HQCA
Health Quality Council of Alberta

March 17, 2010

Quality Assurance Review of the Three Medication and One Expressed Breast Milk Incidents at the Alberta Children's Hospital, Calgary, Alberta

Public Report

As Requested by the Alberta Health Services
and as Mandated by the Health Quality Council of Alberta Regulations 130/2006
of the Regional Health Authorities Act Section 14

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Review of Medication and Expressed Breast Milk Incidents at the Alberta Children's Hospital, Calgary, Alberta

Executive Summary

Three medication incidents and one expressed breast milk incident occurred on the same nursing unit at the Alberta Children's Hospital in Calgary, Alberta over the course of two months. Three of the incidents occurred within three weeks of one another. On February 6, 2009 a two year old child received five oral medications intravenously that were intended for administration through a gastrostomy tube for an enteral feed. The patient required transfer to the pediatric intensive care unit for treatment. On February 7, 2009 a four year old patient was given approximately a 15 fold overdose of a narcotic analgesic (fentanyl) as an intravenous (IV) bolus dose. The overdose was not recognized until the following day and no active interventions were made based on vital signs. The third incident occurred February 24, 2009 and involved a six year old child who received a 5 fold overdose of immunosuppressive oral therapy (azathioprine). Three doses were administered before the overdose was recognized. Lab results showed evidence of bone marrow suppression. A fourth incident occurred March 31, 2009 whereby a nine day old infant received the incorrect expressed breast milk. No immediate adverse effects were identified.

In accordance with section 14 of the Health Quality Council of Alberta Regulation 130/2006 under the *Regional Health Authorities Act*, the Alberta Health Services requested the Health Quality Council of Alberta (HQCA) to study, assess and inquire into* (*hereafter known as "review") the above incidents that occurred in the Alberta Children's Hospital (ACH) for the purpose of improving patient safety and health care quality. The HQCA was charged with identifying the causes and contributing factors of the medication and expressed breast milk incidents at the ACH. Comparison to best practices in medication safety and expressed breast milk processes and review of other Alberta Health Services (AHS) paediatric tertiary care centres with regard to medication and expressed breast milk safety fell within the scope of this review. Key findings and systemic applications will be considered by the AHS for sharing with relevant health care organizations provincially and nationally to improve the safety of medication and expressed breast milk practices and for reducing the likelihood of recurrence of similar events.

A review team was struck by the HQCA, under the direction of Executive Sponsor, Dr. John Cowell, MD, FRCPC, Chief Executive Officer, HQCA, and led by Linda Poloway, BScPharm, FCSHP, Patient Safety Lead, HQCA. The balance of the Review Team consisted of three individuals with expertise in the areas of patient safety and quality; David Matheson, M.Math, MD, FRCPC, Associate Professor Emeritus Department of Pediatrics, University of British Columbia, Principal DMMD Consultants Inc, Maria Golberg RN MN ACNP ET, Nurse Practitioner, Stollery Children's Hospital and Consuelo Ong, RN, BN, Clinical Nurse Educator, Alberta Children's Hospital were selected. Assisting in the review of human factors impacting medication safety and expressed breast milk processes were Munira Jessa, MASc, PEng, Human Factors Engineer, Patient Safety Specialist and Susan Chisholm, M.Sc., Human Factors Consultant, both of Alberta Health Services – Calgary.

Information gathering, fact finding and validation as well as discovery of causes and contributing factors were conducted under the auspices of the Quality Assurance Committee of the HQCA and were protected under Section 9 of the *Alberta Evidence Act.* While the object of the review was primarily the ACH, the Review Team examined processes, reviewed documentation and conducted interviews at the Stollery Children's Hospital (Stollery), located in the Walter MacKenzie Centre, Edmonton, Alberta. Within the AHS – Edmonton, neonatal care is provided on two sites, the Walter MacKenzie Centre and the Royal Alexandra Hospital. Thus, expressed breast milk practices and processes at the Neonatal Intensive Care Unit located at the Royal Alexandra Hospital were additionally examined by the human factors consultants.

The incidents were reviewed with full transparency provided by the administration, staff and physicians of the Alberta Children's Hospital, Calgary, the Stollery Children's Hospital, Edmonton and the Royal Alexandra Hospital, Edmonton; candid and open dialogue on medication and expressed breast milk practices as well as other patient safety topics relevant to the incidents allowed the Review Team to examine all causal issues and provide a comprehensive report.

In the case of the patient who received oral medications intravenously which were intended for delivery through a gastrostomy tube, the primary cause lay in use of a parenteral system (pump, tubing, and syringe) commonly used to deliver intravenous (IV) therapy that was also used to deliver enteral therapy. This was compounded with the failure to trace the lines back to the source to determine if IV or enteral delivery was intended plus absence of labels on lines to identify contents and route. Of significance a similar incident occurred about 3 years prior and recommendations to mitigate the recurrence of such an event were not fully implemented. Three other contributing factors were identified.

The fentanyl overdose incident revealed ineffective communication between the physician prescriber and the nurse regarding a verbal order for analgesia. The lack of an independent double check for the dose and use of an adult parenteral drug monograph led to incorrect confirmation of the dose, which was approximately 15 times that of a usual dose for a patient of similar age and weight. Identification of three other contributing factors was made.

The absence of a medication reconciliation process was the primary cause of the azathioprine overdose. The addition of a potential unrecognized language barrier and failure to perform a safe dose per weight check by medicine, nursing and pharmacy enabled a 5 fold overdose of the drug to be given. Four other contributing factors were identified.

The administration of the wrong expressed breast milk had occurred several times previously at the ACH. In 2006 a full review was undertaken and 11 recommendations made. Incomplete implementation of those recommendations and less than optimal learning from this experience was the primary cause of the expressed breast milk mix up in March, 2009. The lack of a heightened awareness by nursing and the parents of the potential risks of viral pathogen transmission through expressed breast milk contributed significantly to the incident.

The report has implications for improved patient safety across several health care sectors and it is anticipated that broad sharing of the learnings of this review will occur.

Objectives of the Review

The objectives of the review were to:

1. Identify the factors which led to the medication and expressed breast milk incidents identified in the Alberta Children's Hospital utilizing numerous methodologies including but not limited to review of relevant documents, interviews with staff, physicians, patients and families, review of environments where the incidents occurred and re-enactment of work processes relevant to this incident.
2. Utilize a root cause analysis process, if appropriate, to identify the contributing factors and root cause(s) that led to the medication and expressed breast milk incidents.
3. Identify national and international standards, guidelines and best practices for medication ordering, preparation, dispensing and administration in the pediatric patient population.
4. Identify national and international standards, guidelines and best practices for expressed breast milk collection, storage and administration.
5. Review the medication practices at the Stollery Children's Hospital, Edmonton, Alberta to compare and contrast practices at the Alberta Children's Hospital.
6. Review the practices for collection, storage and administration of expressed breast milk at the Alberta Children's Hospital and the Stollery Children's Hospital, Edmonton.
7. Review the patient safety culture at the Alberta Children's Hospital.
8. Make recommendations to ensure the contributing factors and root cause(s) of the medication and expressed breast milk incidents are addressed within the Alberta Children's Hospital and shared with other health care institutions as directed by Alberta Health Services.
9. Upon agreement with Alberta Health Services, the Health Quality Council of Alberta will share findings and recommendations with other health care institutions within the province and across Canada.

Root Cause Analysis – An Overview of the Process

As defined in the Canadian Root Cause Analysis Framework[1], root cause analysis is "an analytical tool which can be used to perform a comprehensive, system based review of critical incidents. It includes the identification of the root cause and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans".

A multi-disciplinary root cause analysis team is established involving individuals with firsthand knowledge of the subject as well as higher level authority and responsibility in the matter. It is optimal to involve individuals with decision making ability in order to facilitate implementation of the recommendations once the analysis is completed.

The Root Cause Analysis (RCA) team first blueprints the events in chronological order to establish facts surrounding the issue. Questions asked are, "what happened", "why did it happen", and "what can we do to prevent it from happening again". The "why" questions result in a series of cause and effect diagrams that identify numerous causes and contributing factors. Those causes and contributing factors are prioritized and the root cause is identified by answering the following question: "If you eliminate or control this cause will you prevent the event from recurring?" In some cases, there is more than one root cause. Causative statements are then developed that show cause and effect relationship and are worded to identify systemic contributing factors. Systemic issues move beyond the individuals involved in the incident and examine safety culture, the working environment, communication between health care providers and the patient, fatigue and scheduling of health care workers, training and education of health care providers and compliance to policies and procedures. Recommendations for action evolve from the causative statements and attempt to incorporate strategies that include strong interventions. A hierarchy of actions (see Figure 1) supports use of strong actions that would eliminate the event from recurring; an example would be a forcing function that utilizes physical barriers to prevent error and provides alarms when a wrong procedure is attempted. Issuing of a memo requesting practice change would be an example of a least effective type of intervention. Changing organizational structure to support patient safety would constitute an action that would reduce the likelihood of recurrence of the event but not eliminate it.

