of almost 2 litres by the time she entered the recovery room. Recommendations regarding fluid resuscitation for liposuction indicate that, if anything, patients undergoing large volume lipo-aspiration should leave the operating room with a volume surplus. A formal protocol and communication between the surgeon and anesthetist of expectations regarding fluid balance and resuscitation during the course of the operation would appear to have been lacking in this particular instance. It is widely recognized that alteration in volume status may be a mitigating factor that governs the physiologic response to a host of stresses including stress hormones, fat or other by-products of tissue damage that may enter the circulation during a surgical procedure.

3. Is there added risk in combining panniculectomy with liposuction? If so, should this be incorporated into practice guidelines?

Comments from Expert: The data from national surveys conducted in the United States suggests that the incidence of fatal complication increases when other surgical procedures are combined with liposuction. The risk of fatality increases from

0.002% for liposuction alone, to 0.01% when liposuction is combined with other surgical procedures and reaches 0.03% when combined with abdominoplasty. However, these mortality rates do not differ with those associated with abdominoplasty alone. It is generally recognized that the severity and frequency of complications increases with the length of the surgical procedure, which in and of itself might be a limiting factor to the number of elective surgical procedures that can be safely performed during one general anaesthetic.

Current practice advisories generally suggest that large volume liposuction in combination with other surgical procedures be avoided whenever possible. It is suggested that specific criteria pertaining to patient selection be undertaken to identify those who might be better managed with staged sequential operations rather than one large procedure, be it large volume liposuction alone or in combination with other surgical procedures. Some U.S. States have mandated that no more than 1000 to 2000 cc of lipo-aspirate be removed at the time an additional surgical procedure is being performed and have mandated maximum times for the length of surgical procedures particularly in the outpatient setting (e.g. Tennessee and Florida). While long and complicated surgical procedures are not uncommon in the field of Plastic Surgery, there is general acceptance that the bar for risk avoidance should be set higher when considering elective surgical procedures for contour enhancement.

[Committee Chair's note - This review pertains specifically to the details of this particular case. Caution should be exercised in extrapolating this analysis to other clinical situations and practice settings.]

To the Plastic Surgery Section of the Ontario Medical Association (OMA):

Recommendation 1

The Patient Safety Review Committee of the Office of the Chief Coroner recommends that the Plastic Surgery Section of the OMA disseminate Best Practice Guidelines around the performance of liposuction and other body contouring procedures. Specifically, such a document could include recommendations around the amount of liposuction to be performed at one time, the combination of liposuction with other procedures (such as panniculectomy), and the optimal intra-operative and post-operative management of fluid balance in patients undergoing such procedures. Wherever possible, these guidelines should be evidence-based.

To the Regional Supervising Coroner:

Recommendation 2

The Patient Safety Review Committee of the Office of the Chief Coroner recommends that the Regional Supervising Coroner ensure that a Quality of Care Review is conducted by the hospital, and that the recommendations arising from that review be provided to the Regional Supervising Coroner. The review should address both the surgical management (both intra- and post-operatively) as well as the anesthesia management, with particular attention to the fluid management of the decedent. Based

on the results of the hospital review, consideration should be given to a Regional Coroner's Review of this case.

Case 2010-06

Date of Death: May 11, 2009

Age: 36 years

Sex: Female

OCC file: 2009-5667

History:

This 36 year old woman died in the ICU at Hospital A (community hospital) on May 11, 2009. The decedent had a lengthy medical history dating back to 1990, when, at the age of 17, she sustained a significant airway injury while waterskiing. She was found to have bilateral vocal cord paralysis and significant subglottic injury (complete separation of the cervical trachea from the larynx). She underwent an immediate tracheostomy with anterior neck exploration and complex surgical repair of the injuries. She was left with bilateral cord paralysis, but was able to breathe through her larynx. In 1994, at Hospital B (tertiary care hospital), she had a left arytenoidectomy for a diagnosis of bilateral vocal cord paralysis and intermittent airway obstruction. In 2007, the patient was assessed by an otolaryngologist at Hospital C (tertiary care hospital) for evaluation of airway status in anticipation of possible pregnancy. A number of options were discussed, including laser arytenoidectomy and cordectomy (with either tracheostomy or T-tube post operatively).

In 2008, the patient became pregnant and in October, a tracheostomy tube was inserted electively at Hospital C. Pregnancy and delivery in December 2008 were uncomplicated. In January 2009, the patient followed up with an otolaryngologist at Hospital C where she was seeking definitive airway treatment and removal of the tracheostomy tube.

On April 23, 2009, the patient was admitted to Hospital C for removal of the tracheostomy tube, laser arytenoidectomy and insertion of a T-Tube (to allow post operative healing). Some post-operative issues arose with aspiration of food (noted to be expected given the anatomy / placement of the T-tube). Suctioning was to be performed after meals (by deceased and her spouse), and thickened liquids were used. Note was made of some thick mucous plugs in the T-tube requiring suctioning +/- saline instillations to clear.

On April 28, 2009 she had a repeat endoscopy which revealed that the T-tube was in good position and functioning. She was discharged home with Community Care Access Centre (CCAC) care in place. Included in the discharge plan was arrangement for suction catheters, a compressor and humidified air at home (via CCAC) and instructions to contact the otolaryngologist at Hospital C for pain, fever, bleeding or swelling. Suction catheters and the compressor were subsequently provided; humidification reportedly was not.

On April 30, 2009, the patient attended the Emergency Department (ED) at Hospital A with a complaint of difficulty swallowing due to swelling secondary to her tracheostomy tube. She reported that she had no fluid intake. Thick mucous discharge on her tongue and decreased urine output were reported. It was reported that fluid that she drank came out around the tube. The CCAC nurse reportedly was concerned about potential dehydration. A fungal tongue appearance was noted. Vital signs and lab testing were normal. Intravenous (IV) fluid boluses were given, and the patient was discharged home with an intravenous catheter in place. She was provided with medication for treatment of oral thrush. On May 1, the family physician arranged for home IV fluids to maintain hydration. Attempts were made to contact / follow up with the otolaryngologist at Hospital C, without success, during this post-discharge period.

On May 5, the patient went to the ED at Hospital A after difficulty clearing the T-tube. A large, bloody mucous plug was cleared just prior to paramedic arrival. The patient was observed in the emergency department for a period of time and discharged home. In the very early hours of May 6, she returned to the ED at Hospital A with a clot blocking the T-tube and difficulty breathing. She initially improved with normal oxygen saturation, but at 0200 hours, developed a complete obstruction and it was not possible to pass a suction catheter distally through T-tube. She became cyanotic with hypoxia and bradycardia. The anesthetist and otolaryngologist were paged, but both were out of the hospital.

At 0216 hours, the anesthetist arrived and there was difficulty bagging due to distal obstruction of the T-tube. Cardiopulmonary resuscitation (CPR) was initiated for loss of pulse. There was some difficulty obtaining a pediatric bronchoscope, and unfamiliarity with the adult bronchoscope available in the ED. It was suggested that the T-tube be removed; however, the anesthetist was unsure as to how the T-tube was anchored distally and was reluctant to remove the tube.

An otolaryngologist arrived and the T-tube was removed (confirming distal obstruction) and an endotracheal tube was placed. CPR continued for 10-15 minutes before return of spontaneous circulation. The patient was taken to the operating room for placement of a tracheostomy.

The patient was admitted to the intensive care unit with severe hypoxic-ischemic encephalopathy and subsequently died on May 11, 2009.

Post Mortem:

A post mortem examination was performed, which confirmed evidence of hypoxic-ischemic encephalopathy. A detailed examination of the tracheal anatomy was also performed.

Cause and Manner of Death:

Cause of Death:

- a. Hypoxic-ischemic encephalopathy, due to
- b. Tracheal obstruction; complicating

- c. Laser arytnoidectomy, for the treatment of
- d. Remote traumatic laryngeal injury

Manner of Death: Accident

Discussion:

The PSRC reviewed the circumstances of the case, and obtained an expert review by an Otolaryngologist from a different centre. The expert reviewer examined the circumstances leading up to the death, and made a number of recommendations. These were reviewed and considered by the PSRC, and the following recommendations were made by the Committee:

To the Ontario Medical Association section on Otolaryngology and the Ontario Hospital Association:

Recommendation 1

A closer link should be established prior to discharge between the tertiary care ENT surgeon and the patient's local health care providers after complex airway surgery is performed, and in particular when a less common airway device is inserted.

Rationale: After discharge, the decedent returned to her home and to the care of her family physician and local hospital. It would appear that the family physician, emergency physician(s) and anesthetist involved in the decedent's care in the time between discharge from Hospital C until her death were not familiar with the complexity of managing post-operative issues in a patient with a T-tube airway device in place. There was an inability to make contact with the otolaryngologist from Hospital C, which undermined the efforts of the local physicians to care for the decedent effectively. By the time the local otolaryngologist from Hospital A was involved, irreparable hypoxic damage had already occurred.

In cases where a patient is to leave hospital with an atypical airway device in place, it is imperative that the physicians responsible for the ongoing care of the patient have ready access to the appropriate expertise. This could occur through facilitated direct access to the otolaryngologist at the tertiary care centre, or through a pre-arrangement for similar access to a local otolaryngologist if available. These arrangements should be in place prior to discharge of the patient from the tertiary care centre. Consideration should be given to having a local community otolaryngologist actively take charge of early post-operative care-related issues, especially in a complex airway case like this one where the patient lives in a community remote to the tertiary care hospital. This could take the form of close follow up, or a supportive resource for the patient or her caregivers.

Recommendation 2

Education should be provided to patients and family members, and written instructions provided to the patient to give to health care providers, regarding the actions to be taken if an airway emergency arises in a patient with an airway device in place.

Rationale: The Montgomery T-tube is an uncommon airway device; although complications are rare, when they occur, they can be fatal. Information regarding the nature of the tube and acute management of tube problems could be life-saving. Simple written information could be given to the patient to pass onto emergency staff and paramedics in case of an airway concern.

To the Community Care Access Centres (via the Local Health Integration Networks):

Recommendation 3

If the Community Care Access Centre (CCAC) is not able to provide humidification as ordered for a post-operative patient following an airway intervention, this must clearly be communicated to the ordering physician.

Rationale: In-home humidity, as ordered by the otolaryngologist at Hospital C, could have decreased the likelihood of mucous plugging, and is considered standard post-op care following an airway intervention such as a tracheotomy or T-tube insertion. If, for whatever reason, it is not possible to provide home humidification, this needs to be communicated to and discussed with the ordering physician so that options can be identified to ensure that either (i) this is acceptable to the ordering physician, or (ii) alternate therapeutic options can be discussed.

Case 2010-07

Date of Death: May 19, 2009.

