Event Analysis Report:

Hydromorphone / Morphine Event
XXX Hospital, XXX, XXX

As conducted by
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(ISMP Canada)

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Table of Contents

Apendices	Contents
Appendix 1	**Timeline of Event**
Appendix 2	**Order for drug**
Appendix 3	**Event Diagram – Initial Understanding**
Appendix 4	**Event Diagram – Final Understanding**
Appendix 5	**Photographs – Work Environment**
Appendix 6	**Photograph - Narcotic Cupboard**
Appendix 7	**Photographs – Packaging**
Appendix 8	**Literature Search**

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Executive Summary

On June 6, 2004, a patient at XXX Hospital accidentally received an incorrect narcotic drug (hydromorphone instead of morphine), resulting in a fatal overdose. The Institute for Safe Medication Practices Canada (ISMP Canada) was invited to investigate the event in order to identify system-based root causes and to make recommendations about the best strategies necessary to prevent a recurrence of this or other similar events in the future.

Human factors engineering is the core science of patient safety. It studies human capabilities and actions in complex environments such as aviation, nuclear power, and the healthcare industry. In analyzing the factors involved in this case, a number of human factors issues were identified throughout the event, as are typically found with other complex catastrophic events. The triggering event, (incorrect drug selection), was strongly influenced by look-alike packaging, sound-alike drug names and workplace distraction. The look-alike and sound-alike confusion between hydromorphone and morphine, which occurred in this case, has resulted in other adverse drug events in both Canada and in the United States due in part to generic drug name similarity. Other environmental factors identified included narcotics distribution, medication storage conditions and handling practices commonplace in various health care settings. In addition, communication and medication safety process issues were identified, which reduced the likelihood of early discovery of the overdose once the event occurred. The ability of hospital leadership to create, nourish, and to maintain a culture of patient safety is critical to the success of any organizational changes made to mitigate adverse events. Some of the recommended actions contained in this report are designed to assist the hospital to support this desired culture of safety.

The recommendations that follow were developed based on the medication/patient safety and human factors engineering literature, as well as the vast experience in medication safety brought by the review team. Strong actions were selected, which will require significant resources and time to implement, but are targeted very specifically to prevent similar events. Strong health-system leadership and commitment to improving safety will be required to implement and manage the changes recommended. Implementation of these recommendations also requires the efforts of Health Canada and ISMP Canada. The lessons learned from this analysis have broad applicability to safety for healthcare organizations locally and worldwide.

Acknowledgements

We begin by offering sincere condolences to the family of the patient. This incident was a tragic accident. Although we cannot undo the harm to the patient and family, steps can be taken to

prevent a similar harm to others. This sentiment was strongly conveyed by family members and hospital staff who played a role in this root cause analysis. The ISMP consulting team is grateful to all individuals who participated in interviews for their assistance and valuable insights.

Introduction

On June 6, 2004, a fatal medication incident occurred at XXX Hospital in XXX. A 69-year-old patient received *hydromorphone* 10 mg by intramuscular (IM) injection instead of *morphine* 10 mg as intended. The patient experienced a cardio-pulmonary arrest in the family car while being driven home by his daughter. His family transported him to the nearest hospital (XXX) where he expired, despite resuscitation efforts in the emergency department.

XXX, which is part of XXX Health Region, contracted with the Institute for Safe Medication Practices Canada (ISMP Canada) to undertake an external review of the hospital's medication safety processes and specifically to conduct a root cause analysis (RCA) of the identified hydromorphone event. The purpose of this analysis was to identify the system-based causes of the event, and to make targeted recommendations to avoid a similar adverse event in the future.

The focus of this report is to describe the team's findings from the RCA, and to make system-based recommendations that should be implemented to prevent the same or similar tragic accident from occurring in other XXX health facilities, and the entire Canadian health system.

Context

The importance of patient safety has recently been raised in Canada with the release of the Canadian Adverse Events Study[1] in May 2004. In this study, researchers estimated that 7.5% of acute care patient admissions in Canada were associated with adverse events causing patient harm, resulting in an estimated 9,250 to 23,750 preventable patient deaths annually. Twenty-four percent of adverse events were found to be related to treatment with drugs and fluids. Similar research in other countries[2,3,4,5,6] has shown adverse event rates in hospitalized patients range from 2.9% to 16.6% of all admissions.

Since the landmark report *To Err is Human: Building a Safer Health System*[7], published by the United States Institute of Medicine in 2000, a paradigm shift toward a culture of safety in health care has begun. Leaders have recognized the complexity of the systems used, such as the medication use process, and the risks often associated with such complicated systems. Most significant is the movement of healthcare practitioners from a culture of blame and individual discipline when an error occurs, to one of shared accountability, by which all stakeholders in healthcare understand the systems-based causes of the event. Systems based changes that will prevent similar events in the future are supported through a shared or team approach. Disclosure of error, while difficult, is a critical first step towards identification of processes where change is needed to protect patients. The root cause analysis process undertaken as part of this external review is an example of a methodology that effectively identifies the underlying or "root" causes of an error.

Root Cause Analysis – Overview

Root Cause Analysis (RCA) is a process for identifying the basic or contributing causal factors that lead to variations in performance involved in an adverse event. A cause may be identified as a set of actions, circumstances or conditions. The RCA process has the following elements:

A. The review is multidisciplinary in nature and includes staff knowledgeable about the event and the processes involved and outside experts if applicable.
B. The probing questions ask "why" and "what" until all factors are considered.
C. The focus is on systems and processes, not individuals, and assumes that the individuals involved did not intentionally act to cause harm (unless facts are uncovered to the contrary).
D. The process encourages system level changes which if implemented will have lasting effects on safety.
E. Recommended changes focus on hard fixes and strong interventions such as architectural change, forcing functions, standardization, simplification, and careful automation, instead of just educating staff and updating policy.
F. Relevant literature and practice standards in formulating recommendations and actions are considered.
G. Staff and patient and/or family members in the event are involved in the event review (through interviews).
H. Delineation of the various factors, which contributed to the event, and which if left unmitigated, could contribute to another event.
I. Corrective actions and outcome measures are identified.
J. Leadership endorsement of the process and the completion of actions are critical to success.

Method of Analysis

The external interdisciplinary review team consisted of four healthcare professionals including three pharmacists and one nurse. All team members have extensive professional experience in acute care settings (both in Canada and the US), knowledge of the RCA process as well as expertise in the area of medication safety. The on-site portion of the project was conducted August 3-5, 2004 at XXX.