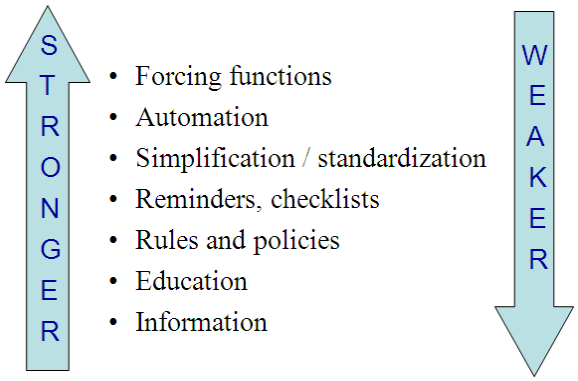


Figure 1. Hierarchy of Actions

All activities of the RCA including development of causes, contributing factors and recommendations are arrived at by consensus of the RCA team.

[1] Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, 2006.

Methodology

The review was conducted in the following phases:

a) Off-site preparation and information gathering

b) Individual interviews

c) On-site review of relevant nursing units and main pharmacy at the Alberta Children's Hospital (ACH), the Stollery Children's Hospital (Stollery) and the Neonatal Intensive Care Unit (NICU) at the Royal Alexandra Hospital

d) Root cause analysis (RCA) meetings to confirm chronological occurrence of events in each incident, identify causes and contributing factors and develop draft recommendations

e) Presentation of preliminary findings to the Steering Committee of the ACH

f) Generation of full report

g) Review of full report regarding the incidents with Steering Committee of the ACH and ad hoc members to validate facts, and confirm causes, contributing factors and recommendations

h) Release of the report

All activities were conducted under the auspices of the Quality Assurance Committee of the Health Quality Council of Alberta (HQCA) and the ACH Steering Committee and were protected under Section 9 of the *Alberta Evidence Act.*

a) Off-site preparation and information gathering

Relevant documents were provided by the ACH, Stollery and Royal Alexandra for review by the Review Team. These included but were not limited to:

- organizational charts
- health records of patients impacted by incidents under review
- quality and safety structures and reporting systems
- safety learning reports / incident reports
- reviews of adverse events
- policies and procedures addressing medication systems and expressed breast milk processes
- disclosure and incident management processes
- terms of reference and minutes from quality and safety committees
- educational resources for nursing and pharmacy
- orientation guides for nursing and pharmacy

Additional documentation reviewed included:

- standards and guidelines on safe medication practices
- standards and guidelines on expressed breast milk
- nursing standards of practice

- physician code of ethics, guidelines for behavior

b) Individual interviews

Interviews were conducted with individuals ranging from direct care providers to senior executive positions as well as physicians to understand the events leading to and following each of the events. Interviews provided additional insight into the procedures and practices, local and regional oversight for medication and expressed breast milk safety as well as a broader understanding of safety initiatives, management and disclosure of adverse events, and organizational culture. Interviewees were not named in the report and information that would otherwise identify them minimized as appropriate.

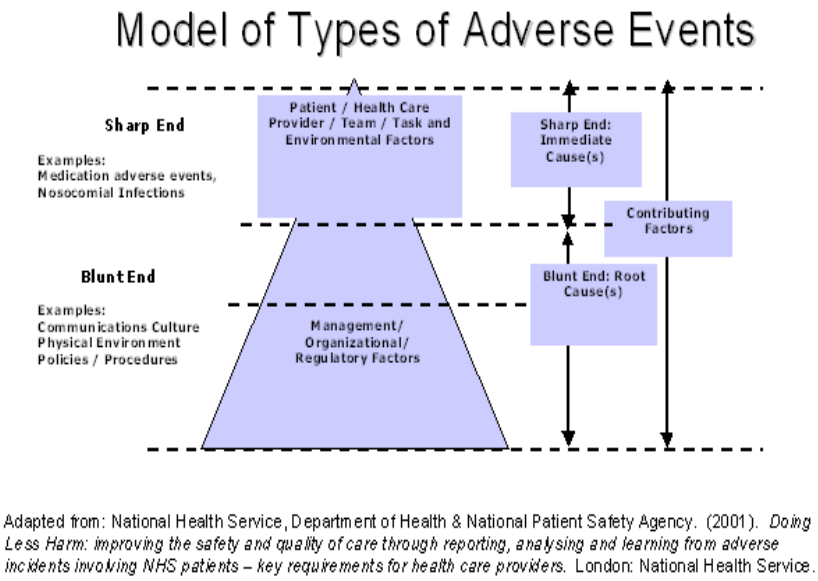
c) On-site review of patient care units and pharmacies

The Review Team and the human factors consultants received a functional tour of the patient care unit at the ACH and an analogous unit at the Stollery with a focus on the medication rooms and areas housing expressed breast milk. The NICU at the Royal Alexandra was observed by the human factors consultants for medication and expressed breast milk processes. Main pharmacy processes at ACH and the Stollery were examined by the Review Team and human factors consultants with the latter spending additional time reviewing and documenting all medication review, dispensing and preparation areas. Human factors consultants, along with select members of the Review Team examined a variety of infusion pumps used and areas for processing and storage of expressed breast milk.

d) RCA meetings to validate facts, identify causes and contributing factors and concurrent information gathering

A root cause analysis was conducted by the Review Team to identify root cause(s), contributing factors and recommendations. Prior to embarking on the RCA process, the RCA facilitator and lead of this review provided just in time learning on a systems approach to investigation of adverse events, the elements of which are depicted in figure 2 below.

The point where health care services are provided to the patient, and the point where incidents are discovered, is referred to as the “sharp end” of the system. The “blunt end” of the system represents the broader management, organizational and regulatory factors involved in the system[6]. It includes such factors as policies and procedures, staffing patterns, physical plant, environmental structures, communication and culture. Figure 2 illustrates that it is not uncommon to find many root causes in the blunt end.



Adapted from: National Health Service, Department of Health & National Patient Safety Agency. (2001). *Doing Less Harm: improving the safety and quality of care through reporting, analysing and learning from adverse incidents involving NHS patients – key requirements for health care providers.* London: National Health Service.

Figure 2. Model of Types of Adverse Events

The systems approach, Swiss Cheese Model[2] was used to illustrate that adverse events rarely occur because of one failure, but occur because of multiple failures that are usually latent within the system[2]. In a well managed system, there are several layers of defense (quality and/or safety systems) represented by the slices of cheese. The holes in the cheese represent areas of weakness in the systems, some caused by active failure of individuals, others caused by latent conditions. These holes are continuously opening and closing and changing position. Serious danger occurs when a set of holes opens up briefly to allow a window of incident opportunity. The more protective the layers of defense are the safer is the system. The Swiss Cheese model has been used to explain how, despite quality and safety controls in place, errors occur resulting in adverse events (see Figure 3).

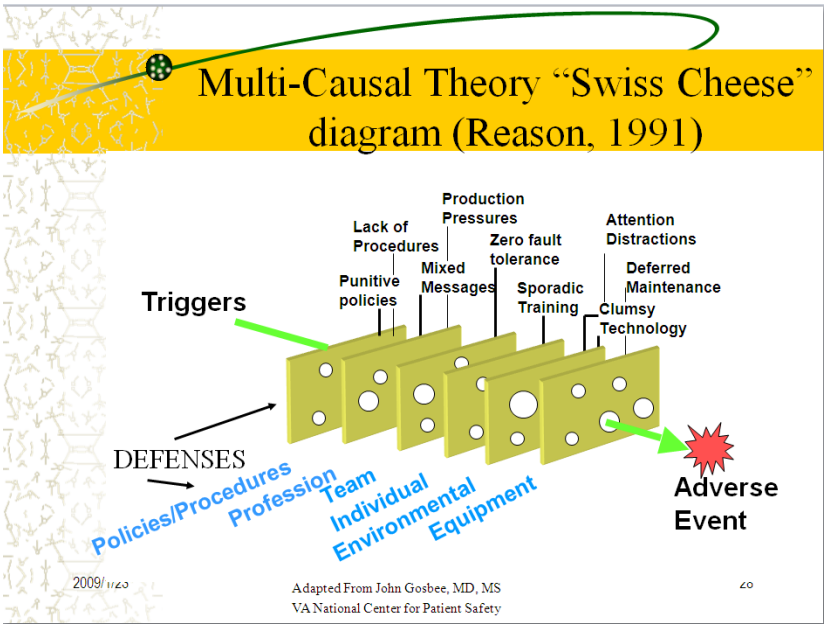


Figure 3. Swiss Cheese Model

[2] Reason, J. Managing the Risks of Organizational Accidents, Aldershot: Ashgate; 1997

The focus of an RCA is to primarily identify and address systemic issues; however, personal and professional accountabilities and responsibilities are not ignored. Should the Review Team identify performance or behavior that has a repetitive history and has not been dealt with, that performance or behavior is referred back to management for an administrative review. Similarly if the incident was linked to a pre-existing duty to act or fulfill a professional responsibility and that responsibility was not carried out, that action will be addressed by the RCA team.