Age: 34 years

Sex: Female

File number: 2009-5939

History:

This 34 year old woman had a history of severe pulmonary hypertension and patent foramen ovale, and had been started (approximately 2 weeks previously) on a Flolan⁵ pump via a Hickman line, by her specialist at Hospital A (a tertiary / quaternary-care hospital). The decedent and her family were given specific training as to the management of the Flolan pump and were provided with a 24-hour hotline in case of emergencies

In the early morning of May 18, 2009 (the Victoria Day holiday), the decedent proceeded to Hospital B (a large community hospital in the same city as Hospital A) via ambulance, in rapid atrial fibrillation. She was cardioverted and discharged home at approximately 0610 hours. Later in the morning, she felt unwell again, now accompanied by abdominal

⁵ Flolan (epoprostenol) is a potent pulmonary and systemic vasodilator indicated in the treatment of primary and secondary pulmonary hypertension for patients who have not responded to conventional treatment.

pain and vomiting. A 911 call was placed, and although she requested transfer to Hospital A, Emergency Medical Services (EMS) returned her to the emergency department of Hospital B, arriving at 1013 hours. She was assessed by the emergency physician who ordered a variety of investigations. Shortly thereafter (about 15 minutes), the decedent was attempting to perform a regularly scheduled change of her Flolan pump cassette, but was unsuccessful as there appeared to be an obstruction of her Hickman line. Numerous attempts by ER staff to contact the Flolan hotline at Hospital A were unsuccessful.

During this time, medication was withdrawn from the cassette, with attempts to inject it through a peripheral intravenous line. The decedent went into rapid atrial fibrillation again, and was given propofol and converted to normal sinus rhythm. However, her oxygen saturation deteriorated and she suffered a cardio-pulmonary arrest at 1115 hours. Resuscitation was initiated, and at around 1125 hours, the Hickman line was reopened, and a new Flolan cassette was started. The decedent's oxygen saturation quickly improved, and a cardiac rhythm was restored at 1130 hours. She was admitted to the intensive care unit at Hospital B in critical condition. She expired the following day on May 19, 2009.

Post Mortem:

Major autopsy findings included:

- a. Primary pulmonary hypertension with hypertrophic right ventricle
- b. Acute right ventricular ischemia related to acute arrhythmia
- c. Status-remote Hickman catheter for therapy administration (patent)
- d. Chronic congestive heart failure, pleural effusions, ascites, nutmeg liver

Cause and Manner of Death:

Cause of Death:

- a. Complication of primary pulmonary hypertension, following
- b. Blockage Hickman Line (for Flolan pump).

Manner of Death: Natural

Discussion:

Following the death, Hospital A conducted a Quality of Care review and identified and implemented a number of process improvements aimed at improving the back-up and response processes in the event of a situation such as this. In addition, the case was referred by the Regional Supervising Coroner for review by the Patient Safety Review Committee (PSRC) in order to identify any further recommendations and/or to identify lessons learned that might be applicable in other institutions which operate community-based medication programs. An expert review was obtained from a clinical pharmacist with expertise in patient safety.

Conclusion:

The decedent's underlying medical condition and the short half-life of epoprostenol are risk factors for an adverse outcome that cannot entirely be mitigated. However, from a medication management perspective, the expert reviewer and the PSRC were in support of the changes implemented by Hospital A.

To Hospital A and to the Ontario Hospital Association (for hospitals overseeing community-based drug-infusion programs):

Recommendation 1

Place laminated labels with emergency information directly on the pumps, including information on:

- Basic troubleshooting steps or alternatives for administering the drug in an emergency;
- Whom to contact, and how, in the event of an emergency;
- A timeframe to expect a call-back, and a back-up pager number.

Rationale: While providing instructions for the patient to carry with them is an important and valuable strategy, in an emergency, the patient may not be able to communicate or provide this information to health care workers.

Recommendation 2

Ensure that instructions are written in a clear and understandable way (for both patients and health care providers)

Rationale: This information may be read by people unfamiliar with the medication or equipment, in a time-pressured or stressful situation. Hospitals should consider working with human factors experts to develop the above-noted warnings and labels to give prominence to critical information and optimize readability and comprehension of information in an emergency.

Recommendation 3

Advise patients to carry their spare pump and additional supplies whenever they leave home.

Rationale: If a malfunction occurs, there may not be sufficient time to return home for additional supplies. In this particular program, patients are provided with two pumps, which are rotated every three days. Current patient information advises patients to bring their pump and other supplies with them if they are going to hospital and anticipate possible admission. Additional measures might include providing patients with a travel bag for spare supplies that is labeled to clearly indicate that it contains critical medical supplies.

Recommendation 4

Consider providing emergency information for the community-based drug infusion program on the Hospital website.

Rationale: Posting key information (such as emergency contact numbers) on the hospital's website would provide a failsafe mechanism in addition to the measures described above.

Recommendation 5

Consider conducting a prospective risk assessment to ensure the processes work as intended.

Rationale: Utilizing methods such as a Failure Mode Effects Analysis or a simulation exercise allows the program / hospital to test the emergency processes in order to ensure that they indeed provide the intended and necessary level of support to patients and health care providers.

Case 2010-08

Date of Death: March 29, 2009

Age: 46 years

Sex: Female

OCC File number: 2009-5098

History:

The decedent was a 46 year old woman with a history of chronic pain due to reflex sympathetic dystrophy resulting from a remote knee injury due to a fall. The decedent's chronic pain had been treated with parenteral narcotics, most recently via a subclavian "Port-A-Cath" access line. The decedent was also obese, with an estimated weight of approximately 135 kg.

On March 21, 2009, she was admitted to hospital with fever and suspected line sepsis (subsequently determined to be due to methacillin-sensitive *Staphylococcus aureus*).

The decedent had a history of prior upper extremity venous thrombosis due to previous peripherally inserted central catheter (PICC) line in 2006, and had apparently been maintained on low molecular weight heparin (LMWH) injections since then. A question was raised in the medical notes as to why the deceased had been maintained on LMWH so long after the previous episode of thrombosis. She was switched from dalteparin 15,000 units subcutaneous daily (home therapy) to enoxiparin 120 mg twice daily on admission to hospital (presumably as enoxiparin was the formulary LWMH at the admitting hospital). Of note, her platelets were normal on admission to hospital.

On March 23, the medical record indicates a plan for General Surgery to see the decedent and arrange for removal of the Port-A-Cath as the source of her line sepsis. There are subsequently daily notes to this effect; however, the Port-A-Cath was not removed prior to her death.

On March 27 the decedent is noted to complain of left lower quadrant abdominal pain. She was examined by the physician; no investigations were ordered. The next day, she developed signs of shock. She was subsequently found to have massive retroperitoneal hemorrhage demonstrated on computerized tomography scanning. She developed multi-system organ failure secondary to shock, and died in the ICU on March 29, 2009.

Post Mortem:

Post-mortem examination revealed a large retroperitoneal hematoma (2600 mL), as well as signs of portal vein thrombosis.

Cause and Manner of Death:

Cause of Death:

- a. Complications of retroperitoneal hemorrhage, due to
- b. Anticoagulation therapy, for the treatment of
- c. Complications of remote knee injury, due to
- d. Fall

Contributing factors:

- a. Portal Vein Thrombosis with Hepatic Necrosis; Reflex Sympathetic Dystrophy; Chronic Pain Syndrome

Manner of Death: Accident

Discussion:

The following issues were identified in this review:

1. The treating internist seemed to lack awareness of retroperitoneal hematoma as complication of LMWH therapy.

Comments: The thromboembolic expert consulted by the Patient Safety Review Committee (PSRC) felt that it was reasonable to conclude that the LMWH contributed to the patient's retroperitoneal hemorrhage, but felt that this was a relatively uncommon presentation in someone on LMWH. Further, LMWH cannot be "reversed" as could other forms of anticoagulation, and thus even if the complication had been identified sooner, the outcome may have been the same.

In discussion at the PSRC, it was identified that there have been previous cases reviewed involving fatal retroperitoneal hemorrhage in individuals on anticoagulant therapy. It was felt that there is an opportunity to raise awareness of this uncommon,

yet significant complication of anticoagulation through a submission for publication by the College of Physicians and Surgeons of Ontario.

2. The deceased was switched from dalteparin to enoxiparin on admission (based on the hospital's formulary). Were the doses and/or effectiveness equivalent, and could this substitution have been a contributing factor in the resulting bleed?

Comments: The deceased's dalteparin dose (from home) was approximately half of a full therapeutic dose. The enoxiparin dose was somewhat higher relative to the dalteparin dose, but still slightly less than a full treatment dose. If the deceased had renal insufficiency, this could have been problematic in the setting of LMWH use, and this effect would be more so for enoxiparin than for dalteparin. However, the deceased's renal function was normal at the time of her retroperitoneal hemorrhage. This was therefore not felt to have contributed to the death, and did not represent a system issue that required recommendations.

3. A decision had been made (predating the deceased's terminal admission) to maintain the deceased on LMWH three years after an episode of septic thrombosis while a PICC line was in situ. Are there established guidelines / best practice to guide whether or not ongoing anticoagulation was warranted in this situation?

Comments: The thromboembolic expert consulted by the PSRC stated that a PICC line is more likely to result in line-related DVT than a Port-A-Cath. His interpretation was that, notwithstanding this, someone must have felt that the deceased was at increased risk of central venous catheter (CVC)-related thrombosis with her Port-A-Cath since she had a CVC-related DVT previously with her PICC line. While the expert felt that it may have been appropriate to have stopped the deceased's anticoagulation sooner after her episode of septic emboli, he indicated that there are no established guidelines / best practice to cover the circumstances of this case.

4. What was the rationale for the deceased receiving narcotics through an indwelling central venous line, rather than through other means of delivery (such as orally or transdermally), given the prior complication related to her venous access line?

Comments: The deceased was followed for her chronic pain by a family physician (CCFP-certified) with a special interest in pain management. She had been receiving extremely large doses of narcotic medications for pain control of reflex sympathetic dystrophy (regional pain syndrome):

- Hydromorphone 10 mg / hr IV via infusion pump / Port-A-Cath
- Fentanyl 100 mcg PRN for breakthrough

It is unclear from the notes how long the decedent had been on parenteral narcotics (although it appeared likely that this had been the case for several years, as she has had central access lines for this purpose for some time). Further, it was not clear as to the rationale for prolonged intravenous administration of narcotics in this case.

The PSRC was concerned about the pain management provided to the decedent. The PSRC felt that this was not a system issue, but rather one related to the particular prescribing practices of the physician involved.

Recommendation 1

That this case (and/or previous similar cases reviewed by the PSRC) be the focus of a “CPSO Dialogue” submission. The Chair of the PSRC should prepare this document and submit it to the CPSO. (*published in Volume 6, Issue 4, 2010.*)

Recommendation 2

That the Chair of the PSRC communicate to the Regional Supervising Coroner (RSC) overseeing the case the concerns of the Committee regarding the narcotic prescribing and pain management practices in this case, and to suggest that the RSC take whatever action he feels is appropriate in follow up.

Case 2010-09

Date of Death: April 6, 2010.

Age: 70 years

Sex: Female

OCC file: 2010-4300

History:

The deceased is a 70 year old female with chronic renal failure, receiving hemodialysis three times per week at Hospital A in Toronto.

On April 6, 2010, she had felt unwell at home prior to her dialysis with vomiting and diarrhea. She was brought by ambulance to Hospital A, where she was briefly assessed at the triage desk in the Emergency Department before being sent to the hemodialysis unit. In hemodialysis, she was assessed by the Nephrologist on duty for the shift, and it was determined that she was well enough to undergo her scheduled hemodialysis. This commenced at approximately 1700 hours. She was dialyzed while lying on a hospital bed, and was covered with multiple sheets and blankets due to complaints of being cold.