In advance of the on-site visit, documents surrounding the event were reviewed. These included but were not limited to policies, procedures, the medical record, autopsy results, as well as photographs taken of the XXX Emergency Department (ED) and packages of the products involved in the error.

During the visit, the ISMP team performed structured interviews with administrators, physicians, pharmacy and nursing staff members from XXX and XXX hospitals, local EMS staff, and hospital educators, to gain first-hand knowledge of the circumstances surrounding the event in

question. The team also had the opportunity to meet with family members of the deceased who provided additional information and unique perspective surrounding the event. In addition to the interviews, the ISMP team had the opportunity to observe the specific environments in the hospital most closely associated with this event including the Emergency Department and the pharmacy.

Initial understanding (verbatim as presented to ISMP Team by XXX)

On June 6, 2004, a 69-year-old male patient presented to the XXX Emergency Department at approximately 1530 hrs following an injury sustained while riding a horse. The horse flipped and fell over on top of him earlier that afternoon. He presented with complaints of chest pain following the incident.

Chest X-rays taken showed an area suspected of being a small sternal fracture. No other apparent injuries were noted. The patient was observed for approximately 2 hours following initial assessment, with vital signs remaining stable. The attending physician discussed the injury with the patient. Potential complications of chest wall injury were also discussed and the patient was advised of the physician's preference to continue to observe the patient for 24-48 hours. The patient declined and indicated he wished to be discharged. Morphine 10 mg IM was ordered for pain control prior to discharge and a prescription for oral Demerol was provided for ongoing pain control.

The attending nurse prepared and administered an injection of what she believed to be morphine 10 mg IM at approximately 18:15 hrs. The patient was discharged at approximately 18:35, alert and in stable condition. At approximately 19:15, during change of shift narcotic count, it was discovered that a substitution error had been made with 10 mg hydromorphone having been administered, instead of the morphine 10 mg as ordered. The Emergency physician on duty was notified and he advised that the patient be immediately contacted to present to the nearest hospital for assessment and observation. At approximately 19:25 the patient was telephoned at home. No response. Message left.

Final Understanding
(Following structured interviews and observations by the ISMP Team)

Timeline of Events: Refer to Appendix 1 for a written timeline of events.

On Sunday June 6, 2004, EMS was summoned to retrieve a patient who had been injured when his horse flipped on top of him while traversing an embankment. When EMS responded the patient was alert, cooperative, yet in a precarious position. At 14:12, knowing that it would take some time and some difficult manoeuvres to get the patient from the scene, the EMS administered 100 mcg of fentanyl intravenously per protocol for pain control from his injury.

The patient arrived via ambulance at XXX and was evaluated by the Emergency Department physician and nursing staff. Initial x-rays and diagnostic studies were performed, and the patient was maintained on a cardiac monitor with blood pressure and pulse oximeter functions. When all results were received, there was discussion between the Emergency Department attending

physician at XXX, the patient, and family about being admitted for additional observation (24-48 hours), however, the patient wanted to be discharged. A discussion ensued with the patient and his family about the need for pain management. The family noted it was getting late, and the patient had not had his scheduled arthritis medicine. The patient routinely took Arthrotec (a non-steroidal anti-inflammatory drug - NSAID) for arthritis pain. The patient and family initially requested an NSAID plus Tylenol and related to the physician that the patient was allergic to codeine and had experienced hallucinations in the past when given morphine. They also stated that meperidine (Demerol) was administered during a recent surgery-related hospitalization, and it was effective. The physician wrote a prescription for oral meperidine for the patient to take at home, but because the patient was presently in some discomfort, the physician wrote an order for analgesia to be given in the ED before discharge. The physician wrote an order for "**Morph 10 mg IM**" (see Appendix 2) on the chart and verbally instructed the attending RN to administer an intramuscular dose of morphine 10 mg. He explained to the nurse that an IM dose (versus an intravenous dose) would have a sustained effect and keep the patient comfortable for a longer period of time.

The RN went to the narcotic cupboard to obtain morphine 10 mg. As she opened the cupboard to obtain the morphine, she saw another patient assigned to her attempting to climb out of bed. She selected a vial from a grey box, which she read as containing "**Morph 10,**" and with the drug in her hand, went to assist the patient climbing out of bed. She returned the patient to his bed. This patient was an "admitted patient" but due to bed allocation difficulties and full capacity in the rest of the hospital, was waiting in the Emergency Department for an assigned room. The XXX Emergency Department was in Code Burgundy status and on ambulance re-direct status.

The attending nurse returned to the medication preparation area and signed out one dose of morphine 10 mg on the narcotic sign out sheet. The narcotic sheet used for drug inventory and accountability listed morphine and "hydromorphine" next to each other on the top line in the parenteral section.

The attending nurse was an experienced RN, yet new to this facility. She mentioned that she had never given hydromorphone before and had only seen it used in an oncology unit (in another hospital where she is also employed). She was familiar with a morphine product (2mg/mL) in a grey box and had frequently administered this drug in her other hospital Emergency Department position. The attending nurse proceeded to draw up the liquid from the container she had in her hand, and administered it to the patient.

Because (i) the patient and family had expressed concern about the use of morphine and (ii) the take-home prescription given to the patient was for oral meperidine, the family was under the impression that the patient was receiving a dose of meperidine IM. There was no discussion or communication by the physician or the nurse with the patient or family as to the medication being administered in the Emergency Department.

Following drug administration, the nurse returned to the charting area of the nurse station, and charted the medication administration onto the Emergency Department record.

The nurse proceeded to remove the cardiac monitoring equipment in preparation for discharge, and the patient began to get dressed. At this time the patient complained about being "dizzy". The family mentioned this symptom to the attending nurse who thought it was too early for this to be drug related. The patient and family were escorted to the discharge area and the patient left via his family member's personal vehicle.

On the way home in the car, the patient became drowsy, and drifted off to sleep but the family noted he could be aroused from this sleep stating he was "okay". The family reported hearing him snoring but shortly thereafter, he took a gasping breath and appeared to stop breathing. The daughter (driver) checked him for breathing, and didn't observe any breaths. As the daughter called 9-1-1, the wife attempted to administer CPR from the back seat of the vehicle. The family proceeded to the nearest hospital Emergency Department (XXX Hospital). The ambulance was summoned but the vehicles were coming from different directions, and did not see each other.