The Review Team collaboratively identified and gathered information to depict a comprehensive understanding of the incidents, why they may have occurred and the significance of their impact. A chronological table of events leading up to and following the incidents was developed for each incident. Information from the individual interviews was used to flesh out the facts of the incident which were known at the commencement of the review. A series of cause and effect diagrams were then developed by the Review Team to identify cause(s) and contributing factors.

The Review Team developed causative statements based on the cause and effect diagrams and knowledge of the incidents. Causative statements follow the 5 rules of causation as described by the United States Veteran's Affairs National Centre for Patient Safety[3]:

- Root cause statements show the cause and effect relationship
- Negative descriptions should be avoided in root cause statements
- Each human error must have a preceding cause
- Management of violations of procedure rather than the procedural violation itself should be the focus of causative statements
- Failure to act is only causal when there is a pre-existing duty to act.

The causative statements were not differentiated into root cause(s) and contributing factors. Rather, they were listed in order of most likely contributing to the incident.

The Review Team drafted recommendations based on a full understanding of each incident and causative statements as described above. Each team member individually developed recommendations and then collectively a consensus of recommendations was reached.

e) Presentation of preliminary findings

The Review Team Lead and Executive Sponsor presented preliminary findings to the ACH Steering Committee for the purpose of sharing available information from the review and receiving feedback on any inaccuracies in the report. Minor changes were made following this presentation and dialogue.

f) Generation of full report

The Review Team developed the full first draft of the report with each member assigned a designated section and using the Health Quality Council of Alberta template for review reports. The Team collectively edited one another's work and the final draft was reviewed by the Executive Sponsor.

[3] http://www.patientsafety.gov

g) Review of full report related to the incidents with Steering Committee of the ACH

Formation of an internal RCA team with ACH front line staff, physicians and management was attempted but due to recurring delays in the review process, influenced by changes within the Alberta Health Services, a decision was made to use the Steering Committee of the ACH to review the report in detail to validate facts, and confirm causes, contributing factors and recommendations. For this purpose ad hoc members who had knowledge of some of the incidents and/or would have responsibility for implementing recommendations from the review were added to the Steering Committee. The Committee requested that recommendations be prioritized to identify the most critical ones which the Review Team felt should be implemented as soon as possible to most significantly improve patient safety.

h) Release of the report

Following the review of the report by the Steering Committee of the ACH, necessary revisions were made, reviewed and supported by the Executive Sponsor and provided to the Steering Committee. The Steering Committee will work with Alberta Health Services to implement recommendations and spread the information for greater learning.

Analysis of the Causes and Contributing Factors and Comparison between Alberta Children's Hospital and the Stollery Children's Hospital

Based on the final understanding and additional information from interviews, documents, photos, patient care unit visits and work simulation with some supplies relevant to the incidents, the Review Team developed an analysis of why each incident happened and what systemic issues allowed the incidents to occur. From all the causes and contributing factors identified there, the most significant are addressed below. From these causes and contributing factors, recommendations were developed to mitigate the likelihood of recurrence of these incidents.

A. Incident - Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously

Use of a Parenteral Infusion System to Administer Enteral Feeds

Enteral infusion pumps dedicated to delivering enteral feeds were not available at the Alberta Children's Hospital (ACH). To accommodate administration of small volumes of enteral feeds or medications, a parenteral infusion pump was used. This pump differed from the SMART parenteral infusion pumps used to administer parenteral medications and fluids. Use of a parenteral pump for enteral feeds was not unique to the ACH; parenteral pumps were also used for enteral feeds at the Stollery Children's Hospital (Stollery). At the Stollery the SMART parenteral infusion pumps were used for both enteral and parenteral administration of medication and fluids.

The use of a parenteral pump is one link in the causal chain involving equipment and supplies. Specifically, the interconnectivity of parenteral and enteral tubing, syringes and portals is a critical supply weakness which sets health care providers up for failure. ACH policy directs that enteral tubing should be used to administer enteral feeds. However, the common practice was to use parenteral tubing as it was found that the enteral tubing frequently plugged / occluded. The cause(s) of the occlusions were not revealed in the review process. Lastly parenteral syringes were routinely used to administer enteral feeds as the correct size of enteral syringes that were compatible with parenteral tubing and infusion pumps were not available at ACH. The luer lock of this syringe connected both to the parenteral as well as the enteral tubing. A true enteral syringe would not have been able to connect to parenteral tubing.

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) in the United States has recognized tubing misconnections as a "persistent and potentially deadly occurrence"[4]. The root cause of tubing misconnections identified in a JCAHO Sentinel Event newsletter is "the ability for functionally dissimilar tubes or catheters to be connected". Other causes, seen in the ACH incident as well, included:

- the routine use of tubes or catheters for unintended purposes, such as the use of IV extension tubing to extend feeding tubes, drains, central lines, and others
- the positioning of functionally dissimilar tubes (e.g. IV, enteral) used in patient care in close proximity to one another

Contributing factors identified in the JCAHO literature include:

- staff fatigue; and
- movement of patients from one setting or service to another

[4] http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm

The Institute for Safe Medication Practices (ISMP) has also recognized this issue and come to similar conclusions as JCAHO as described in their June 15, 2006 safety newsletter.[5] Recommendations from both these sources have been incorporated into this review.

Use of parenteral systems to administer enteral feeds is currently practiced in the Stollery; this practice is subject to the same risks as described above. The Stollery, in concert with the Royal Alexandra Hospital, is actively seeking the purchase and use of enteral supplies that cannot fit to parenteral systems.

Learning from Previous Adverse Events was not Maximized

Expressed breast milk had been erroneously infused into an intravenous line in 2006 at the ACH. Several policies and procedures addressing various aspects of enteral and parenteral therapies and use of supplies and equipment existed at ACH but no one policy and/or procedure clearly identified the safe practices to be employed to prevent an enteral – parenteral mix up. A new policy and procedure with directives to prevent repetition of the adverse event had been under development since the event in 2006 but not yet implemented. Two directives in that policy, to trace the line (tubing) back to source and to label lines directly related to causes in this incident. The remainder of that draft policy and procedure reflected most of the common failures and recommendations for prevention of errors of tubing misconnections. Noteworthy is that immediately after the ACH incident where medications intended to be given through a gastrostomy tube were given IV, management from the Stollery issued a memo entitled, "PATIENT SAFETY: Risk for Misconnection between Enteral Feeding Apparatus and Intravenous Infusions in Pediatrics" for distribution to its staff. The memo addressed potential errors and 6 directives for prevention. This memo was also circulated to ACH staff who were encouraged to attend a teleconference on "tubing misconnections" organized by AHS – Edmonton.

AHS – Calgary has an extensive structure of clinical safety committees that address adverse events; ACH's process for safety learning fell within this structure at the time of the HQCA review. According to their processes, subsequent to a formal review of an incident, a letter is sent to each portfolio with relevant responsibility and authority to act on the findings. The letter briefly describes the "case" and recommendations relevant to that recipient's portfolio as well as a complete list of recommendations from the safety analysis. Information about the case and its causes and/or contributing factors is not communicated to middle or front line management, nor to front line staff who will be impacted by the recommendations and who may be required to change their current practice. "Storytelling" within patient safety is a powerful tool to make a lasting impression of system errors, the likelihood of their occurrence and methods to prevent recurrence. If staff know the story, it is more likely that they will remember the recommendations. Interpretation of Section 9 of the *Alberta Evidence Act*[6] by AHS – Calgary has precluded the sharing of any causes and/or contributing factors. The need for confidentiality of some of the information and respect for the individuals involved in the incident, as appropriate within a just and trusting culture, are acknowledged, but the organization is encouraged to find a way to share enough information to "tell the story" with a focus on systems connecting the recommendations to prevention of recurrence of adverse events.

Recommendations from review of other adverse events were tabulated but not prioritized according to the potential to harm if they were not implemented. Without that prioritization, significant recommendations could be delayed in their implementation and pose undue risk to patients. Audits to determine compliance with the implemented recommendations and/or evaluation of their effectiveness were not conducted.