At approximately 2000 hours, the decedent was noted to unresponsive, and a large collection of blood was noted on, and adjacent to, her bed. It was noted that the “V-port” (one of two connections between the dialysis circuit and the decedent’s indwelling subclavian venous dialysis line), had become disconnected, and that blood was draining from the unattached port of the subclavian line. It was not entirely clear from the documentation whether or not an alarm had sounded from the dialysis machine, and/or whether staff had responded to an alarm. The decedent was found to be in cardiopulmonary arrest and a “Code Blue” was called.

The internist on call arrived and assumed the role of “Code Blue” leader. The internist was reportedly told of the decedent’s underlying medical history, and that she had arrested during dialysis. The internist was reportedly not told of the port disconnection, and was not aware of the hemorrhage that had occurred. [Apparently, much of the blood had been absorbed by the blankets and sheets that had covered the decedent (and

which had since been removed during resuscitation) and would reportedly not have been readily apparent to the internist arriving at the bedside.] The decedent was resuscitated and admitted to the Intensive Care Unit (ICU), where she arrested again. She was pronounced deceased at 2228 hours on April 6, 2010.

Because the internist was unaware of the port disconnection and subsequent hemorrhage, this information was not given to the physician in the ICU, and was not reflected in the death certificate. The family was also not advised at that time of the port disconnection. The Office of the Chief Coroner was not notified until April 13, 2010, after the Chief of Nephrology and senior hospital officials had become aware of the events surrounding the death.

Post Mortem:

A post mortem examination was not performed.

Cause and Manner of Death:

Cause of Death:

- a. Hemorrhagic shock, due to
- b. Dialysis machine port disconnection (V-port) during dialysis due to
- c. Chronic renal failure

Contributing factors:

- a. Cirrhosis; Hepatitis B and C; Non-insulin-dependent diabetes mellitus; hypertension

Manner of Death: Accident

Discussion:

Testing of the dialysis machine was performed by both the hospital's Biomedical Engineering department, and by an external third party. Test results indicate that the machine appears to have been functioning normally. The report also contained a reference from an American study which examined similar incidents and potential measures to prevent and/or detect such disconnections.

From the testing report and other reference material, the following information was obtained:

- The two limbs of the dialysis circuit (the "arterial" or "A-line" and "venous" or "V-line"), carry blood between the patient and the dialysis machine.
- Despite the designation of "A" and "V", both attach to different ports on a central venous catheter; there is no connection between the dialysis machine and the patient's arterial circulation.

- The V-line (colour-coded blue) carries blood from the dialysis machine to the patient. A pressure monitor attached to this line typically detects pressure more than 50 mm Hg above or below the venous pressure measured in the system at baseline. An alarm is triggered if these thresholds are exceeded.
- In some situations, a disconnection in the V-line may not result in an immediate decrease in pressure that is sufficient to exceed this threshold and trigger an alarm. An example of this is when a partial disconnection occurs, but some resistance is maintained in the V-line. In such cases, an alarm may not be triggered until a significant amount of blood loss has occurred.
- It is well-described in the literature that, because of the above, venous pressure monitors in dialysis machines cannot be relied upon alone for early detection of a venous line disconnection⁶.

The hospital commenced a Quality of Care Review immediately upon becoming aware of the incident, and had already implemented a number of measures aimed at preventing a similar occurrence at the time of the PSRC review.

At the suggestion of the Regional Supervising Coroner, a report was also made by the hospital to Health Canada regarding the incident.

The hospital's professional practice leader for nursing has reviewed the nursing care and documentation surrounding the incident. The conclusion of this review was that some of the charting surrounding the incident did not meet the standard of care. The hospital has subsequently reported to the Regional Supervising Coroner that appropriate measures have been taken to address these issues. The nursing care otherwise was felt by the hospital to have met the standard of care.

To the Ontario Hospital Association, the Registered Nurses Association of Ontario, and the Ontario Medical Association Section on Nephrology:

Recommendation 1

Healthcare providers involved in hemodialysis should be aware that a venous line disconnection during dialysis may not trigger an alarm until significant blood loss has occurred. Because of this:

- a. Access sites and connections on the dialysis circuit should be visible at all times, and must be checked frequently during dialysis. Clinicians should be especially vigilant for disconnections in patients with altered mental status and/or decreased level of consciousness.
- b. In addition to frequent visual checking of connections, monitoring protocols should require frequent clinical assessment of the patient including

⁶ Patient Safety Advisory – Bleeding Episodes During Dialysis. Veteran's Health Administration Warning System advisory #AD09-02, October 21, 2008. http://www.patientsafety.gov/alerts/BleedingEpisodes_DuringDialysisAD09-02.pdf Accessed July 29, 2010.

documentation of vital signs, and the frequency of such assessments should reflect the physical condition of the patient. Such protocols should include criteria to notify the most responsible physician of significant changes in vital signs or patient condition.

To the Hospital:

Recommendation 2

The hospital should undertake a Failure Mode Effects Analysis (FMEA) for patients receiving hemodialysis, with a view to identify potential risks and steps that can be taken to mitigate these risks.

Recommendation 3

The hospital should review their internal processes and practices related to communication during resuscitation and at transitions of care for critically-ill patients.

To the Regional Supervising Coroner:

Recommendation 4

The Regional Supervising Coroner should conduct a Regional Coroner's Review with the hospital. This review should focus on concerns identified by the Patient Safety Review Committee related to:

- a. Delays in reporting of this sentinel event, both internally within the hospital, and to the Office of the Chief Coroner.
- b. Gaps in communication that took place at the time of the resuscitation that resulted in the Code Blue leader being unaware of the root cause of the patient's cardiac arrest.
- c. The outcome of the hospital's Quality of Care Review and subsequent implementation of changes to policy and practice.

APPENDIX A

PATIENT SAFETY REVIEW COMMITTEE

Summary of Cases and Recommendations 2005-2009

Case #	Brief Summary of Case	Recommendations
2005-01	This 65 year old male died on post-operative day 6 following aortic aneurysm repair. Prior to his death, he had a significant nosebleed and a period of unexplained hypotension; there were issues identified with communication between staff surrounding these events. He subsequently became lethargic, and was found to have an intracerebral hemorrhage which ultimately caused his death. There was evidence of supratherapeutic anticoagulation with elevated partial thromboplastin time (PTT). Root cause analysis revealed that it is likely that the decedent's central line was flushed with high-concentration heparin solution (1000 U/mL or 10000 U/mL) rather than with the intended 100 U/mL solution	1. Heparin 10000U/mL concentration should be removed from hospital wards. Any heparin of this concentration should be locked in a narcotic cupboard and strictly controlled. 2. Hospitals should consider the use of pre-mixed bags for heparin administration (flushing of lines) wherever possible. 3. Central lines should be removed at the earliest possible time. It is recommended that a medical directive be developed stating that the physician must justify the continuance of the line or the line is automatically removed at a specified point in time, similar to policies regarding antibiotic discontinuation. Hospitals should review evidence-based guidelines regarding optimum time for removal. It is known that central intravenous line insertion and maintenance represent significant opportunities to enhance patient safety. 4. Where possible, the hospital should employ central venous catheters which can be flushed with saline. These catheters are widely available and cost should not be a barrier to such an implementation. 5. The Chief of Staff of the hospital and the Chief Nursing Officer should emphasize to staff that significant changes in a patient's condition (e.g. hypotension) require timely and direct physician assessment. It is recommended that the hospital undertake a review of the team environment on this unit in response to concerns identified by the family.

		6. The hospital should examine whether the team climate on the ward is conducive or not to nursing staff reporting concerns to physicians. The committee is aware of situations elsewhere wherein nurses may be fearful of physician reactions when they notify them of important issues on wards. In this case, based on the review of records, the committee had difficulty discerning reasons that the physician did not attend a hypotensive, bleeding patient. 7. Medication errors and other errors should always be considered as part of the differential diagnosis when working up adverse events including an unknown source of bleeding. This fact should be taught to staff as part of a hospital-wide educational initiative on patient safety.
2005-02	This 48 year old man was transported to hospital in the evening after being found unresponsive in an apartment. Early the next morning, a Respiratory Therapist (RT) was paged to intubate him in the Emergency Department when he developed increasing respiratory distress and neurological deterioration. Following successful intubation, the RT connected the endotracheal tube (ETT) to the ventilator with a mechanical airway consisting of the ETT, an ETT connector, a swivel elbow, a filter and a piece of corrugated tubing, which was connected to the ventilator. The decedent developed increasing respiratory distress and bradycardia, and died shortly following intubation.	1. The hospital reviewed this case and the procedures to be followed when an intubated patient appears to have an obstructed airway, including the most appropriate person to intubate a patient who still has vital signs. 2. The hospital responded in writing, advising that they had reviewed the case and that the following measures had been taken to prevent similar problems in the future: • The swivel elbow connector encased in a plastic bag will no longer be used at the hospital. • Disposable units between the endotracheal tube and ventilator will now be used. • Educational sessions were held for the RT staff at the hospital. • This case and its ramifications has been the subject of educational rounds at the Department of Anaesthesia and shared with the Chief of Emergency Medicine and

	After the patient was pronounced dead, the RT observed a thin piece of plastic between the swivel elbow and the ETT connector, which had obstructed the patient's mechanical airway and prevented him from being ventilated. It was determined that a piece of the plastic bag in which the swivel elbow was packaged tore away when the swivel elbow was removed from it, and became caught on the end of the swivel elbow at its attachment to the ETT connector.	ICU physicians. 3. This case should be brought to the attention of The Canadian Society of Respiratory Therapists, so that it may serve as an educational opportunity for other RTs. 4. The Executive Director of the Canadian Society of Respiratory Therapists responded in writing, advising that a summary of this case (without any identifying information) would be published in the issue of its journal to be published on February 28, 2006. 5. This case should be discussed with the manufacturer of the swivel elbow, asking them to consider packaging it in tear away or peel away material to decrease the likelihood of similar problems in the futures. 6. The manufacturer responded in writing, advising that they had reviewed the matter. The manufacturer advised that over 40,000 similar connectors packaged in the same manner had been sold, and that there was no known previous adverse incident associated with the use or packaging of these connectors. The manufacturer found no basis to suggest that the connector, or the packaging of the connector, is inappropriate for its intended use. It has no plans to change the packaging for the elbow connector. 7. This case be discussed with the Medical Devices Branch of Health Canada. 8. The Medical Devices Branch investigated this matter, and concluded that there was no basis to suggest that the connector, or the packaging for the connector, was inappropriate for its intended use.
2005-03	A 78 year-old man, resident at a long term care home, was receiving outpatient hemodialysis three times per week through a tunneled subclavian dialysis	1. Hospitals that insert central lines should develop and provide clear care policies and procedures related to the care of the catheter, including management of

	catheter. Approximately one month after starting outpatient hemodialysis, the patient was found in his nursing home bed with extensive bleeding from the catheter site. The catheter had been torn. Pressure was applied to the wound by nursing staff. Emergency medical services (EMS) attended the patient and continued to apply pressure. When the patient arrived at hospital, he had developed significant respiratory distress. Air was observed to enter the catheter, after which the catheter was clamped. The patient developed progressive cardiorespiratory failure and died. No autopsy was performed due to strong family objections. The cause of death was determined to be probable air embolism.	catheter-related emergencies. 2. Nursing homes that provide care for patients with central lines must train staff on appropriate catheter care and management of catheter related emergencies. 3. EMS personnel should be trained on management of catheter emergencies. 4. Catheter emergency kits should be stored in the patient's room and at the nursing station, and should be available to EMS personnel. This kit should include a checklist of procedures, clamps, and barrier dressings
2005-04	A 59 year old female had undergone an aortic and mitral valve replacement with St. Jude mechanical prostheses for rheumatic valvular heart disease 12 years prior to her death. She died as the result of cardiogenic shock due to severe aortic stenosis and acute myocardial infarction due to failure of the aortic valve prosthesis. Fibrous tissue had formed on the aortic valve prosthesis, causing it to be fixed in a semi-open position.	1. That Hospital A's Chief Executive Officer, Chief of Staff, Vice-President of Patient Care and Chief Nursing Officer, Professional Practice Leader and Chief of Internal Medicine receive a copy of this report. 2. That Hospital A conduct a quality of care review under the Quality of Care Improvement Protection Act. (QCIPA) 3. That the quality of care review should have access to this report and consider the following recommendations; • Developing standard hospital orders for the notification of the most responsible physician of critically