The ambulance and the family vehicle arrived at the XXX Emergency Department simultaneously. Another EMS crew at XXX removed the patient from the family vehicle immediately, and resuscitation efforts began. The XXX Emergency Department physician arrived from his home within two minutes of the patient's arrival. The initial rhythm on the cardiac monitor at the Emergency Department was noted to be Pulseless Electrical Activity (PEA).

The family proceeded into the XXX Emergency Department and reported to the staff present the history of the patient's injury and administration of "meperidine" for pain prior to discharge. The physician at XXX knew that the patient had a crush injury to the chest and judged the therapeutic meperidine dose (understood to have been administered at XXX to be an unlikely cause of the patient's arrest.

IV start attempts were made, yet scar tissue made IV access problematic. IV access was established and code drugs begun at 19:20. While these attempts were in progress, the EMS and nursing staff suggested giving naloxone to reverse the meperidine effects. Initial intubation attempts were difficult until one of the EMS staff ran to their EMS vehicle to get an alternative-sized blade to insert the endo-tracheal tube. Intubation was accomplished at 19:34 and airway management ensued.

Simultaneous to the resuscitation efforts at XXX, the XXX Emergency Department nurses began their change of shift narcotic count and discovered the discrepancies in the morphine and hydromorphone counts. The two staff RNs (including the charge nurse) questioned the primary nurse who realized at that moment that she must have given hydromorphone 10 mg instead of morphine 10 mg. The charge nurse then contacted the Emergency Department nurse supervisor and the physician on duty. The physician instructed her to call the patient. When the patient could not be reached by phone, a call was placed to the XXX Emergency Department. It was at this time they learned that the patient was there, and in full arrest.

Following the call from XXX, the patient received 2 doses of naloxone 0.8 mg and an additional dose of atropine 1 mg. All resuscitation attempts failed, and the patient expired at 19:40.

Cause and Effect Analysis

Following the site visit, the ISMP team reviewed the information gathered and used it to synthesize time lines (Appendix 1) and create cause and effect diagrams related to the event. Cause and effect diagramming is an effective technique used to support the analysis of complex events. Through the use of these tools and the process of root cause analysis, ISMP has determined system based causes of the medication event in question.

A *root cause analysis* is defined as a systematic process of investigating a critical incident or an adverse outcome to determine multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.[8] Once the event has been defined, the root causes are determined by working backwards and asking a series of "why" or "caused by" questions. Some "why's" are actions performed by an individual, while others are conditions, or circumstances.

As the team asked "why" and looked for causes, some elemental causal sets were created and then expanded to create causal chains to better understand the event.

The defined event for this investigation was the death of a patient due to an overdose of hydromorphone.

The following elemental causes of this event were identified as:

1. Wrong drug administered.
2. Patient not assessed for medication effectiveness and onset of side effects.
3. Patient discharged from XXX Emergency Department.
4. Patient and family unaware of medication ordered in Emergency Department.

Description of Cause and Effect

1. Wrong Drug Administered

The following causes and contributing factors related to the administration of the wrong drug were identified:

Wrong Drug Selection:

- **Concentrated Drug available in floor stock:**
  - Hydromorphone was available as a routine Emergency Department floor stock item for the purposes of management of pain in palliative-care patients and as an alternative to meperidine.

- The concentrated 10 mg/mL hydromorphone product had been added as routine floor stock in the Emergency Department during the months previous to the event.
- There was a past practice for nurses to aliquot doses of narcotics (i.e., dilute 10 mg of the drug in 10 mL normal saline and give partial doses from the same syringe). According to staff this was the reason for originally stocking the more concentrated form of the drug.
- Prior to this incident, the last dose of hydromorphone administered had been in April 2004 (approximately two months earlier).
- Pre-filled syringes of narcotics in commonly used clinical doses are not available in Canada and therefore the purchasing options are limited.
- The option of stocking the 2 mg/mL hydromorphone product was not exercised, suggesting limited awareness of high alert medication use precautions.
- The process for risk assessment and selection of floor stock items was informal, with limited professional oversight of the floor stock system.
- There is an apparent regional/national practice to treat floor stock items as "supplies" (e.g., examples in this hospital include pre-mixed solutions containing medications supplied by Central Supply; nurse driven process for ordering and returning narcotics to pharmacy, inability to obtain single doses of narcotics for patients when requested, pharmacy assistant oversight responsibilities in the narcotic and floor stock process).
- There is limited floor stock inspection or drug use evaluation (DUE) activity at XXXX for controlled substances and high alert drugs.
- There is limited local Pharmacy and Therapeutics Committee oversight of drug safety, possibly due to a regional versus local oversight focus.
- There is limited guidance on a national level for the implementation of patient safety standards.

- **Confirmation bias** (i.e. "seeing what one expects to see") likely played a significant role in the selection of the incorrect drug.
  - Morphine and hydromorphone products had 'look-alike' packaging because of the grey side panel and the letters "morph" on the products. The packages were stored side-by-side in the cupboard and only the side panels were visible. In addition, the distinctive front of the packaging (drug name and secondary colour) had been removed (along perforated line) from the hydromorphone product to facilitate narcotic counting.
  - The nurse had prior experience and was familiar with morphine packaged in grey boxes. She was also familiar with Sabex products that are packaged in vials instead of ampoules.
  - The "HP" (high potency) on the hydromorphone packaging is not distinctive. Additionally there are no clear warnings to indicate that this is a concentrated opiate and should not be routinely used in opiate naïve patients.
  - The dose designation of "10 mg" was relatively more prominent on the package than the drug name.

- The above factors, combined with a lack of expectation to find hydromorphone stocked in the Emergency Department led the nurse to conclude that the hydromorphone package was an extension of the morphine product line stored in the cupboard. This perception was easily re-created by the ISMP consulting team.

- **Drug name similarity**:
  - The use of drug name abbreviations makes it more likely that drug name confusion could occur. The order written for this patient referred to morphine as "morph." (It is a common practice to abbreviate drug names as was observed during the on-site visit.)
  - The brand name "Hydromorph Contin" indirectly promotes the use of abbreviated drug names in Canada. The World Health Organization recommends that brand or proprietary drug names not include "stems" of generic drug names to avoid confusion.[9]
  - The staff member administering the medication was not familiar with hydromorphone in Emergency Department use, and had not administered hydromorphone previously in an Emergency Department. These in turn led to probable confirmation bias and perceptual error.
  - A typographical error on the narcotic record sheet, which listed hydromorphone as "hydromorphine," may have increased the likelihood of drug name confusion.
  - That there is a worldwide nomenclature issue with morphine and hydromorphone and there have been previous reports of confusion between these products both in Canada and the US supports the above interpretation errors.
  - Drug information (e.g., generic/brand name cross reference) was not readily accessible to the nurse as she was selecting or preparing the drug.