[5] http://www.ismp.org/newsletters/acutecare/articles/20060615.asp
[6] www.qp.gov.ab.ca/Documents/acts/A18.CFM

The value of shared learning from adverse events beyond the site of occurrence is illustrated in the findings of the Review Team where an almost identical incident occurred in an Edmonton hospital in September, 2008. The causes and/or contributing factors in both cases were the same:

- The same infusion pump was used for both enteral and parenteral / IV infusions
- IV tubing was routinely used for enteral feeds
- The tubing (line) was not traced back to source as a result of not wishing to disturb sleeping child
- Patient handover communication was incomplete

The Edmonton hospital immediately implemented use of enteral lines exclusively for enteral feeds and discontinued the use of luer lock syringes (used in parenteral administration) for enteral feeds or oral administration of medication. At the time of writing this report AHS – Edmonton and AHS – Calgary were investigating different options to achieve a similar outcome. Standardization of approaches should be strongly encouraged. Other recommendations from the Edmonton hospital incident mirror those of the Review Team included in this report. AHS – Edmonton and the Edmonton hospital worked with the Foothills Hospital in Calgary, the site of the Neonatal Intensive Care Unit in Calgary to develop immediate and longer range recommendations to prevent recurrence of such an event but the information was not shared with ACH at the time.

Failure to Check the Line Back to Source in Order Not to Wake the Patient

The patient was familiar to the staff as was the family's desire to avoid any unnecessary wakening of the child. The primary care giver did not pull back the blanket and unwrap the sleeping child before administering the syringe of medications intended for delivery via the gastrostomy tube. ACH embraces "family centred care" described as the following in their March 20, 2007 *Frontlines* newsletter: "Patient and family centred care is an approach to the planning, delivery, and evaluation of health care that is grounded in mutually beneficial partnerships among health care patients, families, and providers. Patient and family centred care applies to patients of all ages, and it may be practised in any health care setting". *(Taken from the Institute for Family-Centered Care.)* This review does not examine the merit of family centred care but clearly identifies that safety of the patient must be the primary determinant in providing care. In this incident the fundamental professional responsibility and safe practice to trace back the tubing (lines) to the source was compromised.

The interpretation and application of family centred care at the Stollery is likewise inconsistent and requires clarification to ensure safety is not compromised in satisfying family's perceived expectations.

Lack of Knowledge of Current Treatment Regimens

At the start of the day shift, a request was made for transfer of patient assignment from a nurse who had not cared for the patient during previous hospitalizations to one who had historically provided care to this patient. Information about the care required for the patient was gleaned from the taped morning report about all patients on the unit as well as historical familiarity with the patient. Previously the patient's oral medications were prepared into a slurry and infused directly into the gastrostomy port using a parenteral syringe. Reliance on the patient's previous care resulted in lack of knowledge of the patient's changed regimen for enteral feeds with regard to the method of administration and the addition of a new infusion pump.

Last minute changes in patient assignment happen frequently. Two way communication where the critical information necessary to safely care for the patient is exchanged between care givers in a patient handoff is best practice and a required organizational practice of Accreditation Canada. That optimal exchange of information did not occur in this incident.

Omission of Labeling Infusion Lines

Lines to identify the route and contents of the infused solutions were not labeled and did not give the primary nurse instructional information for delivery of the enteral feed. Labeling of lines is identified as a best practice and recommended in American literature[4] to prevent tubing misconnections. A directive to label lines was also included in the draft policy and procedure under development in reference to a similar incident in 2006 but not yet implemented as discussed above.

Pressure to Administer Multiple Medications at a Common Standardized Administration Time

0800 h is a common standardized time for administration of medications; most medications to be given on a "daily" frequency are administered at 0800. The primary nurse was precepting a student nurse as well as caring for 2 additional patients who also had medications due at this time. The nurse was conscious of the desire of the patient's family to have the medications administered on time. Meeting that expectation, coupled with the other concurrent duties, may have adversely impacted the attention to detail required to administer the medications safely.

Causes / Contributing Factors in Order of Priority

1. A parenteral infusion system was used to deliver an enteral product and included parenteral infusion tubing that could connect to an IV port; use of enteral tubing, as required by ACH policy, would not have connected to an IV port.
2. Recommendations from previous similar adverse events were not implemented and other learning from those events were not maximized to prevent recurrence of future adverse events.
3. While respecting the family's wishes to not disturb their baby, the infusion lines were not tracked back to source to ensure that oral medications intended for enteral delivery would be given through the enteral line and not the IV line.
4. There was a last minute change in the patient assignment followed by failure to gain full familiarity with the patient's current treatment regimens that would have revealed the changed regimen for the enteral feeds and the addition of a new infusion pump.
5. Infusion lines were not labeled identifying the route and contents of the infusion which would have differentiated the enteral line from the intravenous lines.
6. Pressure to administer multiple medications, along with many competing priorities at the beginning of the shift, decreased the attention to detail in selecting the correct infusion pump.

B. Incident – Fentanyl Overdose

Ineffective Communication between the Prescriber and Nurse Receiving the Medication Order

During the evening of the patient's surgery, the patient experienced pain not managed by the indwelling epidural analgesic. By the following morning it was necessary to obtain medication orders to augment the current analgesia. A physician was called as directed in the orders written the day of surgery. A verbal order was given and transcribed as "(telephone order) Dr (X), give Fentanyl bolus 15 mcg/kg x 1, start Fentanyl infusion". The order was repeated back to the physician prescriber and no changes were made. Documentation on the chart showed that communication from the physician to the nurse was ineffective.

The dosage range for sedation or analgesia pre-procedures for children 1 to 12 years of age is 1 – 3 mcg/kg/dose IV every 30 to 60 minutes as needed. The patient received approximately 12 mcg/kg. It appeared that compliance with the Regional Nursing Policy M-1 titled "Medication – Ordering, Preparation, Administration and Disposal" was demonstrated; the policy indicates that a nurse "may accept an order for medication over the telephone from a physician and will document and read back the medication, dose, schedule, route and patient's name for whom the order was intended to the physician giving the order".

Interviews at the Stollery with various levels of staff and physicians in both clinical and administrative roles revealed instances of inappropriate verbal communication and other behaviours that are not respectful of others. The "Respect in the Workplace" policy and process whereby complaints against staff and physicians are dealt with by a 3 member interdisciplinary panel is a deterrent toward continuing unprofessional behaviour. For those who must appear before the panel, there is an opportunity for a mediation process between the staff or physician and the individuals named in the complaint. Lack of physician leadership at the senior level to address this issue was identified as the most significant cause of unresolved physician behaviours. Commendably, one department head supported a zero-tolerance policy for disruptive and unprofessional acts of physicians within this department.

The issue of health care provider behaviour that is inappropriate and not respectful of others is receiving increasing attention internationally and has been recognized as a "behaviour that undermines safety culture"[7] Described as "disruptive behaviour", it has been defined as "aberrant behaviour manifested through personal interaction with physicians, hospital personnel, health care professionals, patients, family members, or others, which interferes with patient care or could reasonably be expected to interfere with the process of delivering quality care".[8]

Lack of an Independent Double Check

The Child Health Policy/Procedure M-1.1 titled "Medication Administration: Pediatric Intravenous Drug Administration" January 2009, indicates that an "independent double check is required for medications administered direct IV and for narcotics." The administration of "Fentanyl IV bolus" met the criteria on two counts. However, in examining the policy and procedure, a definition and clear description detailing the steps for performing an independent double check was lacking and thus did not provide adequate direction to the staff.

An independent double check procedure is an important safeguard for high risk medication administration. The procedure requires a health care worker to read the order, ensure appropriate drug for the indication, do calculations for the correct dose, select the medication and the dose for administration. A second health care

[7] http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_40.htm

[8] Federation of State Medical Boards of the United States, Inc. Special Committee on Professional Conduct and Ethics. *Report of the Special Committee on Professional Conduct and Ethics.* Dallas: Federation of State Medical Boards of the United States, Inc. 2000.

worker with no prior knowledge of the previous drug selection or calculations completed, goes through separate preparatory steps to administer the correct drug and dose; each health care worker conducts their own independent calculations.[9] The final calculations from each health care worker are compared and any discrepancies are addressed before the medication is administered.

An independent double check was not performed in this incident. Frontline staff and nurse managers were not able to clearly differentiate the unique parameters of an independent double check and how it differs from a routine double check.

The primary nurse independently completed her calculation to determine whether the dose prescribed was a safe dose. However, those calculations were then reviewed in a group setting and subject to confirmation bias. An independent double check would have required that the second and third nurse accessed reference information independently and performed their calculations entirely without influence of the first nurse or one another. The deviation from the correct procedure was based on a misunderstanding of what constituted an independent double check.

Perceived pressure to administer the drug as soon as possible also contributed to failure to perform an independent double check. The family was concerned about their child's pain and it was understood that the medication was to be administered before the prescriber physician arrived on the unit. The understanding of a true independent double check was not in place at the Stollery either.

Access to both Adult and Neonatal/Paediatric IV Monographs, Close Proximity of One Another on the Computer Screen and Difficulty in Accessing Critical Information in the Monograph

The online medication monographs were consulted to obtain information necessary to administer the fentanyl IV bolus dose. In this incident, the adult monograph was accessed rather than the neonatal/paediatric monograph. Erroneous selection of the adult monograph was facilitated by its availability to a unit that did not routinely use the adult monograph and by its immediate proximity to the neonatal/paediatric monograph on the computer screen. No forced functions prevented easy access and use of the adult monograph.