	On review of the decedent's records, it was found that there were a number of opportunities to improve upon her care, and potentially to have identified and managed this complication differently. The areas of concern included: Documentation and communication issues related to her emergency department care and subsequent admission Lack of effective communication between the echocardiography technologist, interpreting echocardiography physician, and treating physician Issues with the timing, format, generation and communication of echocardiography reports	abnormal vital signs. - Revising its current emergency patient triage process to ensure that each patient's vital signs and CTAS score are recorded on the form upon which the emergency physician records his/her history. - Auditing its current provision of echocardiogram reporting to ensure compliance with the Guidelines for the Provision of Echocardiography in Canada recommendations of a Joint Cardiovascular Society and Canadian Echocardiography Consensus Panel, October 23, 2004. - Developing a policy whereby the time and date of interpretation and transcription of echocardiograms is recorded on the report. - That the Department of Cardiology and the Department of Pathology of Hospital A liaise and report to the manufacturer of the St. Jude prosthetic heart valve the clinical and pathological details of this patient so that the data base of valvular complications can be expanded for future reference. - Revise Section 3.2, "Components of the Report" to reflect the addition of the following study information: - The date and time the study was interpreted by the physician. - The date and time the study was transcribed. - The presence of any high risk findings and how these findings were communicated to the referring physician. - Communicate with the College of Physicians and Surgeons of Ontario and request that the College consider developing mandatory standards for the training of physicians seeking to interpret
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		echocardiograms consistent with the policies of the Provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Quebec. 7. Communicate with all hospitals and independent healthcare facilities; • Warning of the potential risks to patients when echocardiogram reports are not received in a timely manner. • Requesting that they perform quality assurance audits of the provision of echocardiography services to ensure compliance with the Guidelines for the Provision of Echocardiography in Canada, October 23, 2004. • Requesting that they immediately comply with the guidelines reporting requirements which recommend that: • Routine studies be available within 5 working days • Urgent studies or studies on hospital patients be available by the end of the day on which the examination was carried out • Unexpected high risk findings are communicated immediately by the interpreting physician to the referring physician.
2005-05	An 82 year old female, resident in a long term care home, underwent open reduction and internal fixation of a fractured hip sustained as the result of a fall. She received low molecular weight heparin injections for four weeks following the surgery for venous thromboembolism prophylaxis. Following this four-week period, the treating physician at the long term care home elected to	1. Through the use of journals and other educational forums, physicians should be educated as to the following: • Appropriate protocols for prophylaxis of venous thromboembolism, • Appropriate testing frequency and dosage adjustment, including indications for more frequent monitoring • The occult signs of bleeding in patients on warfarin, and • Common drug interactions with

	maintain the decedent on warfarin; the rationale for this decision was not clear. She was continued on her previous medications, which included ASA and diclofenac – misoprostol. Over the following 11 months, the decedent had a number of complications related to the warfarin therapy, including vaginal and rectal bleeding. One month prior to her death, she was treated with a macrolide antibiotic for a urinary tract infection. Her International Normalized Ratio (INR) rose to 12.7. Despite treatment with vitamin K, the decedent died of complications of her anticoagulation.	warfarin. - Hospitals, physicians and health care institutions should consider computer assisted prescribing programs for physicians. - Health care institutions, especially long term care facilities, should arrange adequate and regular review of medications by a qualified pharmacist, especially high-risk medications such as warfarin. - Discharge documents from hospitals should be clear about ongoing management plans and should be provided in a timely manner. - Health care institutions should ensure institutional protocols deal with circumstances where nurses' concerns are not allayed by physician response. - Case management of patients by Primary Care Nurse Practitioners should be considered in nursing homes. - Long-term care institutions should utilize regular patient reviews. These should be multidisciplinary with all key members of the health care team present. - Health care institutions should establish a non-threatening process for family members to follow if they are concerned about medical care in a long-term care institution.
2005-06	The decedent is a 22 year old female who was receiving treatment for a psychiatric illness which included an eating disorder. At the time of her death, among other medications, she was prescribed lamotrigine and lithium. She was documented to have episodes of hypokalemia, thought to be related to vomiting. She died suddenly, of an apparent cardiac arrhythmia.	- The importance of identifying a coordinating physician or “quarterback” for patients with complex medical problems should be emphasized by the College of Physicians and Surgeons of Ontario and included in their education materials that are sent to all members in the province. - The Ministry of Health and Long-Term Care, working with the Ontario Medical Association, should move ahead with initiatives to support hospitals, health

	While there was some controversy as to the role played by the combination of medications and hypokalemia, versus an underlying cardiac abnormality, a number of areas were identified where the care of the decedent could have been improved upon. These concerns included: Lack of coordination of care between providers Challenges with the sharing of relevant medical records Awareness and follow-up of potential adverse drug reactions	care clinics and all physicians with the development of electronic medical records as quickly as possible as one method to improve the timely and seamless transfer of medical information amongst medical care givers and other members of the health care team. 3. The Office of the Chief Coroner should establish a mechanism to ensure that all adverse drug reactions (or potential adverse drug reactions) identified during coroner's investigations be forwarded to Health Canada to ensure that Health Canada is receiving as much information as possible with respect to these real or potential adverse events. This would ideally be done at a central location to ensure completeness, consistency and uniformity of reporting. 4. The Office of the Chief Coroner should prepare a short paper highlighting the potential risks associated with Lithium in the setting of hypokalemia for publication in "Dialogue" a publication sent to all physicians in the Province of Ontario through the College of Physicians and Surgeons of Ontario.
2005-07	The decedent is a 94 year old female receiving palliative care in a long term care home for cancer. She had been ordered and was receiving, subcutaneous morphine 1 to 2mg every 3 to 4 hours as needed. Two hours prior to her death, the patient was given 10mg of morphine in error. The registered practical nurse drew up and administered 0.7 mL of morphine solution in instead of the correct dose of 0.07 mL as intended to deliver morphine 1 mg. The patient died shortly thereafter.	1. Ontario Drug Benefit purchasing guidelines should provide for more appropriate concentrations of morphine to be supplied to health corporations such as long term care facilities e.g. 2 mg/mL and 10mg/mL, which are easier to dilute and provide enough volume when diluted to allow accurate volume measurement. 2. Health corporations should post charts showing dose/administration of high alert medications. 3. Health corporations should require that independent and double checks should be used when high alert medications are being administered. 4. Agencies should have policies and

		procedures to ensure that they employ registered nursing staff members who are familiar / competent with high alert medications and how to administer them.
2006-01	The decedent was an 83 year old male with coronary artery disease who was admitted for coronary artery bypass graft surgery. He was taken to the operating room where central lines were placed in preparation for surgery. Shortly after placement of a pulmonary artery catheter, he developed massive hemoptysis. Despite resuscitation efforts, the decedent died on the operating table prior to the start of surgery. The cause of death was rupture of the pulmonary artery due to the pulmonary artery catheter.	No new recommendations.
2006-02	Special investigation for Province of New Brunswick.	No new recommendations.
2006-03	This 35 year old male presented to the emergency department (ED) with left shoulder pain following an episode of vomiting. He was also noted to be tachycardic, but was afebrile with a normal blood pressure. He had tenderness over the left chest wall which increased with movement of the left arm. An electrocardiogram and chest x-ray were both normal. He was assessed and discharged with analgesic for musculoskeletal pain. He returned to the ED four hours later with worsening pain, now severe. Some tenderness was again noted over the chest wall. Vital signs were normal except for mild tachycardia. Blood work, including a D-dimer, was ordered.	1. Emergency physicians and emergency nurses must be extra cautious in patients with abnormal vital signs. Their presence signals autonomic dysfunction which should prompt clinicians to determine the underlying cause. Abnormal vital signs call for close monitoring and thorough documentation. Should vital signs remain abnormal during an emergency department visit through to discharge, the cause should be apparent and should be expected to resolve. 2. Patients who have an unusual pattern of presentation such as repeated visits to the Emergency Department with unexplained symptomatology and abnormal vital signs within a short period of time, should be regarded as high-alert patients. In such situations, clinicians should be reminded of the increased potential for occult serious disease.