- **Storage of morphine with hydromorphone:**
  - Morphine and hydromorphone products were stored in close proximity to each other in the narcotic cabinet.
  - A traditional floor stock storage system, with manual record keeping, was used to provide narcotics to the Emergency Department. There was no use of automation to manage controlled substances; not uncommon in Canada.

- **Distracted by falling patient at time of drug selection:**
  - At the time of drug selection, the nurse was distracted by a confused patient attempting to climb out of bed**:** In order to protect the patient from injury, the nurse interrupted her selection and preparation of the medication to return the patient to a safe position. Without her intervention, it was likely the patient could have been injured. This patient had previously been identified for admission to the hospital, but could not be moved to an inpatient bed due to the Code Burgundy status and bed allocation difficulties.
  - The open architecture of the medication preparation area made it vulnerable to distractions.

2. <u>Patient not assessed for medication effectiveness and side effects</u>

- The primary nurse thought the patient's near-immediate complaint of dizziness was too soon to be morphine-related and thus had a low index of suspicion regarding the potential for opioid toxicity.
- According to XXX policy, ongoing assessments are at the discretion of the primary nurse. There is no specific policy on the follow-up assessment and monitoring requirements in the Emergency Department after the administration of opiates and other high alert medications.
- The Emergency Department health record form is not structured to encourage the complete documentation of follow-up pain assessments or side-effect monitoring following the administration of medications.
- The cardio-respiratory monitoring equipment was removed shortly after administration of the medication, in preparation for discharge.
- The nurse was not aware of preventable adverse drug event statistics involving high alert medications that may have prompted her to act differently. There was no organizational infrastructure at XXX for staff to learn about similar medication-related adverse events (or near-misses) within the hospital, or from external sources.
- There is a limited national infrastructure to learn from adverse or near miss events.

3. <u>Patient discharge from the Emergency Department</u>:

- The physician weighed the decision whether to discharge the patient or admit him for observation.
    - The physician encouraged the patient to be admitted; however, the patient requested discharge, believing that he would get more rest, and easier recovery at home.
    - There are bed allocation and resource issues that impact the ability to move patients through the Emergency Department in a timely way. This led to overcrowding in the Emergency Department and a situation where nurses were caring for admitted patients requiring continuing care, along with others needing prompt emergent attention. This mix of patient acuity creates an unpredictable situation and directly impacts the Emergency Department environment and workflow

4. <u>Patient and family unaware of medication ordered in Emergency Department:</u>

- The patient and family misunderstood the medication ordered and administered in the Emergency Department to be Demerol (meperidine), due to incomplete communication received from caregivers. The roles and responsibilities for provision of patient education and follow-up instructions are not well-defined.
- The physician viewed meperidine as a sub-optimal drug due to previous informal work at XXXX on a pain management formulary. There are no specific clinical guidelines or protocols for pain management in the Emergency Department.
- The need for medication was discussed with the patient and family but they were not actively involved in the decision to use morphine. The family stated that had the patient

known morphine had been ordered, he would have refused the drug. There does not appear to be a structured process for involving patients in direct care decisions.
- The history given by the patient to the physician and nurse, followed by the outpatient prescription for meperidine led the family to believe the injectable medication administered to the patient was also meperidine.
- No verbal or written discharge instructions were given to the patient and family. No structure or policy is in place to provide formal discharge instructions.

Incidental Findings

The defined event in this analysis was the demise of a patient after receiving a drug overdose; and thus, the entire spectrum of care for this patient was reviewed, up to and including the resuscitation efforts at XXXX Hospital. As with all root cause analyses, incidental findings are often established during the investigation, and such findings are discussed below. Although these findings may not be directly linked to the outcome in this case, as safety issues they are worthy of mention due to their potential to impact the quality of health care provided to the DTHR communities.

Delayed recognition of side effects:
- Clinical symptoms of drug toxicity began to appear as the patient was leaving XXXX, but were not recognized.

Ambulance could not find patient:
- There was a delay in access to EMS services because the ambulance was unable to locate the family vehicle.

Delay in code drug administration:
- In a code situation, medications can be administered intravenously or by endotracheal tube. Code drug administration was delayed due to difficulties with both intravenous access and intubation (insertion of the endotracheal tube).
- Intubation attempts were unsuccessful due to a difficult airway (patient condition) and lack of selection of blade sizes in the XXXX Emergency Department.
- IV access was problematic due to scarring of the patients arms (patient condition).

Delay in reversal agent (naloxone) administration:
- Naloxone (a narcotic reversal agent used to treat respiratory depression often associated with narcotic overdose) was not immediately administered in the XXX Emergency Department due to a low index of suspicion of symptoms being narcotic-related based on the patient's initial injury, history, and presentation.

Resolution of Chart Discrepancies:
- Therapeutic lidocaine levels were found at autopsy but there was no chart documentation of prescribing or administering this medication. This was identified by the XXX ED physician as a charting omission, as he recalled ordering the drug during the resuscitation.

- Hardcopy cardiac monitoring recording printouts from the resuscitation attempts at XXX Emergency Department were not available for review as part of the health record because the cardiac monitor was inadvertently shut off before permanent rhythm strips could be printed.

Recommended Actions

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 1	**Look-alike, sound-alike medication name:** Look-alike and sound-alike drug names and the cultural norm to use abbreviated drug names increased the likelihood that (through the impact of confirmation bias) a nurse would select and administer hydromorphone instead of morphine as intended.					
Wrong drug selected	Drug available in floor stock	**1 A**	Remove high potency concentrations of narcotics from ward stock in Emergency Department	Eliminate	Immediate	Hospital Leadership or Designee
	Undefined process for risk assessment of floor stock	**1 B**	Review all ward stock to be sure that what is stocked are agents needed for care based on P&T Committee and pain management guidelines for the care area	Control	Intermediate	Hospital Leadership or Designee
	Look alike packaging; storage of morphine with hydromorphone; manual record keeping, etc.	**1 C**	Implement automated dispensing devices in the Emergency Department (ideally a system with unit dose dispensing and bar-code verification of stocking function)	Control	Long Term	Hospital Leadership or Designee

* Time-frame: Immediate = 3 months; Intermediate = 12 months; Long Term = 36 months