Once selected, the presence of a constant header identifying the monograph as either adult or neonatal/paediatric was absent. While the formatting of the adult monograph differed from that of the neonatal/paediatric one, on quick glance they were not discernibly different.

The policy portion of the neonatal/paediatric monographs that grants authority for administration of "direct IV administration" is inserted as a footnote on the bottom of the first page only. That location can easily be overlooked; such information should be clearly identified in the body of the monograph. Secondly, the nurses were attempting to find direction in the monograph on whether they could administer fentanyl as an IV bolus dose; such direction was not clear in the monograph. Even had the pediatric monograph been accessed, the policy statement read, "Approved for direct IV administration by critical care registered nurses and qualified practitioners in accordance with the Child Health Policy - Procedural Sedation S-5". That policy suggests direct IV administration of fentanyl in paediatrics is only for procedural sedation. The information from the adult monograph indicates that fentanyl may be given by "direct IV" with the qualifying statement, "For nursing professionals in the Calgary Health Region" IV direct is considered a specialized clinical competency. Successful completion of the "Administration of Direct IV (IV push) Medications" learning module is required before administering medications via this route. That qualifier suggests that the ability to administer fentanyl by direct IV is dependent on the training of the nurse

[9] White, R, Easty, A. 2008. Checking it twice: Developing and implementing an effective method for independent double checking of high-risk clinical procedures. Retrieved from: http://www.patientsafetyinstitute.ca/uploadedFiles/Research/Final%20Report(5).pdf

administering the medication rather than the training and location of administration; i.e. if the nurse completed the learning module, she/he could administer direct IV fentanyl anywhere in the facility.

Critical information within the monographs was often difficult to readily locate and standardization of terminology, particularly to identify doses that are given directly from a syringe into the vein or an IV line was required; various terms included to mean the same thing are tube direct, IV push, direct IV administration, and bolus dose. The adult monograph content generally appeared better organized and facilitates greater ease in finding critical information quickly.

Reliance on hard copies of parenteral drug monographs is the most common approach used by nursing at the Stollery. The monographs have both adult and pediatric information available within one monograph.

Causes / Contributing Factors in Order of Priority

1. A telephoned order for an analgesic to relieve acute pain was ineffectively communicated between the physician prescriber and the nurse accepting the order.
2. An accurate description of an independent double check and instructions on how to conduct same were absent in the organization's policy and procedure and a true independent double check of the dose was not conducted.
3. Information from the adult monograph, located in close proximity on the computer screen to the pediatric/neonatal monograph, was used to verify the pediatric dose.

C. Incident – Azathioprine Overdose

Lack of a Medication Reconciliation Process, Language Barrier, Lack of Medication Profile

Best practice for ensuring continuity of home medications for an admitted inpatient requires that the best possible medication history be performed. A best possible medication history is one obtained by a pharmacist or their designate, which includes a thorough history of all regular medication use (prescribed and non-prescribed), using some or all of the medication containers, review of a personal medication list, and/or follow-up with a community pharmacy or review of a current medication list printed by the community pharmacy.[10]

Such a history is conducted by a variety of individuals who could include the prescriber, the primary nurse or a pharmacist. An accurate history is possible only by authenticating the actual medications taken through a combination of a history from the patient and/or family, review of medication vials or other containers brought in, consultation with the dispensing pharmacy and review of on-line medication history. Medication reconciliation is a focused and structured process that organizations commit to with dedicated resources and/or responsibilities clearly designated to key individuals.

A comprehensive medication reconciliation process was absent in the determination of the azathioprine dosing taken by the patient at home. Medication reconciliation is a required organizational practice of Accreditation Canada and facilities must demonstrate compliance of the following to receive full accreditation status:

- Medication reconciliation process implemented at admission in one unit/service area or site, and
- Medication reconciliation process implemented at transfer/discharge in one unit/service area or site, and

[10] Getting Started Kit: Medication Reconciliation Prevention of Adverse Drug Events, *Safer Health Care Now!*, May 2007.

- Medication reconciliation roll out plan for the organization

Accreditation is mandatory in Alberta albeit it is acknowledged that the accrediting body need not be Accreditation Canada. Medication reconciliation was first introduced into the Canadian Council of Health Services Accreditation (now known as Accreditation Canada) standards in January 2006 as part of the 6 patient safety goals. Since then organizations have been working to incorporate medication reconciliation into their practice.

In contrast, medication reconciliation is a structured process well entrenched in the Stollery and led by the prescriber. Significant resources and time have been dedicated to implement the program and a continuous improvement process is in place to modify the processes as necessary.

The family communicated that the child received 4 milliliters (mL) of azathioprine daily. Confirmation of the number of milligrams (mgs) was obtained by asking the family what the concentration was. 50 mg/mL was determined to be the concentration; this provided a dose of 200 mg daily. English was not the first language spoken by the family. The use of an interpreter was beneficial when the Review Team interviewed the family.

Medication reconciliation would also have included consultation with the dispensing pharmacy and/or electronic review of medications dispensed in the community. The Pharmacy Information Network (PIN) of NetCare®, the province wide electronic health record, provides information on all prescriptions filled for the general public in community or designated outpatient pharmacies. PIN was not accessed by the prescribers in reconciling the patient's home medications. Through the interview process few prescribers routinely used this information source or were aware of its content. When the order was reviewed by pharmacy, the pharmacist screening the orders did not have access to PIN; this was an anomaly in the pharmacy department and was rectified after the incident. While the Stollery has an active medication reconciliation process in place, prescribers generally do not use PIN.

There was no evidence of requesting the patient's old chart or accessing information from the gastrointestinal clinic where the azathioprine order originated.

Lack of a Safe Dose per Weight Check by Physicians, Nursing and Pharmacy and Medication Written without the Clear Dosage Intended

The prescribers and nursing staff relied on the family's confirmation of the concentration of azathioprine used to write an order for azathioprine 200 mg. The order was initially written as "Azathioprine 4 mL @ 6p.m. daily"; "50 mg/mL" was inserted at a later time resulting in a 200 mg dose. This action reveals two systemic weaknesses. Medication orders were observed to be written in terms of the volume to be given (i.e. number of milliliters) instead of the actual dose (e.g. number of milligrams) required. Drug errors could result when these orders apply to medications with several different concentrations or strengths. Best practices in writing pediatric medication orders require that the dose per weight for each dose, route and frequency (e.g. number of mg/kg/dose po daily) be clearly identified. At ACH orders written for volumes of medications were accepted. Secondly, any changes to medication orders made by a prescriber for orders written by another are to be rewritten as a new order; strikeouts and overwrites are unacceptable practices. Orders written for volumes of medication instead of true dosages exist at the Stollery as well. Neither facility mandated a standardized approach to medication order writing.

In this case, there was no evidence that the dose of 200 mg of azathioprine was validated as a safe dose for the patient's indication and weight. Once the order was written, it was still subject to a safe dose per weight check by nursing as part of the 5 rights of medication administration as defined by the Calgary Health

Region “Regional Nursing Policy and Procedure M-1 Medication – Ordering, Preparation, Administration and Disposal” as well as the “Child Health Policy/Procedure M1-1, Medication Administration: Pediatric Intravenous Drug Administration” (right patient, right drug, right dose, right route, right administration time). This did not occur. Azathioprine was not a commonly used drug among the pediatric prescribers; the dose of 200 mg was not identified as highly unusual. A safe dose per weight check was not performed by the attending physician.

Clear articulation of processes to ensure the “right dose” by nursing at both the ACH and Stollery was inconsistent and did not regularly include description of calculation of a safe dose per weight check. A factor that may have contributed to the above interpretations is the wording of the “Child Health Policy/Procedure M1-1, Medication Administration: Pediatric Intravenous Drug Administration”. “Verification” was as defined as “checking the medication, according to the ‘five rights’ checking the patient name, medication, dose, route and administration times with the original physician order”. However, determination of a safe dose also includes verification that the original physician order is correct with respect to the drug and dosage regimen.

Once the azathioprine order was received in pharmacy it was reviewed by the pharmacist responsible for screening all new orders and ensuring they are appropriate before entry into the patient’s medication profile. Azathioprine doses up to 15 mg/kg had been recollected for patients in the outpatient pharmacy; the current azathioprine dose equated to 13.9 mg/kg for the patient. A call to the nursing station identified that the family had confirmed the concentration of the azathioprine as 50 mg/mL, 4 mL of which constituted a 200 mg dose. No references were sought to perform a safe dose per weight check and a 200 mg dose was dispensed.

Failure to complete a safe dose per weight check occurred with all three disciplines involved (medicine, nursing, pharmacy) and all had a duty to act to perform this function.