	Both the white blood cell count and the D-dimer were elevated. A computerized tomography (CT) scan of the chest was performed. This was negative for pulmonary embolus and the aorta was normal. The radiologist's impression on the CT report was: "left pectoralis minor tear, small left pleural effusion with small amount of left base atelectasis/pneumonia." He was discharged home with analgesia. The decedent returned to the ED a few hours later with respiratory distress, cyanosis and an oxygen saturation of 70% on room air. He suffered a cardiac arrest shortly after arrival. Post mortem examination determined the cause of death to be sepsis due to necrotizing fasciitis due to Group A Streptococcus.	3. Transfer of care is well recognized as a high risk event. Clinicians need to be mindful of the potential risks and caution should be exercised at handover periods. An appropriate reassessment of each transferred patient should occur at a fitting time after transfer of care. 4. Clinicians should be reminded of the importance of pain that is out of proportion to physical findings. This can be a harbinger of serious conditions that lack other findings early in their course (e.g. vascular emergencies, compartment syndromes and necrotizing fasciitis). 5. Radiologists need to be careful to consider a broad differential diagnosis in interpreting films. This is especially true in situations where there are unusual findings and when the findings are inconsistent with the clinical scenario. In unusual situations, a direct discussion with a clinician can be very helpful in the diagnostic process. The most serious possibilities for each radiological finding must be considered.
2006-04	This 79 year old male died following surgery for a repeat aortic valve replacement and coronary bypass grafting. About 30 minutes into the procedure, while on extracorporeal circulation, it was noted that there was decreased arterial pump flow, decreased mean arterial pressure followed by decreased venous oxygen saturation. The flow could not be increased by adjustment of the centrifugal pump or by switching to a hand pump. Therefore, the decision was made to switch over to a roller pump. The period of absent flow that occurred during this time was	1. Platelets should be reduced prior to cardiac bypass surgery to reduce the likelihood of HPE. 2. The absence of documentation of the critical events made analysis of this case more difficult. It is recommended that critical incidents be documented in sufficient detail in the health record to allow later reviewers to adequately understand events. 3. The manufacturer and the cardiac surgical team should review and consider the likelihood of the venous reservoir level dropping too low. Strategies both from the hardware and personnel to prevent this occurring should be developed.

	documented as between four and seven minutes. At the time that the patient was placed back on extracorporeal circulation, air was observed entering the aorta from the arterial line. A number of techniques were employed in an effort to minimize the presumed embolic event, but the patient unfortunately never regained consciousness and died thirteen days later in the ICU. There was some disagreement by experts who analyzed this case as to the root cause(s). One theory involved a phenomenon called "High Pressure Excursion" (HPE) which occurs when the fine pores in the membrane oxygenator used to oxygenate blood in the heart-lung machine become clogged with aggregates of protein and platelets. The decedent's platelets were elevated pre-operatively, which would contribute to the development of HPE. Another theory involved the entrainment of air into the circuit due to a decreased level of blood in the venous reservoir of the bypass machine.	4. The cardiac surgical multi-disciplinary team should review this report, and develop a checklist for dealing with unexpected low-flow states which occur during extracorporeal circulation. This checklist should include key steps such as the sequence of checks, the formation of an AV loop, and surveillance for and prevention of air embolization. It is recognized that these will all be very elementary and familiar to these personnel. However, the use of the checklist may prevent omission of key steps or the development of avoidable complications. 5. There appears to have been a failure of the critical incident reporting system in this case from OR personnel to senior administrators at the hospital. This case occurred during a holiday period, which may have contributed. The hospital should consider how such reporting can be ensured. 6. The extracorporeal circuit should be set up so as to "stop-link" the cardioplegia pump to the main arterial pump to prevent negative pressure accumulation when the arterial pump is not operating
2006-05	This 56 year old woman presented to the emergency department with severe abdominal pain, back pain and vomiting. Investigations included blood work (essentially normal apart from a mildly elevated white blood cell count), chest and abdominal x-rays (interpreted by the emergency physician as normal) and an abdominal ultrasound (negative for abdominal aortic aneurysm).	1. The medical and administrative staff of Hospital A must set reasonable expectations regarding the timing of radiological reports and opinions when the PACS system is used so as to ensure optimal patient care outcomes. 2. The action plan identified by the Quality of Care Committee at Hospital A be followed and an urgent completion date for these actions be identified. Further, there must be review and acceptance by the medical staff at Hospital A of this

	She was admitted to hospital and treated with narcotic analgesic and antiemetics. She seemed somewhat improved and was discharged home the next day. She reportedly experienced increasing abdominal pain at home during the day and died at home. Post mortem examination showed evidence of necrotic small bowel due to torsion from adhesions resulting from previous surgery. The admission radiographs were interpreted by a radiologist (working at another facility, and receiving the images electronically) and reported some 56 hours after they were obtained. The radiologist noted evidence of mechanical bowel obstruction. The radiologist did not inform the treating physician of these findings (other than via the dictated radiology report).	committee report. 3. The Medical Advisory Committee review the physician process for admission of inpatients to the Hospital A, specifically with respect to its compliance with the Public Hospitals Act of Ontario in the area of documentation of a patient history, physical examination and treatment plan. 4. The medical and nursing staff will review and make recommendations regarding the purpose and intent of late entries to the health record (if any) for any patient admitted to Hospital A.
2007-01 and 2007-16	The Committee reviewed two cases of post operative deaths following elective surgery. Both individuals underwent relatively minor operative procedures and died about a week postoperatively. Through examination of the medical records performance of post mortem examinations, both decedents were recognized as having significant medical co-morbidities which were not fully appreciated preoperatively. In	1. It is recommended that a system be developed to identify patients with significant anesthesia risk factors. 2. Patients with significant anesthesia risk factors should be seen pre-operatively and evaluated appropriately. 3. Patients who have significant risk factors should have a written anesthesia plan which would include the plan for post-operative pain management both in the hospital and on return to the community. 4. The post-operative pain management plan should be communicated to the family and the family physician,

	both cases, the investigating coroner noted an apparent lack of significant preoperative screening and written protocols.	especially in cases where the patient may be at risk, i.e., patients with narcolepsy, obesity, sleep apnea. 5. Ongoing continuing medical education for community anesthetists regarding co-existing conditions that place patients at higher risk for anesthesia and post-operative recoveries.
2007-02	This is a 5 month-old child who had been diagnosed with a congenital inguinal hernia at two months of age. A surgical specialist assessed the child, and indicated that he should be followed up for the hernia after three months. It does not appear that a follow up appointment was booked at that time. Approximately three months later, the child was seen in a walk-in clinic for a fever and vomiting. There is no documentation of examination of the abdomen, and no mention of a hernia at the time of that visit. The next day, the child's condition worsened and he became vital signs absent at home. Post mortem examination determined the cause of death to be complications of an incarcerated inguinal hernia.	No recommendations from the Patient Safety Review Committee [NB: This case had previously been reviewed by the Pediatric Death Review Committee of the Office of the Chief Coroner]
2007-03	The decedent is an 87 year old male who was admitted to hospital with chest pain. An electrocardiogram in the emergency department was abnormal. Troponin I (cardiac enzyme) testing was reported as normal. Three days after admission, he suffered a cardiac arrest and died.	1. The Committee recommends that this incident be drawn to the attention of the Ontario Hospital Association so as to ensure other hospitals are aware of the potential risk.

	It was later identified that the initial troponin I level was, in fact, elevated at several times the normal value. This error in reporting occurred as a consequence of a modification in the Laboratory Information System on the same day as the decedent was admitted. This modification led to the system erroneously reporting abnormal troponin I tests as normal. This affected 13 patients, one of whom was the decedent; his was the only death. The hospital took a number of actions to prevent a similar situation occurring with future modifications to the laboratory system.	
2007-04	This 31 year old female had a history of chronic pain syndrome, panhypopituitarism and borderline personality disorder. She was receiving narcotic medications prescribed by two different providers and filled through different pharmacies. She was also receiving a number of other psychoactive and hormone replacement medications prescribed by other physicians. She died suddenly, with no anatomic cause of death and elevated (but non-fatal) levels of hydromorphone and diphenhydramine, as well as therapeutic levels of lorazepam and olanzapine.	1. The College of Pharmacists of Ontario, in collaboration with the Government of Canada and the Government of Ontario, should re-examine methods to enhance patient safety by sharing critical information about drugs with a high potential for abuse. Consideration should be given to maintaining a central computerized database of narcotic prescriptions so as to allow verification of all illicit / licit sources of narcotics for a given patient. 2. Pharmacists should be reminded of the importance of verifying the medication profile of all patients, particularly with respect to opiates. Patients should be asked if they are receiving opiates from any other source each time opiates are dispensed or prescribed.
2007-05	This 93 year old female was a resident in a long term care home (LTCH). She had a history of prior falls resulting in significant head	1. "M rails" should not be used on hospital beds. 2. Institutions that use "M rails" should

	injury, and was considered high-risk for further falls. Arrangements were made by her family for a hospital bed because of her care needs and the family requested side rails on the bed to prevent falls. The LTCH had a restraint-free policy and the side rails requested were considered to be restraints and therefore prohibited. However "M rails" were suggested as an alternative that the LTCH would accept. An "M rail" is a temporary, detachable hand-rail device that is anchored by a support piece that is placed between the mattress and box spring of a bed. It is described by the manufacturer as "an ergonomic leveraging system for people that experience difficulty sitting up and getting out of bed on their own." In other words, it acts as a grab-bar to help the user to pull themselves to sit up and stand; it is not designed to prevent the user from getting out of bed. In the early hours one morning, the woman was found deceased on the floor beside her bed, entrapped in the "M rail" with the mattress of the bed on top of her and her wrist wrapped in a strap that was used to secure the "M rail" to the bed frame. The cause of death was determined to be probable mechanical asphyxia.	ensure that their staff are educated and oriented to their installation and reattachment. 3. Manufacturer's instructions about use and installation of side rails should be communicated to purchasers and those leasing the equipment. 4. If a device is used to restrict freedom of movement or normal access to one's body, it must be considered a restraint and protocols for monitoring both the individual and the restraint need to be developed and followed. 5. If an institution has a restraint free policy and a resident requires restraint, restraint should be avoided. 6. Recommendations from professional mobility assessments should be acted on.
2007-06	The decedent is a 77 year old female who had a history of prior	1. The team at Hospital A should review the management of traumatic esophageal

	biliary surgery and who presented with ascending cholangitis. Attempts at endoscopic treatment at a tertiary care academic health science centre were complicated by esophageal perforation which was treated non-operatively. Following medical treatment for the esophageal perforation, she was discharged home, but presented to her community hospital a few days later with signs of sepsis. There was difficulty in contacting the original treating physician (and other physicians from that physician's clinical service) at the tertiary care centre. She was ultimately admitted to a different tertiary care centre in the same city, but died of complications of sepsis due to neck and mediastinal abscesses resulting from the initial esophageal perforation.	perforation. There are points to be learned from this case that could inform the development of a management algorithm. This is an uncommon problem that can be a complex issue with some specific nuances that need to be addressed. Most of the issues will not be addressed by Level 1 randomized controlled trials, making it difficult to develop a clinical practice guideline. 2. There should be a process for the admission and discharge of very ill patients from within the region. This is especially important for patients with complex problems that are best managed in the tertiary or quaternary center. Such a process should address but not be limited to the following issues: • Urgent vs. Non-urgent transport • Method of contact into the tertiary/quaternary center from outside • Responsibilities of sending and receiving parties • Handling of urgent referrals when resource limitations exist • Communication of critical information for discharge/transfer • Consistent chain of command, delegation of authority
2007-07	The deceased is a 66 year old male with a history of sciatica. He had been receiving codeine (Tylenol #4) from his family physician, which was not effective in controlling his pain. He returned to his family physician who prescribed hydromorphone (2 mg tablets, 1-2 every 4 hours as needed) and arranged for computerized tomography imaging	1. Transdermal fentanyl should not be available in ED stock (or night cupboard). If required for admitted patients in ED, transdermal fentanyl should only be provided from the pharmacy one dose at a time (e.g., q3 days) and only after a pharmacist review. (Fentanyl patch is never required urgently or in an emergency.) 2. Review and revise ED forms to provide appropriate prompts for practitioners to write a complete medication history