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
Wrong drug selected	Drug name similarity; world-wide nomenclature issue	**1 D**	Recommend to Health Canada that the generic name of hydromorphone be changed to reduce name confusion in the future	Control - Regulatory	Immediate	ISMP Canada
	Drug name similarity; look alike packaging	**1 E**	Identify and, at a minimum, annually review a list of look-alike/sound-alike drug names used in the organization, and take action to prevent errors involving the interchange of these drugs.	Control	Immediate	Hospital Leadership or Designee
	Drug name similarity (Hydromorph Contin)	**1 F**	Recommend to Health Canada that Canada follow the World Health Organization's (WHO) policy on avoidance of drug stems in proprietary names such as Hydromorph Contin (WHA 3.11). Work in cooperation with the manufacturer(s).	Control - Regulatory	Immediate	ISMP Canada
	Medication ordered as "Morph"; cultural norm to abbreviate drug names	**1 G**	Standardize a list of (error prone) abbreviations, acronyms, symbols and truncated (stem) drug names that are NOT to be used throughout the organization.	Control	Immediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 2	**Look alike packaging -** The packaging design of hydromorphone injection which reduced the nurses' ability to view the contents, encouraged removal of portions of the drug packaging material. This resulted in removal of drug identification information and increased the likelihood of a look-alike medication being selected					
Wrong drug selected	Confirmation bias; look-alike packaging	**2A**	Recommend to the manufacturer and Health Canada to re-design the packaging of controlled substances. Use human factors principles to improve differentiation between products, strengths and dosages and to allow for easier counting by staff.	Control - Regulatory	Immediate	ISMP Canada
	Look alike packaging; limited risk assessment of look-alike sound-alike floor stock	**2B**	Implement a process to evaluate the potential for look-alike sound-alike products in Emergency Department and Pharmacy which: a) allows purchase of drugs which do not look alike where possible, b) use of auxiliary labeling, c) segregation or separation of products where possible	Control	Immediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 3	**Lack of unit dose packaging of high-alert medications:** Lack of unit dose packaging of high-alert medications (such as potent opiates) reduced the likelihood that the packaging would meet the clinical needs of the patient. This increased the likelihood that a multi-dose drug would be selected and administered inadvertently.					
Wrong drug selected	Undefined process for risk assessment of floor stock; lack of unit dose packaging	**3 A**	Review all controlled substance (and high alert medication) inventory hospital-wide (pharmacy stock, materials management, and ward stock) to replace bulk or multi-dose drug packages with the lowest dose packaged in unit dose that is commercially available.	Control	Immediate	Hospital Leadership or Designee
	Lack of unit dose packaging	**3 B**	Petition the manufacturers (through Health Canada) to provide controlled substances and other high-alert medications in unit dose packaging	Control - Regulatory	Immediate	ISMP Canada
	Drug available in floor stock; lack of prefilled syringes	**3 C**	Contact Hospira corporation to request the provision of controlled substances in unit dose syringes to the Canadian marketplace.	Control - Regulatory	Immediate	ISMP USA

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 4	**High-alert medications treated as supplies:** The handling of high-alert drugs (such as potent narcotics) as supplies, resulted in the routine stocking of concentrated hydromorphone in the Emergency Department. The routine availability of a high-potency yet uncommonly used opiate (hydromorphone 10 mg) increased the likelihood that a wrong drug selection could occur.					
Wrong drug selected	Drug available in floor stock; undefined process for risk assessment	**4 A**	Institute an interdisciplinary oversight process (locally by facility) to review and formally approve the medications which are available via ward stock area by area. Re-evaluate the list at least annually and anytime the patient care services of the area change. Focus on: minimizing the number of units in inventory, the amount of drug per container and clinical appropriateness for the patient care area.	Control	Intermediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 5	**Assessing the effects of high-alert medications:** Lack of a defined or structured process for monitoring patients receiving high-alert medications increased the likelihood that an opiate would be given without the necessary follow up clinical monitoring of the patient. (Currently there is no policy at XXXX to suggest that special precautions are necessary when prescribing, dispensing, administering, or monitoring high-alert medications)					
Patient Not Assessed	No Formal Policy	**5 A**	Implement formal guidelines for the prescribing, dispensing, administering and monitoring of high-alert drugs used at XXXX, using the most recent high alert drug list from ISMP USA as a reference.	Control	Intermediate	Hospital Leadership or Designee
	Limited awareness of high alert medication adverse events	**5 B**	Incorporate drug safety information (such as events known from the literature, events or close calls at the facility) for the specific drugs administered for each area into the orientation and ongoing staff competency evaluation for each area.	Control	Intermediate	Hospital Leadership or Designee
RC 6	**Controlled substance automation and recordkeeping:** The manual nature of controlled substance forms processing (with a typographical error seen on the form every day) increased the likelihood that the drug names would be confused.					
Wrong drug selected	Name similarity	**6 A**	Re-design the current narcotic sheets to physically separate and better differentiate hydromorphone and morphine and add brand names where applicable	Control	Immediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
	Narcotic sheet typographical error	**6 B**	Eliminate the use of manual narcotic records in the ED when automated dispensing devices are available	Eliminate	Long Term	Hospital Leadership or Designee
Wrong drug selected	Narcotic sheet typographical error; Manual prescribing and record keeping	**6 C**	Implement interdisciplinary clinical oversight and proofing of all documents (forms, pathway orders, guidelines and protocols, electronic and printed, patient teaching materials, etc) which have medication specific information (sign off on proof required). Check for terminology, spelling, removal of abbreviations, drug nomenclature, and coordination with the clinical care of the patient and information system use. Review documents annually for obsolescence and accuracy. Automation is encouraged here. Include dating of forms if applicable so that care givers have a method to assure use of current form.	Control	Intermediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 7	**Patient and Family education:** The absence of a structured process for caregivers to provide patient and family education (in ED) increased the likelihood of miscommunication to the family and decreased the likelihood that the family could communicate the treatment to other subsequent caregivers.					
Patient and family unaware of medication	No structure or material support for patient education in Emergency Department	**7 A**	Implement a process to actively communicate ongoing treatment plans to patients and family as care is being delivered.	Control	Immediate	Hospital Leadership or Designee
		7 B	Implement an infrastructure (including resources) for the provision of patient and family education in the ED specific to disease and treatment received. This should include verbal and written post care instructions appropriate for the health literacy of the patient. The use of automation here is encouraged.	Control	Intermediate	Hospital Leadership or Designee
		7 C	Include patient and family education in patient satisfaction, staff orientation and competency, and QA activities of the department	Control	Intermediate	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 8	**Work environment:** Bed allocation practices (hard bed allocation and limited inpatient discharges over the weekend) led to a "Code Burgundy" situation in the ED on Sunday. This increased the likelihood that an admitted patient requiring frequent nursing intervention would wait in the ED, and contribute to distractions in the work place.					
Distraction in the work place;	Discharge from Emergency Department; Code Burgundy	**8 A**	Implement inpatient utilization review and discharge planning process which includes coverage for weekends	Control	Intermediate	Hospital Leadership or Designee
	Open architecture of Emergency Department	**8 B**	Conduct a human factors engineering evaluation of distractions in the work place related to medication prescribing, transcribing, preparation, administration and monitoring in ED. Implement changes based on findings. Coordinate the evaluation of the work environment with the installation of automated dispensing devices to assure correct placement and quantity.	Control	Long Term	Hospital Leadership or Designee