No Written Medication Profile was Available for the Parents

Reliance on the history provided by the family was the basis for the admitting orders for the patient. All medication containers, with the exception of azathioprine which was kept in the home refrigerator, were brought to the hospital at the time of admission by the parents. To aid in the identification of the azathioprine dose, the family provided a hand written list of medications that did not contain all necessary details of the dose. The patient had been frequently treated at the ACH and had several prescriptions filled at the ACH pharmacy. The generation of a current medication profile from the outpatient pharmacy or inpatient pharmacy at the time of discharge could have supported the family care providers in communicating the complex medication therapy of their child.

A current medication profile was not regularly provided from the inpatient or outpatient pharmacies at the Stollery.

Causes / Contributing Factor in Order of Priority

1. A medication reconciliation process was not used to establish an accurate medication history.
2. A safe dose per weight check was not performed.
3. A current medication profile (drug name, dose, frequency, duration) had not been made available to the family to assist them in providing an accurate medication history.

4. A potential language barrier was not recognized in communicating with the family to obtain an accurate medication history.

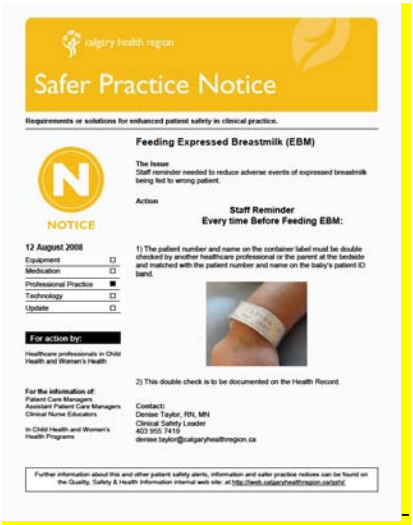
D. Expressed Breast Milk (EBM) Mix Up

Learning from Previous Adverse Events was not Maximized

A thorough review of the expressed breast milk incidents that were reported 21 times across Calgary Health Region in the period of 2001 to 2006 was conducted in 2006 and 11 recommendations were approved for implementation. Their recommendations included 3 "red rules". "Red rules" are rules that cannot be broken; they are standards that should be undertaken every time in a particular process except in rare or urgent situations[11]. The red rules called for:

- "consistent and complete labeling: patient name and unique identifier number, date and time of expression of the milk, thaw date and time if applicable"
- "double check and double sign of the information on the container or infant and documentation as per CHR policy for identification and documentation"
- "individual fridge/freezer storage bins/trays, labeled and place in the fridge/freezer in alphabetical order"

A "Safer Practice Notice" (see figure 5) for "Feeding Expressed Breast Milk (EBM)" issued August 2008 and distributed throughout the ACH identified the need to verify the patient number and name before feeding EBM and to document this check. However, no visible prompt in the chart for a double signature was implemented. Staff did not relate any knowledge of an actual EBM mix up that would have prompted the Safer Practice Notice. At the time of the incident of March 31, 2009, the Safer Practice Notice was still taped to the fridge but it had faded reducing its legibility. Other than the Safer Practice Notice, the Review Team had difficulty determining if the 11 recommendations were implemented as no progress report to the recommendations was made. Some changes in practice were observed that aligned with some of the recommendations but a standardized approach to implementation of the recommendations was not evident.


calgary health region

Safer Practice Notice

Requirements or solutions for enhanced patient safety in clinical practice.

Feeding Expressed Breastmilk (EBM)

NOTICE

12 August 2008

Equipment ☐
Medication ☐
Professional Practice ■
Technology ☐
Update ☐

For action by:

Healthcare professionals in Child Health and Women's Health

For the information of:
Patient Care Managers
Assistant Patient Care Managers
Clinical Nurse Educators

In Child Health and Women's Health Programs

The Issue
Staff reminder needed to reduce adverse events of expressed breastmilk being fed to wrong patient.

Action

Staff Reminder
Every time Before Feeding EBM:

1) The patient number and name on the container label must be double checked by another healthcare professional or the parent at the bedside and matched with the patient number and name on the baby's patient ID band.

2) This double check is to be documented on the Health Record.

Contact:
Denise Taylor, RN, MN
Clinical Safety Leader
403 955 7419
denise.taylor@calgaryhealthregion.ca

Further information about this and other patient safety alerts, information and safer practice notices can be found on the Quality, Safety & Health Information internal web site at http://web.calgaryhealthregion.ca/qshi/

Figure 5. Safer Practice Notice

[11] Scarf WR. Red Rules: An Error-Reduction Strategy in the Culture of Safety. Focus on Patient Safety, A Newsletter from the National Patient Safety Foundation 2007;10;1

The hierarchy of interventions discussed in the "Root Cause Analysis – An Overview of the Process" indicates that reminders or checklists are more powerful interventions than are education or information. There was no evidence of implementation of a checklist. The majority of recommendations from the 2006 review are educational in nature.

It has already been discussed that recommendations from reviews conducted within AHS – Calgary had not been prioritized. Without that prioritization, significant recommendations could be delayed and pose undue risk to patients. As stated above, follow up on the 11 recommendations from the 2006 EBM review appeared incomplete and several of the critical recommendations had not been implemented 3 years later.

The issue of EBM mix ups is not unique to the ACH. In the review of corollary practices at the Stollery, it was reported that the Stollery had 6 EBM mix up incidents from January 2007 to March 2009 while the ACH had 4 such incidents from October 2006 to March 2009. Overall, at both the ACH and Stollery there was a lack of a consistently applied standardized procedure for the handling, use and storage of EBM.

Lack of Heightened Awareness of Risk of Transmission of Viral Pathogens in Expressed Breast Milk (EBM) by Nursing

The recommendations from the 2006 review did not address the reason for the concern about a potential EBM mix up, namely that of potential viral transmission of human immunodeficiency virus (HIV), and hepatitis B and C. The Safer Practice Notice (figure 5 above) issued in August 2008, similarly did not communicate the concerns of viral transmission. This review identified that a cause of the incident was a lack of a heightened awareness of this risk precluding the checking of a novel procedure before engaging in it. Nursing standards require that before any product is provided to a patient, a match between the patient information on the label of the product and the patient's identification must be made. Patient identification was not validated in this incident. The bottle of EBM was to be placed in bins in the fridge labeled with the patient's name to provide a second check for patient identification. It was not known whether the bin was labeled or whether the label matched the EBM bottle label. Comparatively, bins of EBM at the Stollery were not always labeled with the patient's name.

The need for correct patient identification and risks of viral transmission were taught in the orientation of new nurses. However, there was no evidence of evaluation of the EBM orientation to indicate its effectiveness. The Review Team was advised that the orientation consisted largely of didactic lecture as well as demonstration of use of a breast pump; interactive learning has been shown to provide superior results. Additionally the use of "story telling" whereby a parent's testimonial on the impact of an EBM mix up may have delivered a more memorable message.

Parents not Aware of Risks of Transmission of Viral Pathogens in Expressed Breast Milk (EBM)

While in the Pediatric Intensive Care Unit (PICU) the parents did not receive instruction on safe handling and storage of breast milk that should have included an alert about the potential for viral pathogen transmission. EBM orientation is not compulsory for staff in the PICU and knowledge of viral transmission may or may not have been known. By comparison, EBM orientation at the Stollery is optional for all nurses.

On transfer out of PICU, the parents received information about the storage and labeling of the EBM but instruction on potential viral transmission and the need to confirm identification of EBM was absent. Review of the instructional material distributed to parents was mute on viral transmission as well. Rationale for this resided in the lack of consensus within the organization of whether explicit information about viral transmission should be given to parents and the concern that such information may bias them against breast

feeding. It was communicated that many mothers were already very anxious about the health and well being of their baby and overwhelmed with the new responsibility of being a mother. Needing to consider the risk of viral transmission was felt to potentially add unnecessary stress to the already stressed mother and/or parents and decrease the likelihood of breastfeeding. The position of the Stollery is similar. The likelihood of choosing not to breast feed based on this knowledge was felt to be unfounded by the Review Team as there are other significant benefits to breast feeding; e.g., the significant decrease in necrotizing enterocolitis in breast fed babies.

Without the heightened awareness of the potential for viral transmission and lack of instructions to confirm the identification of the EBM, the mother administered the EBM to her baby without checking to ensure it was the correct EBM. Only after the EBM was ingested did the mother recognize that the name on the label did not match her that of her child.

The accountability of nursing to communicate all necessary aspects pertaining to the correct provision of EBM is not clearly expressed and documented. Checklists identifying coverage of all necessary information are lacking; use of checklists is a moderately effective intervention for patient safety. The Nursing Flow Sheets were used for co-signing for EBM and evidence from the charts reviewed showed that co-signing was inconsistent. At the Stollery, the Medication Administration Record was most often used to document EBM. Signatures for documentation of EBM were found in the Nursing Notes at the Neonatal Intensive Care Unit at the Royal Alexandra Hospital.

Lack of Standardized Orientation and Comprehensive Assessment of New Graduates' Readiness to Practice

In review of the orientation process for new graduates at Alberta Children's Hospital, it was found that the various units' approach to orientation is not consistent. Whereas, some may have a checklist and guidelines in place for the graduate nurse, others may not. There seems to be a lack of standard approach to orientation which may present obstacles to consistent practice.