	of the spine. The next day, the decedent went to the emergency department (ED) with severe back pain. He was started on a transdermal fentanyl patch (75 micrograms per hour) in the ED and discharged with a prescription for same, and instructions to continue his pain medications. Three days later, he returned to his family physician who increased his transdermal fentanyl to 125 micrograms per hour, with instructions to continue the hydromorphone for breakthrough pain. He was seen again the next day by the family physician and was noted to have some improvement in his pain. The following day, he was found vital signs absent at home; resuscitation was un-successful. The cause of death was determined to be fentanyl toxicity.	(drug, dose, frequency and last dose). 3. Review and revise ED forms to provide sufficient space for prescribers to write medication orders and for practitioners to document their administration. 4. Enhance communication between the hospital and family physicians. Consider providing a copy of the ED record to the family physician directly or to the patient. 5. Financially support the implementation of a 24-hour telephone hotline for health care practitioners to access for questions or assistance in the management of transdermal fentanyl (and other opioids). 6. Include a checklist for initiation and titration of transdermal fentanyl in the product monograph, all product packages and on an easily accessed web-site (similar principle to a checklist a pilot would use prior to take-off). Alternatively, an algorithm would be helpful. 7. Review and revise the equianalgesic charts provided for transdermal fentanyl to highlight the reference to the chronic dose equianalgesic potency. The chronic dose conversion factor for morphine should be prominent in the eqianalgesic potency table in the transdermal fentanyl product monograph – transdermal fentanyl is only indicated in management of chronic pain and in opioid tolerant patients. 8. Human factors engineering expertise is recommended to enhance the ease of use of the equianalgesic chart for the purpose of conversion to oral morphine equivalence and to address the need to reduce the number of calculation steps (e.g., potentially following a T-chart format as provided to convert oral morphine dose to transdermal fentanyl dose), and to ultimately make the chart intuitive (i.e., reduce the level of training needed to use the chart).
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		9. Include additional information in the transdermal fentanyl product monograph to assist practitioners to assess opioid tolerance. 10. Implement computerized alerts in pharmacy information systems for any new order or titration order for transdermal fentanyl that is greater than 25 mcg/hour, to prompt pharmacists to confirm the appropriateness of the fentanyl patch order (i.e. for new prescriptions, whether the patient is opioid tolerant...etc.). [NOTE: Other automated systems such as computerized order entry should at minimum have alerts for prescribers.] 11. Consider sharing this case widely with healthcare professionals for the purposes of learning and preventing a recurrence.
2007-08	A 43 year old male with a history of schizoaffective disorder was admitted to the inpatient psychiatry service at an academic health science centre. On admission, he was on several medications which included olanzapine, ciprofloxacin and fluconazole. Neither a physical examination nor an electrocardiogram was performed at the time of hospital admission. Nine days after admission, he was found deceased in his bed. Post mortem examination did not identify an anatomic cause of death. Toxicology testing showed an elevated (but not fatal) level of olanzapine (although it was noted that olanzapine degrades after death, and the actual ante-mortem level may have been higher than that measured in post mortem blood samples).	1. Written communication about this incident to health care professionals might be useful. Despite the fact that there is no conclusive evidence that the combination of ciprofloxacin and olanzapine (or fluconazole and olanzapine) contributed to this patient's death, it would be useful to inform health care professionals about the potential for increased olanzapine levels with drugs such as ciprofloxacin and fluconazole. Increased olanzapine levels can increase the risk of side effects such as sedation, orthostatic hypotension and, possibly (though not proven) increase the QTc interval (as indicated by case reports in the literature). 2. It should be recommended that all pharmacies (in community and hospital settings) have a psychiatric pharmacy reference textbook (such as the Clinical Handbook of Psychotropic Drugs) because it can provide information that might not appear on computerized drug-interaction systems. 3. There should be communication by this

	Expert review of the case concluded that death likely resulted from a cardiac arrhythmia. Both fluconazole and ciprofloxacin are known to increase the concentration of olanzapine. In addition, olanzapine, fluconazole and ciprofloxacin are all known to increase the QT interval on the electrocardiogram, and therefore predispose to lethal arrhythmias.	Committee with manufacturers of computerized drug-interaction detection systems recommending that the ciprofloxacin-olanzapine interaction be added to their databases (if not already present). - Where a patient in an institutional setting is receiving multiple medications, a pharmacist should review the medications with a view to detecting and preventing adverse interactions between the medications. - Mental health professionals, e.g. the Canadian Psychiatric Association, should give consideration to the development of guidelines for the assessment and surveillance of cardiac side effects in patients who are prescribed novel antipsychotic medications such as olanzapine and clozapine. Such guidelines should also refer to potential drug-drug interactions when these medications are used.
2007-09	A 67 year old woman was admitted to hospital with an acute ST-elevation myocardial infarction which was treated with thrombolysis using tenecteplase in the emergency department (ED). As part of thrombolytic therapy, she also received low molecular weight heparin (fondaparinux). She was intubated and had a temporary pacemaker inserted before transfer to the Coronary Care Unit (CCU). In the CCU, the treating physician initiated intravenous heparin. It does not appear that the physician was aware of fondaparinux having been given in the ED. She subsequently developed bleeding in her oropharynx, and her partial thromboplastin time (PTT) was	- Consideration should be given to requiring the mandatory use of preprinted orders whenever appropriate, and specifically in the case of complex thrombolytic protocols. Preprinted orders serve to (a) standardize complex treatment protocols, thus reducing unnecessary variability in their application (b) ensure adherence to complex clinical treatment guidelines, resulting in reduced unintentional deviations, and (c) provide an easily accessible record of critical pharmacologic administration. - Consideration should be given to formalizing the handover process between all units and between all care providers in this hospital, with specific consideration given to the transfer of patients from the Emergency Department to Critical Care units. This can and should include consideration of formal handover tools, such as mnemonic aids,

	noted to be elevated. A computerized tomography (CT) scan of the head showed an intracerebral hemorrhage. Her condition continued to deteriorate and she was pronounced brain dead.	and of clear documentation of all details in the chart of patient particulars, including medications received and confirmation of the use of preprinted and standardized protocols.
2007-10	A 55 year old male was admitted as a voluntary patient to the psychiatry inpatient service of a hospital. He had a history of chronic pain, for which he used large amount of morphine sulphate which he had reportedly been tapering prior to admission. He was admitted with an exacerbation of chronic pain and possible suicidal ideation. On the day prior to his planned discharge, the decedent was noted by other patients to have a large quantity of 100 mg tablets of morphine sulphate in his possession. They noted that he appeared to be showing signs of toxicity. At one point during the day, he was allowed to leave the unit on a grounds pass. At 0440 hours, staff performing routine rounds found him vital signs absent in his bed. Post mortem determined the cause of death to be an acute mixed drug overdose (morphine and amitriptyline).	Recommendations made from Regional Coroner's Review 1. Development of a complex case management program for use with particularly challenging mental health patients. 2. Implementation of point of care drug screen urine testing with immediate results to minimize contraband drug use within the unit. 3. Development of a "Safety is Up to Us" type of program that could be included in the inpatient brochure to make inpatients aware that contraband such as weapons, illicit drugs, as well as smoking and inappropriate behaviour, should and could be identified by the patients and reported to staff while remaining totally confidential. The program could be introduced by nursing as part of an admission procedure. 4. Increased in-house training/education with respect to withdrawal/intoxication symptomatology. 5. Development of a strict policy for dealing with contraband where there is reasonable grounds to believe such exists. 6. Implementation of an education program for staff with respect to psychodynamic transference.
2007-11	The decedent is a 68 year old female, diagnosed with gastric cancer, who underwent surgery consisting of a total gastrectomy, Roux-en-Y, and a feeding	Information Not Available

	jejunostomy. She was initially managed in the ICU and then transferred to the ward on post-op day 3. The next day, she became more ill and was again transferred to the ICU. She became progressively hypoxic with signs of Acute Respiratory Distress Syndrome, and following discussion with the family, was extubated. Post mortem examination determined the cause of death to be "Acute pancreatitis complicating total gastrectomy for gastric carcinoma."	
2007-12	The decedent is a 93 year old female with a history of atrial fibrillation. She was admitted to hospital from her long term care home for treatment of a femoral arterial embolus. At that time, she was started on warfarin therapy. One month later, she was treated with antibiotics (moxifloxacin and metronidazole) for pneumonia. She developed a large, spontaneous hemorrhage into the soft tissues of her neck. Her International Normalized Ratio (INR) was found to be greater than 10. She died as the result of a cardiac event, thought to have been precipitated by the neck hemorrhage and resulting anemia.	This case was felt to raise similar issues to a previous case [2005-05] reviewed by the Committee. The previous case report was published in the College of Physicians and Surgeons of Ontario "Dialogue". No new recommendations.
2007-13	The decedent is a 68 year old male who sustained a knee (tibial plateau) fracture. Surgical repair was performed four days later. No anticoagulation was administered	1. The committee endorses the hospital's plan to develop an automatic referral process for assessment of patients who might require thromboprophylaxis. It is recognized that the reality of a smaller

	between the date of injury and the surgery. The day after surgery, low molecular weight heparin and warfarin were initiated for thromboprophylaxis. Later that day, the decedent was noted to have slurred speech. Anticoagulants were held, pending computerized tomography (CT) scan the following day. This showed evidence of an ischemic stroke. Anticoagulation was re-started. Approximately two weeks post-operatively, the decedent collapsed suddenly and was found to be vital signs absent. Resuscitation was unsuccessful. Post mortem examination determined the cause of death to be a massive pulmonary embolism.	community Hospital is that it may not be possible to dedicate a full-time practitioner to this task but automatic referral to a knowledgeable individual such as an internist with an interest in thrombosis would likely result in more appropriate thromboprophylaxis application. 2. The hospital should review its A, B and C pre-operative categories to ensure that cases are appropriately triaged. Further, the committee believes no patient should wait longer than the 48 hours recommended by the Expert Panel on Trauma with a closed lower extremity fracture, including hip fracture. C category cases should be upgraded to B once the 48-hour mark has been reached.
2007-14	The decedent is a 56 year old female with an extensive past medical history which included chronic obstructive pulmonary disease (COPD), hypertension, diabetes and recurrent deep venous thromboses. She presented to hospital with shortness of breath with bilateral lung infiltrates. She was admitted to the medical short-stay unit and started on therapy for pneumonia and exacerbation of COPD; investigations for venous thromboembolic disease were negative.	1. Consideration should be given to developing a policy for when EIU is used for care of inpatients and the expectation for regular reassessment of options to limit this. 2. Consideration should be given to ensuring there is understanding at the level of ED charge nurse and ED manager of patients in this area and their associated care needs and whether staffing needs to be adjusted to accommodate for higher care needs. This information should be considered in developing the staffing assignments. 3. Assessment of primary nurse's knowledge in relation to this patient condition is recommended. Consideration should be given to providing a case presentation of this and