Root Cause / Contributing Factor #	Root Cause / Contributing Factor Statements	Action #	Recommended Action(s)	Type of Action (Control, Eliminate, Accept)	Time-frame *	Individual Responsible
RC 9	**Monitoring/discharge criteria:** The lack of standard monitoring and discharge criteria from the ED increased the likelihood that a patient would be discharged without monitoring for effects of medications administered while in ED.					
Patient not assessed	No discharge criteria or observation criteria for Emergency Department	**9 A**	Implement QA/CQI/UR process, which addresses the clinical appropriateness of visits, and the clinical outcomes of patients cared for and discharged from Emergency Department.	Control	Immediate	Hospital Leadership or Designee
RC 10	**No pain treatment guidelines in ED:** Lack of formal pain treatment guidelines in the ED (addressing the standardization of the prescribing, dispensing, administering and monitoring of pain medicine) reduced the likelihood that care would be coordinated and that communication would occur among care givers and to the patient and family.					
Patient and family unaware of medication	Physician clinical judgment re: pain management	**10 A**	Establish interdisciplinary pain management guidelines through the P&T Committee, which are communicated to all staff and readily available for reference. Match the floor stock to the drugs in the pain management guidelines (if applicable)	Control	Intermediate	Hospital Leadership or Designee

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Appendix 1
Hydromorphone Event Timeline

Time	Item	Notes
	EMS Call	
14:12	Fentanyl 100 mcg given Slow IV Push	From EMS record
15:32	Arrive ED	From XXX chart
15:45	Vital Signs in Upon arrival at XXX	From XXX chart
16:00	Seen by ED physician	From XXX chart
17:05	Pt returned from X-ray and Vital Signs taken	From XXX chart
misc	RN caring for dementia patient and 2 other patients	
misc	Dr and family discussion regarding admission and pain management	RN did not fully hear discussion due to physician's soft voice
18:00	ED Drs Final Note	From XXX chart
	Dr tells RN to give Morphine 10 mg IM and writes "Morph 10 mg IM" on record	Medication order untimed
	Nurse takes chart to narcotic preparation area	From RN interview
	Narcotic dose removed from narcotic cupboard and RN noticed other assigned patient (with dementia) climbing out of bed	Time written over in the narcotic sheet?
	RN read "morph" and "10 mg" on grey box - and took medication vial with her	Per RN interview
	RN went to attend to dementia patient with drug in hand	Per RN interview
18:12	RN documents removal of drug on narcotic sheet and prepares to administer the drug	From RD narcotic record
	RN administers the hydromorphone	From RN interview
	RN goes back to the medication station	From RN interview
18:13	Nurse charts that patient requested analgesic before discharge	Doesn't match family interview that Dr said to give it him; but, RN and Dr. independently gave same information
18:13	Morphine dose charted on ED sheet	Per XXX chart
	Daughter tells RN that patient is dizzy (as they help him with clothes) but RN did not reply	From family interview
	RN vaguely remembers patient complaining of dizziness, but does not think it is drug (morphine) related	From RN interview
18:35	Time of discharge per ED Record	Discharge time charted before pt was wheeled out to car - per RN interview
18:40	Patient's daughter states leaving parking lot and driving towards XXXX and calling a XXXX pharmacy to fill the prescription	Per family interview

Deleted: believes dizziness is from morphine beginning to work for patien

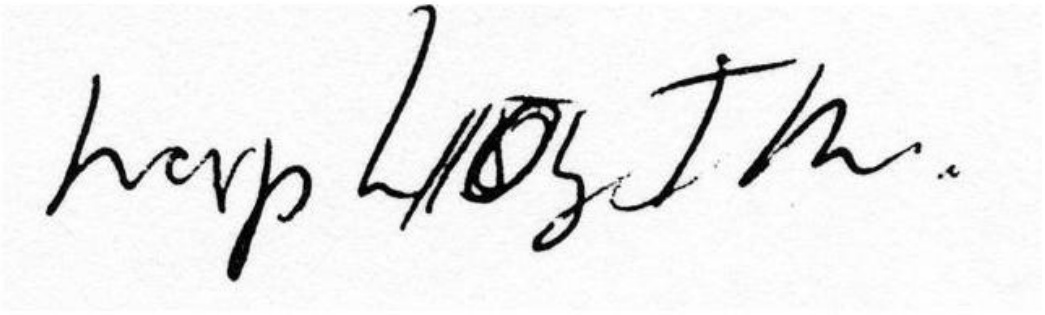
Deleted: t

Time	Item	Notes
misc	Family driving home	
misc	Stopped by light at Capri Hotel and patient was snoring and he responded back that he was ok	Per family interview
misc	As speed limit changes, daughter asked patient if she was driving too fast for his comfort, but patient said no, he was ok, but dizzy	Per family interview
misc	At the XXX bridge – the patient gasped 2x and daughter put hand in front of his mouth to check for breathing (not breathing)	Per family interview
19:01	Patient's daughter called 9-1-1	
19:10	XXX received call that patient was on route in respiratory arrest	Per XXX records
19:10	Physician notified and on the way	Per XXXl records
19:10	Dr states he was called to come to ED	Per XXX records
19:11	Pt Arrived at XXX Hospital	
19:11	Resuscitation Started by XXX Ambulance staff	Strip says 19:09 from XXX
19:11	Daughter informed XXX staff of prior treatment at ED	Per family and staff interview
19:12	Attempting to start IV	From XXX chart
19:12	Bag Value mask resuscitation initiated	From XXX chart
19:12	Intubation attempted	From XXX chart
19:15	Narcotic count begins at XXX ED	Per narcotic sheet at XXX
19:20	Shift count finds narcotic discrepancy for both morphine and hydromorphone products	Per staff interview at XXX
19:17	XXX ED staff calls patients home	From family interview per pt's answering machine
19:20	Atropine 0.6 mg given IV to patient. CPR compressions, asystole	From code sheet
19:21	Epinephrine 1mg / 10 mL given	From code sheet
19:22	Atropine 0.6 mg / mL given	From code sheet
19:24	Epinephrine 1mg / 10 mL given	From code sheet
19:25	Atropine 1 mg / 10 mL given	From code sheet
19:25	XXX Dr. documented that XXX ED called and related that patient had been given hydromorphone instead of morphine	XXX documents this call took place at 19:30
19:27	Still attempting intubation with difficulty; Epinephrine 1 mg / 10 mL given	From code sheet
19:28	IV naloxone 0.8 mg given	From code sheet