Orientation and preparedness for readiness to practice also includes "buddying" the new nurse with a more senior nurse or an educator for a scheduled number of times. The effectiveness of that buddying system and the evaluation of the practice is not subject to objective criteria but rather more subjective self analysis by the new nurse. The nurse who is still training may "not know what she/he does not know" and self evaluation should not be relied on.

It is recognized that assessment of readiness to practice is done at several levels and no one level can likely observe examples to demonstrate competency in all areas so a comprehensive and accurate assessment is not easily accomplished.

High Level of Stress Negatively Impacted Ability for Critical Thinking

Concurrent needs to meet the expectations of the patient's parents to provide care, dealing with a perceived heavy workload, adapting to numerous changes on the unit, involvement in a recent medication incident, and the need to give expressed breast milk for the first time all contributed to significant stress for the care giver. The need to admit a new patient, start a new IV, administer medication to another patient and concern about a deteriorating patient contributed to the perception of heavy workload. The ability to request assistance if deemed necessary had been communicated but there was reluctance to do so by the care giver despite good experiences with such help in the past.

Repeatedly during interviews, the Review Team heard concerns about the number of recent, significant changes introduced to the unit in a short period of time. The changes included the following:

- Clinical database conversion in preparation for the order and Sunrise Clinical Manager (SCM) conversion
- Sunrise Clinical Manager (SCM) – acute care roll out of electronic health record
- Syringe pump and standard concentration conversion
- Conversion from Baxter Colleague® pumps to MedFusion® pumps
- SMART pumps with initial implementation in spring 2008. Drug library information conversion for January 2009 but then delayed due to SCM conversion
- Staff orientation for pumps, drug library use and standard concentrations
- Baxter pump implementation. Baxter Colleague pumps with updated software implemented for larger volume delivery
- Introduction of wireless medication carts with attached computers (WiMed® carts)

These changes were heard to have impacted all staff and required that staff continuously learn new procedures without having time to stabilize in the practice setting. Evaluation of the impact of these changes on staff was not evident and such an evaluation could have signaled a need to slow introduction of new practices to allow staff to implement what they have recently learned and provide safe care. In particular, new nurses or those with limited experience may be anticipated to be most impacted by the changes; their ability to adapt to a constantly changing environment may be compromised. These changes appeared to be a factor in the performance of the nurse involved in the incident. A comprehensive change management system would not only assist in introducing change but assess the readiness of staff to incorporate change, especially in the light of the rapidly changing environment in modern health care.

Causes / Contributing Factors in Order of Priority

1. Recommendations from previous adverse events involving EBM were not implemented and other learning from those events were not maximized to prevent future EBM adverse events.
2. Administration of EBM was a novel procedure for the primary care provider; lack of knowledge of the risk of transmission of viral pathogens in donor breast milk contributed to not checking of the policy and procedure prior to performing this novel procedure.
3. Patient identification on the label of EBM was not matched with that of the patient receiving the EBM.
4. A heightened awareness of the risk of transmission of viral pathogens in donor breast milk was not present to influence the selection of the correct bottle of EBM from the fridge by the primary care provider.
5. Parents were not educated on the risk of transmission of viral pathogens in donor breast milk and the need to confirm that the patient information on the EBM label matched that of their child.
6. Lack of a standardized orientation and a comprehensive assessment of new graduates' readiness to practice increased the likelihood that a new graduate could incorrectly perform a novel procedure.

7. A consistent requirement for two signatures documenting the confirmation of correct patient identification with the information on the EBM label in a dedicated area of the patient record was not implemented.
8. Pressure in managing multiple competing priorities to provide care to several patients concurrently negatively impacted the requirement for critical thinking and full attention to selecting the correct bottle of EBM from the fridge.

Causes, Contributing Factors and Recommended Actions

The recommended actions in Appendix I, while aimed primarily at the Alberta Children's Hospital may be applicable to other health care organizations within the Alberta Health Services (AHS). The scope of the implementation of the recommendations will be determined by the AHS.

The following systemic factors as defined by the United States Veteran's Affairs National Centre for Patient Safety[3] were considered in identification of the causes and contributing factors:

Human Factors – Communication (HF-C)

Consideration of human factors – communications helps assess issues related to communication, flow of information, and availability of information when it is required. This systemic factor also reveals the importance of communication when using equipment and implementing policies and procedures, the unintended barriers to communication and the organization's culture with respect to sharing information.

Human Factors – Training (HF-T)

Consideration of human factors – training helps assess issues related to routine job training, special training, and continuing education including the timeliness and effectiveness of that training. Training issues may concern application of the approved procedures, correct use of equipment or appropriate application of protective barriers.

Human Factors – Fatigue/Scheduling (HF-FS)

Human factors – fatigue/scheduling need to be considered when weighing the influence of stress and fatigue which may result from change, scheduling, staffing issues, sleep deprivation, or environmental distractions such as noise. The relationship of such stress and fatigue in relationship to training issues, equipment use, as well as management concerns and involvement.

Environment/Equipment (E)

In examining systemic issues related to the environment or equipment, the following are considered: use and location of equipment, fire protection and disaster drills, codes, specifications and regulations, the general suitability of the environment, and the possibility of recovery after an error has occurred. Equipment failure may relate to human factors issues, policy and procedure questions and training needs.

Rules, Policies and Procedures (R)

In examining systemic issues related to rules, policies and procedures, the following are considered: existence and ready availability of directives including technical information for assessing risk, mechanisms for feedback on key processes, effective interventions developed after previous events, compliance with national policies, the usefulness of and incentives for compliance with codes, standards and regulations.

Barriers (B)

Barriers protect people and property from adverse events. In examining barriers, their effectiveness in supporting individuals to comply with rules, policies and procedures as well as properly use equipment is considered.

The relevant contributing systemic factor(s) is assigned to all recommendations below using the following legend:

HF-C = human factor - communication **HF-T** = human factor - training **E** = environment / equipment

HF-FS = human factor – fatigue, scheduling **R** = rules / policies / procedures **B** = barriers

The recommendations listed in Appendix I evolve from the causes and/or contributing factors and are presented in a detailed fashion to identify this link as part of the RCA methodology. Several of the recommendations are broken down into steps required for their implementation; it is recognized that, therefore, some of the recommendations appear operational in nature. They are provided for direction and guidance. The prioritized recommendations are listed in the Summary of Recommendations section. Several of the recommendations are the sum of more detailed recommendations from Appendix I and are referenced accordingly.

Summary of High Priority Recommendations

The following recommendations have been identified as high priority for implementation as soon as possible. The relevance of each recommendation to each incident reviewed is identified with a check mark (√) in the column of the related incident. Inserted in the column of the related incident is a cross reference to the detailed recommendation as it appears in Appendix I.

Recommendation	Enteral Medications Given IV	Fentanyl Overdose	Azathioprine Overdose	Expressed Breast Milk (EBM) Mix Up
A. Maximize the learning from previous similar adverse events with a potential for a catastrophic outcome to reduce the recurrence of similar adverse events.				
1. Implement and assess compliance to the outstanding recommendations from previous reviews: a. Trace infusion lines back to source to confirm route of administration before administering any product parenterally or enterally; and b. Label all infusion lines; and c. Implement and audit compliance to a procedure requiring two personnel to verify patient identification using two unique identifiers before administration of EBM and document in a designated section of the patient record with two signatures.	√ 2A			√ 7A, 7B, 7C
2. As part of the incident review process, assess the potential risk for serious harm or catastrophic outcomes and prioritize the new and outstanding high risk recommendations for rapid action.	√ 2B	√ Generally applicable	√ Generally applicable	√ 1A
3. Establish a reporting structure, accountability processes and strategies that oversee recommendation implementation and follow prioritized recommendations to ensure implementation in a timely manner.	√ 2D, 2E, 2G	√ Generally applicable	√ Generally applicable	√ Generally applicable
4. Communicate recommendations for mitigating risk of repeating an adverse event by providing sufficient context of event, through techniques such as “storytelling” that describe details of the incident, its causes and the logic of the recommendations whilst respecting the confidentiality and sensitivity of those directly involved in the event.	√ 2C	√ Generally applicable	√ Generally applicable	√ Generally applicable