	When the decedent developed a fever and worsening respiratory status on the short stay unit, she was moved to the Emergency Isolation Unit (EIU; an 8-bed negative pressure isolation unit adjacent to the Emergency Department). Here her condition continued to worsen over the next approximately 48 hours. She required 50% oxygen in order to maintain her oxygen saturation. She was subsequently found vital signs absent in her bed, and resuscitation was unsuccessful. On review of the case, issues were identified with respect to: Use of the EIU as an isolation unit for inpatients (which was not its intended use) The level of staffing and experience of nursing staff in the EIU relative to the severity of illness of patients treated there Apparent lack of appreciation and communication of the decedent's worsening condition to the responsible physician and/or charge nurse.	similar cases to educate staff of the significance of such clinical deterioration and appropriate actions to take. - Staff should be educated of the expectation that the most responsible physician should be advised expeditiously of significant clinical changes. In addition, there should be protocol to advise the charge nurse of significant clinical changes. - Nurses need to be encouraged to express concerns to leadership when care needs are expected to exceed their capacity and to seek direction and further support. - Experienced nurses who are working with novice nurses should be encouraged to be directive in making suggestions in situations where patient condition is deteriorating. If action is not proceeding as expected, in the patient interest, they should be encouraged escalate concerns to the charge nurse or others in leadership. - Reassessment of the equipment located in this area and formal identification of the patient conditions that are appropriate and those that are not appropriate for the EIU is recommended.
2007-15	This 78 year old male was admitted to an inpatient palliative care service with metastatic melanoma. Part of the therapeutic intervention was pain management which included narcotic medications. The amount of narcotic medication administered had increased during his admission, but had been decreased due to concerns about over-sedation. He was found vital signs absent approximately two	It is noted that the hospital identified and implemented recommendations in response to this incident. One example is the introduction of a new flow sheet for documentation of medications and infusions. Such changes are useful. It is recommended that the hospital also review its communications policies and procedures in palliative care, particularly as these relate to caregiver-next of kin-patient conflict or disagreement.

	hours after having last been seen alive. The decedent's family raised concerns as to the possibility that the death may have resulted from narcotic toxicity, based on the decedent's clinical course prior to death. Post mortem blood samples were not obtained prior to embalming, and therefore toxicology testing was not able to resolve this issue. The hospital conducted a quality of care review and implemented a number of recommendations arising from that review.	
2007-16	[See case 2007-01]	[See case 2007-01]
2007-17	The decedent is a 47 year old female with a history of chronic obstructive pulmonary disease. She was admitted to hospital with a diagnosis of bilateral lobar pneumonia (which was later proven on autopsy). At the time of her admission, she required supplemental oxygen. There was apparently difficulty keeping the oxygen on the decedent, and she would desaturate when the oxygen was removed. Due to all of the acute care beds being occupied in the hospital, the deceased was placed in a palliative care bed on an inpatient unit, at the far end of the corridor from the nurses' station. She was subsequently found vital signs absent, and did not respond to	1. The institution should consider developing a policy/procedure, which sets out the process to be followed when there is no appropriate bed to deal with the patient requires admission. This policy should include but not be limited to: • Identification of the situation i.e. no appropriate bed available. • Persons to be contacted in this circumstance, including senior nursing and/or medical personnel. • Steps to be taken to attempt to free up an appropriate bed. These should proceed from an internal survey to seeking an external bed either elsewhere in the institution or in another institution. • The policy/procedure should state that the patient should not be moved from an area of higher care to one

	advanced life support.	with less intense care capability unless the patient's condition has improved sufficiently to warrant this move.
2007-18	A 68 year old male with a history of prior bioprosthetic aortic valve replacement was admitted to hospital with a diagnosis of endocarditis and aortic abscess. He had been assessed by cardiovascular surgery as well as a number of other specialists, and a decision had been reached to manage the decedent non-surgically with antibiotic therapy and close follow up. He died suddenly and unexpectedly prior to discharge home.	No recommendations.
2007-19	An 81 year old female was admitted to hospital for emergent surgical treatment of a colonic perforation complicating a diagnostic colonoscopy. She had a complicated post-operative course. On post-operative day #17, a nurse was administering pain medication which was ordered as hydromorphone 1 mg subcutaneously every 4 hours as needed. The nurse obtained a 2mg/mL vial of hydromorphone, but dropped the vial. She obtained what she believed to be another vial of 2 mg/mL hydromorphone from the narcotic drawer and drew up and administered what she believed to be the prescribed dose of hydromorphone. Medication counts at end of shift led to the conclusion, however, that the second vial was in fact 50 mg/mL morphine. This meant that	1. Assess staff competencies regarding the usage of units (e.g. mg) to express the dose of medications. 2. Assess risk associated with narcotic stock in patient care areas. 3. Remove morphine ampoules or vials with concentration greater than 15 mg/mL. 4. Add labels to reduce confusion, consider including the brand name equivalent (e.g. hydromorphone – for Dilaudid). 5. On an ongoing basis, evaluate the contents of the narcotic stock drawer or cupboard for look-alike products and packaging. 6. The Regional Supervising Coroner of this case is to be commended for adopting a medication system based approach in investigating the medication error. This is evident from his questions to the hospital (e.g. “How were doses of morphine and Dilaudid stored in the ICU at the time of the death?”). Other coroners are encouraged to take in consideration the role of medication system failures when investigating medication errors.

	the decedent received 25 mg sc of morphine; an approximately 6-fold overdosage of narcotic. The decedent's condition continued to deteriorate and a decision was made to withdraw care. Post mortem examination determined the cause of death to be complications related to her colonic surgery and multiple medical co-morbidities. The morphine level in post mortem blood was within or below the therapeutic range. While the medication error did not in itself cause death, it was felt that it may have contributed to hastening the death. It was also felt to highlight a potentially preventable error that would benefit from recommendations aimed at preventing similar event in future.	
2007-20	The Patient Safety Review Committee reviewed two deaths in young persons (a 30 year old female, and a 26 year old male) who were taking clozapine for management of schizophrenia. In both cases, the cause of death was felt to be sudden cardiac death. The 30 year old female had been investigated for "irregular heartbeats" in the days prior to her death. She died suddenly at home. Post mortem did not identify an anatomic cause of death; clozapine level was higher than therapeutic, but not at a level expected to cause death. Serious arrhythmias are a rare, but recognized complication of clozapine. Other factors, such as	1. Education should be given (and reinforced) about how to follow a healthy lifestyle such as smoking cessation, healthy diet and exercise (although it can be very difficult to change behaviours in patients with schizophrenia). 2. Report similar cases in the future to the Canadian Adverse Drug Reaction Monitoring Program.

	hypokalemia, may increase the likelihood of such arrhythmias. The 26 year old male had experienced significant (100 lb) weight gain since starting on clozapine (which is a recognized side effect of the medication). He died suddenly in hospital while being investigated for a paralytic ileus. Post mortem demonstrated dilated cardiomyopathy, as well as ischemic bowel. Both dilated cardiomyopathy and ileus are recognized complications of clozapine. Additionally, weight gain, medical comorbidities and unhealthy lifestyle can cause or contribute to the development of dilated cardiomyopathy.	
2008-01	A 48-year-old male underwent catheterization of the right internal jugular vein in preparation for renal transplant. After the procedure, the line was transduced and the waveform was noted to be arterial and consistent with that of the noninvasive blood pressure reading. The catheter was removed with pressure applied for five minutes. There was no bleeding or hematoma. An internal jugular catheter was inserted on the left side without incident. Unfortunately, some hours later, the patient developed profound left-sided weakness while in the intensive care unit, and subsequently had dilation of the right pupil. Computerized tomography (CT) scan revealed a	1. The Patient Safety Review Committee recommends that hospitals and practitioners review the potential use of ultrasound-guided central catheter insertion. We believe that serious consideration should be given to adopting this technique of central venous catheterization more widely.

	large right-sided cerebral infarct with mass effect and evidence of clot in the right internal carotid artery. The patient developed hemodynamic instability followed by cardiac arrest from which he could not be resuscitated. At autopsy, the most important finding was that the patient had suffered a large cerebral infarct in the middle cerebral artery territory with thrombus from the origin of the right internal carotid artery up to the right middle cerebral artery. There was a 3 mm transverse tear of the common carotid about 5.5 cm above the origin of the common carotid with associated peri-arterial hemorrhage. The expert reviewer identified that the risk of such complications can be mitigated through the use of ultrasound guidance during central catheter insertion.	
2008-02	The Patient Safety Review Committee reviewed the deaths of two patients who died following hypoglycemic episodes in an acute care hospital setting. Both patients were elderly and critically ill with complex medical conditions. Both patients had percutaneous gastrostomies and were receiving intermittent enteral feedings (16-18 hours each day). Intermediate acting insulin was administered twice daily supplemented with sliding scale regular insulin for blood glucose levels in excess of 8 mmol/L. Point-of-care glucometry was conducted twice daily.	1. The Patient Safety Review Committee wishes to emphasize that the decision to adopt more aggressive glycemic control practices must be accompanied by review and revision of diabetic management protocols, relevant clinical care guidelines and education programs to ensure that appropriate safeguards are in place to mitigate the associated risk of hypoglycemia. Physicians and hospitals (and their respective Medical Advisory Committees and Professional Practice leaders) should ensure that the adoption of tighter glucose control is accompanied by a review of educational and clinical management programs for critically ill patients to ensure that they reflect current recommendations for the safe

	Both patients developed severe hypoglycemia following a period of suspended enteral feeding with devastating neurological consequences. Each patient died without regaining consciousness in the hours to days following these events.	implementation of these practices.
2008-03	The decedent is an 83 year old female with multiple medical comorbidities. She died in hospital as the result of complications of acute renal failure resulting from obstruction of her solitary kidney. On review of this case, a number of areas of concern were identified; the themes included: Lack of effective communication between the emergency physician, hospitalist and cardiologist involved in the care of the decedent. Timeliness of consultations Nursing assessment and communication; and specifically, a perceived reluctance on the part of nursing staff to raise concerns with physicians. Barriers to effective investigation and treatment of patients, particular over weekends.	1. The Medical Advisory Committee and/or Emergency Department Chief should review the circumstances surrounding the decedent's admission and the apparent discord between the expectations of the emergency physician and attending Hospitalist including the processes and policies that guide the admission of patients and the transfer of responsibility for care with a view to ensuring that any systemic impediments to the smooth transfer of care are addressed. 2. The Medical Advisory Committee should review the availability and/or criteria for engagement of specialty consultation services to support the care of patients with complex medical conditions. 3. If the absence of documentation does not reflect a deficiency in the material available for review, Nursing Administration should review the policies and practices pertaining to the monitoring and recording of fluid input and output for patients who are actively being treated for dehydration / volume depletion. 4. Nursing Administration should review the policies, practices and criteria used by nursing staff to ensure that any systemic impediments to the timely notification of the attending physician when significant changes in a patient's condition arise are addressed. 5. The Medical Advisory Committee and/or the service Chief responsible for hospitalist care, in collaboration with hospital administration, should review the circumstances surrounding the

		decedent's death to identify and address factors that impeded the timely investigation and treatment of her medical conditions over the weekend.
2008-04	The decedent was a 77 year old female who present to hospital with atraumatic left hip pain. She had a history of chronic atrial fibrillation and was on warfarin. She was admitted from the emergency department to an inpatient unit that evening. An International Normalized Ratio (INR) value at admission was markedly elevated (indicating over-anticoagulation). This result was sent to the inpatient unit to which the decedent was admitted, but the result was not directly communicated from the laboratory to the treating physician or nursing staff caring for the decedent. Early the following morning, the decedent was found lifeless in bed. Post mortem examination showed evidence of left pyelonephritis, as well as a 1.5 L hematoma arising from the left perirenal space and extending into the inguinal canal and thigh.	1. The Committee recommends that the Regional Supervising Coroner discuss this case with appropriate hospital personnel to clarify whether or not the communication, as depicted in the chart, reflects what really happened. Further, in this conversation, the committee recommends that the hospital be reminded of the requirement for direct and clear communication from the laboratory staff to clinical staff when a significantly abnormal laboratory value is received.
2008-05	The deceased is a 75 year old male who was treated in the Emergency Department (ED) for back pain after suffering a fall two days previously. He was assessed and diagnosed with musculoskeletal pain, and was discharged home on hydromorphone 2mg tablets for pain. The decedent's family state that they had informed the ED staff that the decedent had had "bad	No new recommendations.