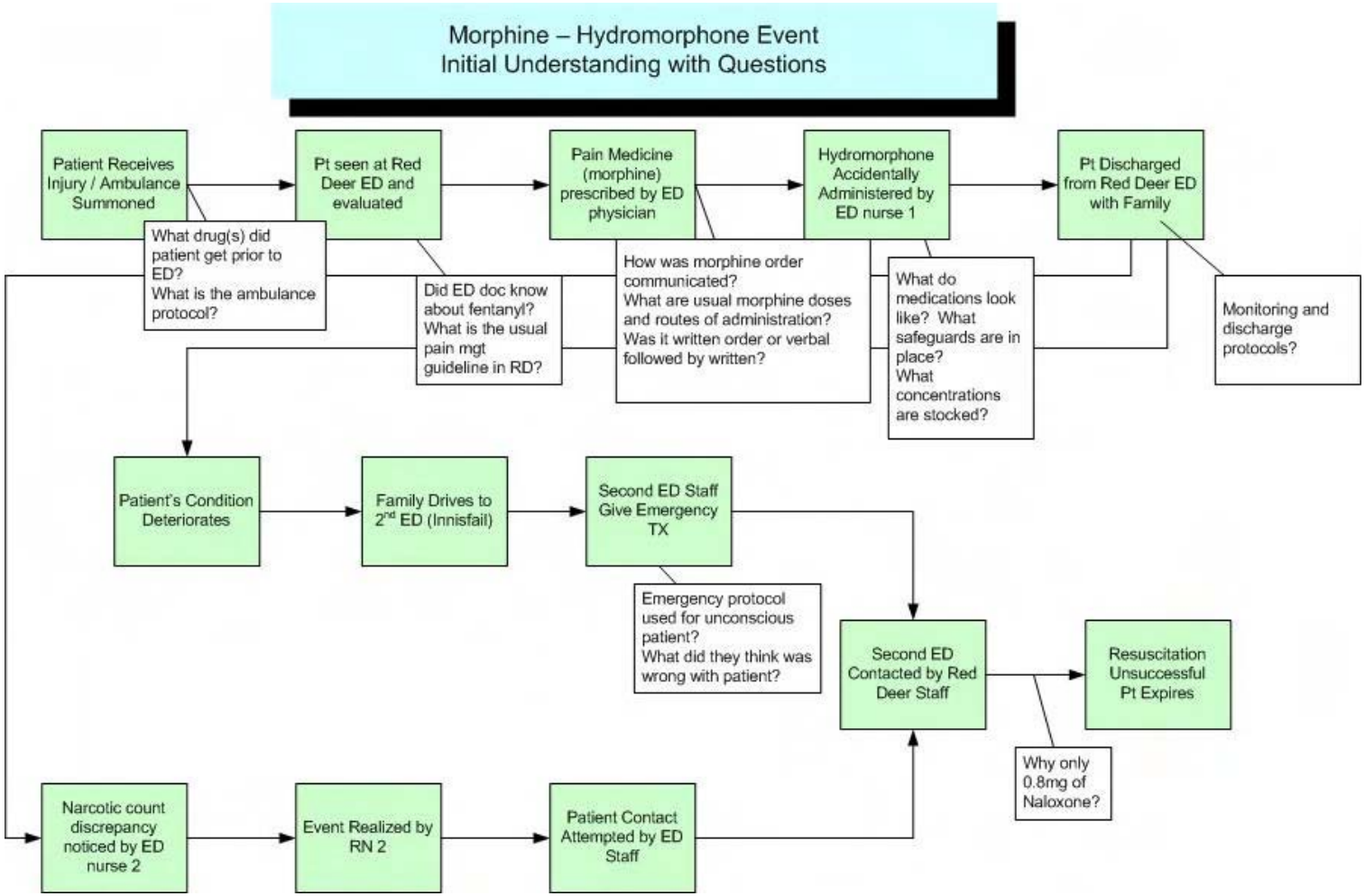
Time	Item	Notes
19:32	IV naloxone 0.8 mg given	From code sheet
	EMS crew goes to ambulance for alternate blade size	Per EMS interview
19:34	Endotracheal Tube size 7 inserted	From code sheet
	IV Lidocaine administered - not charted	Per medical examiner; per XXX ED doc
19:40	Atropine 1 mg given	From code sheet
19:40	Patient was pronounced	From code sheet

Appendix 2

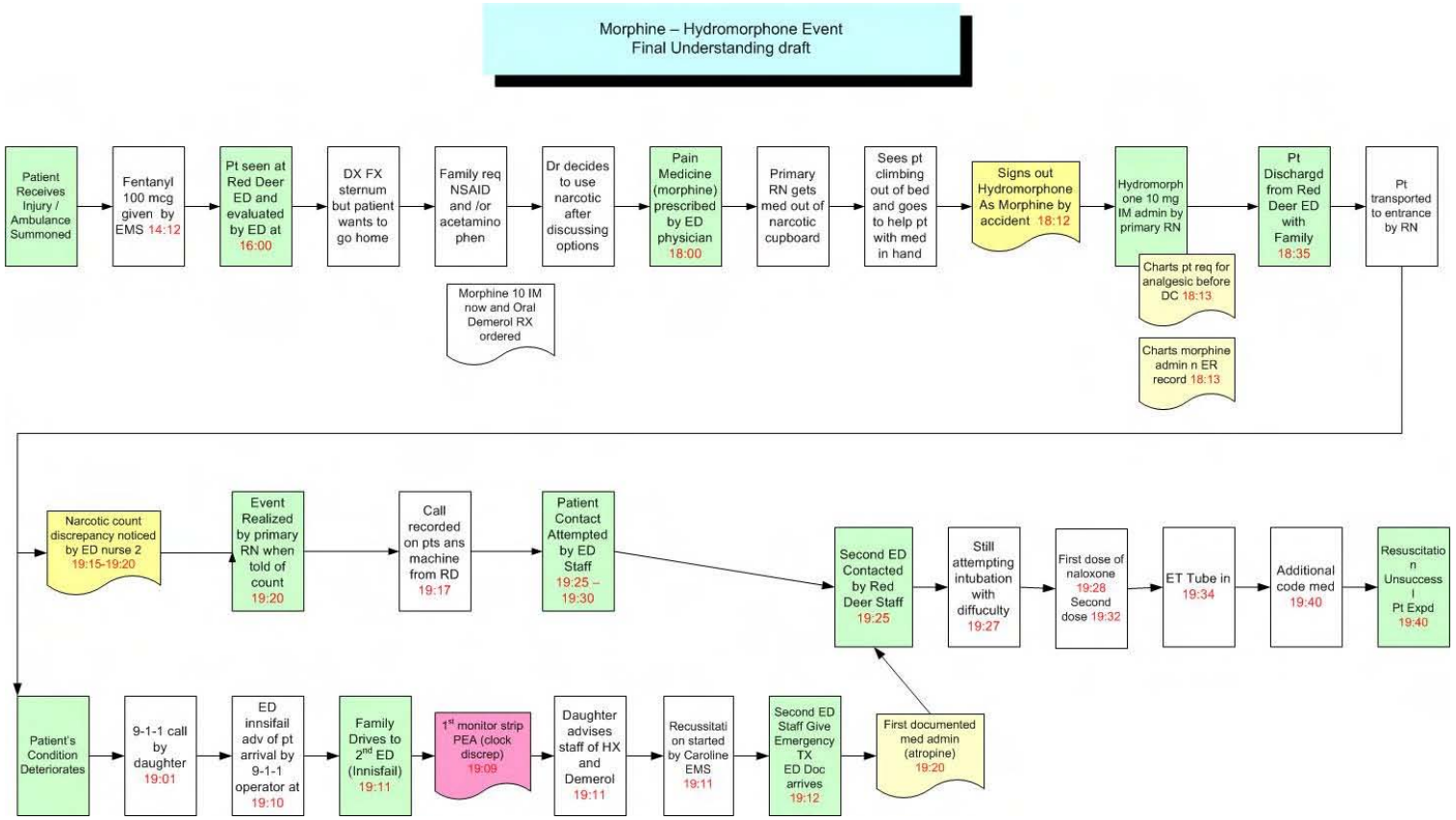
Written order in ED record for “morph 10 mg IM”



Appendix 3


Morphine – Hydromorphone Event
Initial Understanding with Questions
Patient Receives Injury / Ambulance Summoned
Pt seen at Red Deer ED and evaluated
Pain Medicine (morphine) prescribed by ED physician
Hydromorphone Accidentally Administered by ED nurse 1
Pt Discharged from Red Deer ED with Family
What drug(s) did patient get prior to ED?
What is the ambulance protocol?
Did ED doc know about fentanyl?
What is the usual pain mgt guideline in RD?
How was morphine order communicated?
What are usual morphine doses and routes of administration?
Was it written order or verbal followed by written?
What do medications look like? What safeguards are in place?
What concentrations are stocked?
Monitoring and discharge protocols?
Patient's Condition Deteriorates
Family Drives to 2nd ED (Innisfail)
Second ED Staff Give Emergency TX
Emergency protocol used for unconscious patient?
What did they think was wrong with patient?
Second ED Contacted by Red Deer Staff
Resuscitation Unsuccessful Pt Expires
Why only 0.8mg of Naloxone?
Narcotic count discrepancy noticed by ED nurse 2
Event Realized by RN 2
Patient Contact Attempted by ED Staff

Appendix 4


Morphine – Hydromorphone Event
Final Understanding draft
Patient Receives Injury / Ambulance Summoned
Fentanyl 100 mcg given by EMS 14:12
Pt seen at Red Deer ED and evaluated by ED at 16:00
DX FX sternum but patient wants to go home
Family req NSAID and /or acetamino phen
Morphine 10 IM now and Oral Demerol RX ordered
Dr decides to use narcotic after discussing options
Pain Medicine (morphine) prescribed by ED physician 18:00
Primary RN gets med out of narcotic cupboard
Sees pt climbing out of bed and goes to help pt with med in hand
Signs out Hydromorphone As Morphine by accident 18:12
Hydromorph one 10 mg IM admin by primary RN
Charts pt req for analgesic before DC 18:13
Charts morphine admin n ER record 18:13
Pt Dischargd from Red Deer ED with Family 18:35
Pt transported to entrance by RN
Narcotic count discrepancy noticed by ED nurse 2 19:15-19:20
Event Realized by primary RN when told of count 19:20
Call recorded on pts ans machine from RD 19:17
Patient Contact Attempted by ED Staff 19:25 – 19:30
Second ED Contacted by Red Deer Staff 19:25
Still attempting intubation with diffuculty 19:27
First dose of naloxone 19:28 Second dose 19:32
ET Tube in 19:34
Additional code med 19:40
Resuscitation Unsuccessful Pt Expd 19:40
Patient's Condition Deteriorates
9-1-1 call by daughter 19:01
ED innsifail adv of pt arrival by 9-1-1 operator at 19:10
Family Drives to 2nd ED (Innisfail) 19:11
1st monitor strip PEA (clock discrep) 19:09
Daughter advises staff of HX and Demerol 19:11
Recussitation started by Caroline EMS 19:11
Second ED Staff Give Emergency TX ED Doc arrives 19:12
First documented med admin (atropine) 19:20

Appendix 5

PHOTOGRAPHS OF THE WORK ENVIRONMENT

Appendix 6

PHOTOGRAPH OF THE NARCOTIC CUPBOARD

Narcotic cupboard showing the close proximity of the morphine and hydromorphone products on the lower shelf (red-circled area).

Appendix 7

PHOTOGRAPHS OF THE PACKAGING

Hydromorphone 10 mg/mL vial.

Morphine 10 mg/mL ampule and hydromorphone 10 mg/mL vial.

Hydromorphone 10 mg/mL box with front cover removed to facilitate narcotic counts.

Appendix 8

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