	reactions” to morphine-based analgesics in the past. Over the next few days, the decedent became delirious, and developed urinary retention. He was admitted to hospital and had a computerized tomography (CT) scan which revealed a stable lumbar compression fracture. CT scan of the head was normal. He died suddenly in hospital the next day. Post mortem revealed extensive atherosclerotic coronary and cerebrovascular disease. Mechanism of death was felt to be a cardiac dysrhythmia, and concerns were raised as to whether the apparent adverse reaction to the narcotic medication had contributed to his death.	
2009-01	The decedent was a 24 year old woman who was admitted as to an inpatient mental health facility. She had taken a multiple medication overdose on a background history of prior suicide attempts (including a number of prior admissions to that psychiatric facility). She was admitted with a diagnosis of overdose, depression and social pressures. The Axis I diagnosis of major depressive episode due to dysthymia was made. A possibility of borderline personality trait was noted, but the diagnosis was not made. The decedent made some progress in hospital in that she became more involved with social situations and accepted quetiapine for her anxiety. However, there were episodes where she was anxious, angry and would not	1. Providers of mental health care services in the inpatient setting should be reminded of the guideline that mental status examinations including evidence of suicidal thought should be done during each shift for each patient. 2. Institutions which provide healthcare, and mental health care particularly, should consider developing a policy which would require that the patient be offered the opportunity to either consent or refuse to consent to the sharing of information with persons he/she wishes to involve his/her care. This might be the next-of-kin or a significant other person. Consent should be sought at an opportune time during treatment when the patient is capable of considering the matter. Further, it is recommended that the policy require that an appropriately qualified staff member be designated as the family liaison for each case. 3. In this case, there was evidence of sub-optimal communication between the

	participate in groups. On at least one occasion, contraband was removed from her living quarters. When she did not appear for a scheduled woman's group, staff went in search for the patient and found her unresponsive on the hospital grounds. She had taken a massive overdose of diphenhydramine was not able to be resuscitated. It was determined that her death was due to overdose of diphenhydramine, and the manner of death was deemed to be suicide.	family and the institution. A useful strategy employed in other settings has been to implement a community/patient/family advisory body designed to give a forum for discussion of relationships between the institution and the community that it serves. The Patient Safety Review Committee is aware of literature endorsing the precept of family involvement in care, and believes that this is important in all health care settings. Family involvement enhances the safety of patients. 4. The Regional Supervising Coroner should conduct a Regional Coroner's Review with the institution to share the foregoing recommendations and seek their input and response.
2009-02	A 45 year-old male with hemophilia A presented to a medium-sized community hospital at 0700 hours with a two day history of diffuse abdominal pain, nausea and vomiting, and loose stools. Initial vital signs were stable. The decedent was seen promptly, and treatment with intravenous fluids, analgesic and antiemetic medication was commenced. A number of laboratory investigations and a computerized tomography (CT) scan of the abdomen and pelvis were ordered. Initial blood work showed a decreased haemoglobin (94 g/L) and a mildly elevated creatinine. Bicarbonate was decreased at 12 mMol/L with an elevated anion gap. Coagulation studies were not obtained at this time. The CT scan (done without	1. The Medical Advisory Committee and the clinical service Chief responsible for medical care in the Emergency Department should ensure that the circumstances surrounding this tragic event are fully investigated and addressed. The deceased was not the beneficiary of timely diagnosis and treatment in the ED. The Committee was troubled that a known diabetic haemophiliac with undiagnosed abdominal pain, metabolic acidosis, and anemia waited in excess of 10 hours to have INR/PTT measured and an assessment performed by Internal Medicine. Available information led the Committee to conclude that this was not an issue of missed diagnosis, but failure to the system of care. There is little evidence available to suggest that the deceased received more than cursory medical attention for many hours following his presentation to the ED. The hospital should seek to understand and address the factors that contributed to this situation, potentially including:

	contrast due to the elevated creatinine) showed intraperitoneal fluid and a distended gall bladder. Hemoperitoneum was included in the differential diagnosis. Blood work was repeated at 1715 hours; this showed a hemoglobin of 64 g/L, International Normalized Ratio (INR) =1.4, Partial Thromboplastin Time (PTT) greater than 180 seconds; serum ketones were negative but serum lactate was reported at 21 mmol/L. Transfusion with packed red blood cells was started at 1800 hours, and factor VIIa administration was started at 1815 hours. The decedent subsequently developed signs of hemodynamic instability, requiring aggressive resuscitation with crystalloid and colloid fluids and the use of pressors. Despite ongoing efforts, he developed multisystem organ failure and died. A post mortem was not performed.	• Policies, processes and practices governing timely ED referral and acceptable responses to ED requests for consultation and/or specialist care • Policies, processes and practices concerning identification of the most responsible physician and the transition of responsibility for care between the ED physician and the admitting service. • Physician performance issues • Expectation concerning the availability of physician support for high acuity clinical care environments and whether these are being met. 2. The hospital and its medical leadership should assess whether its available facilities and expertise were adequate to manage the deceased's emergent, complex care needs and, if appropriate, develop strategies to address gaps. It is unknown from the material reviewed if the deceased was familiar with the care team, the number of haemophiliac patients treated at the hospital, or the familiarity of staff with the management of complex haemophiliac patients. Response to treatment with Factor VIIa is primarily directed by clinical evidence of control of bleeding as traditional measures of coagulation, such as PTT, are not as reliable in this context. Evaluating ongoing bleeding is challenging when the source is intra-abdominal and particularly retroperitoneal. Despite these circumstances, available information offers little insight with respect to whether haematology advice was available, or requested, to guide management although a preterminal request for Hematology consultation was noted. Alternatively, there is also no record that consideration was given to escalating care to another centre.
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2009-03	The decedent is a 61 year old male who was admitted to hospital for treatment of community acquired pneumonia. Past medical history included dilated cardiomyopathy, atrial fibrillation, hypertension and alcoholic cirrhosis. At the time of admission, his International Normalized Ratio (INR) was noted to be 2.1. He was taking aspirin, but not warfarin. On admission, he was started on antibiotics, as well as low molecular weight heparin. His aspirin was continued. He remained stable until the fifth day following admission, at which time he developed left flank pain. The following day he became hypotensive, with a drop in haemoglobin. A computerized tomography (CT) scan of the abdomen revealed a massive left retroperitoneal hematoma. Despite attempts to correct his coagulopathy and stabilize him hemodynamically, he developed multisystem organ failure thought to be on the basis of abdominal	1. Anticoagulants have been classified as high-alert medications. Numerous recommendations have been advanced to enhance the safety profile of these drugs. If it has not done so, the hospital should review its policies and practices related to the ordering and administration of antithrombotic therapy to ensure that they are consistent with current best practice. The Institute for Safe Medication Practices (ISMP) has published a hypothetical Failure Mode and Effects Analysis (FMEA) for anticoagulants that may be a helpful aid in identifying potential opportunities to enhance safe practices. 2. The hospital should consider adopting an anticoagulation checklist or standardized approach to prescribing antithrombotics (such as a preprinted order set) that includes appropriate demographic information and a review of high risk conditions to enable the prescriber and other members of the care team (especially nursing and pharmacy) to confirm dosing and the presence of high risk conditions prior to implementing the order. It is clear that the deceased had a serious cardiac condition. However, the Committee members noted that despite high risk conditions for bleeding complications there is no documentation to suggest that the indications for continuing antithrombotic therapy were

	compartment syndrome, and care was ultimately withdrawn. A post mortem examination was not performed.	re-evaluated by the attending physician following admission. It also noted that there is no documentation to suggest that the administration of combination of antithrombotic therapy to a patient with a well documented coagulopathy and low platelet count was questioned by any of the members of the healthcare team (physicians, nurses, pharmacists, etc) over the six days of inpatient care that preceded the hemorrhagic event.
2009-04	The decedent is a previously-well 21 year old male who was admitted to hospital with acute upper back pain. He was admitted for treatment of possible sepsis, and for observation and pain management. He was started on antibiotics and morphine. The morphine was initially ordered as 1 – 5 mg intravenously (IV) every 2 hours as needed, and later was increased to 5 – 10 mg IV every 2 hours as needed. The following day, his pain was still not well-controlled and in the early evening, an order was written to discontinue morphine and to start hydromorphone 5-10 mg IV every 4 hours as needed. The next morning, he was found vital signs absent and resuscitation efforts were unsuccessful. Cause of death was determined to be mixed drug overdose (morphine and hydromorphone). In the analysis of this case, it was noted that hydromorphone is roughly 5 times more potent than morphine, and the use of hydromorphone ordered in the	Prescribing: 1. Used standards protocols (e.g., preprinted orders, electronic order sets) for parenteral opioids whenever possible 2. Ensure that orders are reviewed by a pharmacist prior to administration whenever possible. Monitoring and Documentation: 3. Implement guidelines and practices for assessment, monitoring and documentation (e.g., vital signs, pain and sedation scales) for opioid therapy. Consider the use of standardized forms (order sets, protocols and flow sheets). Include clear criteria for the identification and treatment of toxicity. Include criteria for when to hold opioid therapy and when to use naloxone, so that it can be given quickly when needed, even before calling the physician. 4. When developing protocols for assessment and monitoring, the following circumstances should be considered: 5. The initial period of opioid therapy (e.g., 24hours or longer) and especially at night when nocturnal hypoxia can occur; 6. The use of concomitant medications that may further depress respiration (e.g., sedatives. 7. Consider the manner in which patients are assessed. Patients experiencing opioid-induced respiratory depression or

	same dose as morphine, in a non-opiate-tolerant individual, was felt to contribute to his death. In addition, it was felt that there was an opportunity to improve upon the clinical monitoring of patients receiving narcotic medication in order to facilitate the early detection of signs of toxicity.	over-sedation can easily be temporarily stimulated to an increased level of consciousness and respiratory rate. This observed momentary level of consciousness and respiratory rate may mask symptoms of toxicity and once this stimulus is removed, patients quickly fall back into an over-sedated state. The respiratory rate needs to be assessed without disturbing the patient. Monitoring a patient's level of consciousness accurately appears to be an extremely important assessment component as it has been noted to be the only predictor of an impending opioid-related adverse event. Educate and Inform Practitioners: 8. Ensure that analgesic equivalency charts are readily available to prescribers and other practitioners. Include examples of typical starting doses for opioid-naïve patients. 9. Educate practitioners about the differences between morphine and hydromorphone.
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Questions or comments pertaining to this report may be directed to:

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