Recommendation	Enteral Medications Given IV	Fentanyl Overdose	Azathioprine Overdose	Expressed Breast Milk (EBM) Mix Up
5. Develop a process that evaluates the effectiveness of implemented recommendations to prevent reoccurrence of the adverse event.	√ 2F	√ Generally applicable	√ Generally applicable	√ Generally applicable
B. Use forced functions and technology as high hierarchy interventions to prevent recurrences of adverse events.				
1. Administer enteral products (including medications when necessary) using exclusively enteral technology (i.e. pumps, syringes, lines etc.) that is incompatible with parenteral infusion systems.	√ 1A			
2. In the absence of an enteral pump that will deliver small volumes, use a parenteral syringe pump to administer enteral products with enteral syringes and enteral tubing that are not compatible with parenteral ports.	√ 1B			
3. In the absence of an enteral pump and enteral syringe, use a parenteral syringe with enteral tubing that is not compatible with a parenteral port.	√ 1C			
4. Investigate the potential to utilize technology (e.g. bar coding) to ensure correct patient identification and remove reliance on human recognition of label information.				√ 3B
5. Provide electronic access to visually unique adult parenteral monographs by neonatal and paediatric units only after specific steps are completed to ensure the ADULT monograph is being requested; utilize human factors consultation to determine process.		√ 3A, 3B, 3C		
6. Utilize robust clinical decision support technology to validate dose based upon patient's weight and/or body surface area at the time of order entry.		√ Generally applicable	√ 2B, 4C	
C. Improve medication safety				
1. Implement and assess compliance to an independent check procedure that is accompanied by a clear policy and procedure which identifies the purpose of the check, defines and describes the process, when it is to be used, how the check is done, and who may perform the check.		√ 2A, 2B, 2C, 2D		

Recommendation	Enteral Medications Given IV	Fentanyl Overdose	Azathioprine Overdose	Expressed Breast Milk (EBM) Mix Up
2. Implement and assess compliance to a standard for writing medication that facilitates a safe dose check and includes the total dose, dose per weight or body surface area, and frequency of administration.		√ Generally applicable	√ 2C, 2D	
3. Implement and assess compliance to a policy and procedure that requires that all disciplines involved in dispensing and/or administering the medication order complete a safe dose per weight check prior to dispensing and/or administering the medication.		√ Generally applicable	√ 2A, 4A, 4B, 4D, 6A, 6B, 6C, 6D	
4. Implement medication reconciliation as an integral part of a process to obtain a comprehensive medication history and that includes the utilization of the Pharmacy Information Network (PIN) as appropriate.			√ 1A, 1B	
5. When completing a medication history, ensure health care providers to maintain a heightened awareness and assess comprehension of English for patients or parents whose first language is not English; consider offering interpreter services when in doubt about clear comprehension of the English language and advertise the availability of these services in public areas using common foreign languages.			√ 5A, 5B, 5C	
6. Inpatient and outpatient pharmacies to provide a current medication profile for patients discharged from inpatient or ambulatory care and when drug dispensing services are accessed from the outpatient pharmacy.			√ 3A	
7. Revise the format of IV drug monographs to easily identify critical information and use standard terminology to describe routes of administration.		√ 3D, 3F		
D. Address professional practice roles and responsibilities				
1. Senior medical leadership to develop and implement a code of conduct with criteria for what constitutes disruptive behaviours by physicians that interferes with the provision of safe patient care.		√ 1A		

Recommendation	Enteral Medications Given IV	Fentanyl Overdose	Azathioprine Overdose	Expressed Breast Milk (EBM) Mix Up
2. Senior medical leadership develop, implement, and measure compliance with policies, by-laws, and employment or contractual agreements to address disruptive behaviour by physicians based on best practices that includes but is not limited to: o Zero tolerance for disruptive behaviour o Processes to address disruptive behaviour that include a written plan outlining expectations and the escalating consequences of repetition of disruptive behaviour; the plan is agreed to and signed by the physician. Ensure responses are prompt, constructive and sustained o Active support and advice by senior medical leadership to assist the department or division head if he/she is unable to deal with the physician exhibiting disruptive behaviour		√ 1B, 1C, 1D, 1H		
3. Alberta Health Services to invest in programs that can help all physicians develop the skills they need in a rapidly changing environment that supports positive, effective interactions and teamwork.		√ 1I		
4. Ensure a process of reporting includes reporting incidents of disruptive behaviour by physicians as well as identifying disruptive behaviour as a contributing factor to an adverse event where applicable and that this information is communicated to the department or division head.		√ 1F, 1G		
5. Establish a process that ensures all nurses understand, apply and are assessed for compliance with regulatory practice standards.	√ Generally applicable	√ Generally applicable	√ Generally applicable	√ 2B
6. Establish a process that enables and supports the nurse to provide safe care within a patient/family-centred environment.	√ 3A, 3C	√ Generally applicable		
7. Establish a process that ensures all nurses understand and maintain professional boundaries in the provision of safe patient care.		√		

Recommendation	Enteral Medications Given IV	Fentanyl Overdose	Azathioprine Overdose	Expressed Breast Milk (EBM) Mix Up
8. Develop a standardized evaluation process that includes direct observation and objective evaluative criteria to ensure that new staff, including new graduates, are ready to practice and demonstrate overall competency.				√ 6A
E. Improve education of health care workers and patients/families to reduce occurrence of adverse events				
1. Educate health care providers and patients and/or families to understand that patient safety is used as criteria in applying a family-centred care philosophy.	√ 3A, 3B			
2. Educate health care providers on strategies to manage physicians with disruptive behaviour.		√ 1E		
3. Educate parents on the importance of keeping an active medication profile for their child(ren) and of providing it to health care providers when accessing health care services.			√ 3B	
4. Provide compulsory education of nursing staff about the management of expressed breast milk that includes information on the collection, storage, retrieval, patient identification and risks of viral transmission including the prevalence of HIV, Hepatitis B and C and audit practice to ensure compliance with expected processes.				√ 2A, 4B
5. Provide verbal and written health information to families about expressed breast milk that includes a description of the process that should be followed to provide the correct expressed breast milk to their child. Make use of checklists, completed by the parent, to ensure all important points communicated verbally have been given by the staff and understood by the family.				√ 5B

Summary

The staff, physicians and management of the Alberta Children's Hospital (ACH) and the Stollery Children's Hospital (Stollery) who participated in this review consistently demonstrated a commitment to improve patient safety and health care quality. The findings and recommendations were shared and validated with the ACH Steering Committee that had ad hoc member representation from relevant levels of staff and physicians from both the ACH and the Stollery.

It is hoped the learning from this review will be shared widely by Alberta Health Services to improve patient safety and health care quality.

Appendix IA – Recommendations -- Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
1	A parenteral infusion system was used to deliver an enteral product and included parenteral infusion tubing that could connect to an IV port; use of enteral tubing, as per ACH policy, would not have connected to an IV port.					
	1A	Administer enteral products (including medications when necessary) using exclusively enteral technology (i.e. pumps, syringes, lines etc.) that is incompatible with parenteral infusion systems.	E, B	E	High	Long
	1B	In the absence of an enteral pump that will deliver small volumes, use a parenteral syringe pump to administer enteral products with enteral syringes and enteral tubing that are not compatible with parenteral ports.	E, B	C	High	Short
	1C	In the absence of an enteral pump and enteral syringe, use a parenteral syringe with enteral tubing that is not compatible with a parenteral port.	E, B	C	High	Short
	1D	Keep enteral pumps separate from parenteral infusion pumps in the alignment at the patient's bedside, particularly with lookalike infusions such as lipids and enteral feeds.	E, B	C	High	Short

***Systemic Factors: **HF-C** = human factor - communication **HF-T** = human factor – training **E** = environment / equipment
HF–FS = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	1E	Route all enteral feeding tubing toward the patient's feet or to the opposite side of the bed as the parenteral tubing to differentiate the two.	E, B	C	High	Short
2	Recommendations from previous similar adverse events were not implemented and other learnings from those events were not maximized to prevent recurrence of future adverse events.					
	2A	Implement outstanding recommendations from previous similar adverse event, if still relevant, as soon as possible that include a requirement to trace the line back to source and to label all lines for content and route.	HF-C R	C	High	Immediate
	2B	As part of an incident review process, assess the potential risk for serious harm or catastrophic outcome and prioritize the potential high-risk recommendations accordingly for rapid action. (See reference #13, figure 2 for potential list of criteria that can be weighted and used to determine priorities.[12])	HF-C R	C	High	Short

[12] National Patient Safety Agency, Report of Expert Prioritisation Panel. March 2005 (http://www.ncas.npsa.nhs.uk/EasySiteWeb/getresource.axd%3FAssetID%3D777%26type%3Dfull%26servicetype%3DAttachment+npsa+report+of+expert+prioritisation+panel+march+2005&hl=en&gl=ca)

***Systemic Factors:** **HF-C** = human factor - communication **HF-T** = human factor – training **E** = environment / equipment **HF–FS** = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

****Timeline:** Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	2C	Communicate recommendations for mitigating risk of repeating an adverse event by providing sufficient context of said event, through techniques such as "storytelling" that describe details of the incident, its causes and the logic of the recommendations whilst respecting the confidentiality and sensitivity of those directly involved in the event.	HF-C R	C	High	Long
	2D	Develop a strategy to follow prioritized recommendations from reviews that ensures implementation in a timely manner.	HF-C R	C	High	Short
	2E	Develop audit process that assesses compliance with implemented recommendations.	HF-C R	C	Medium	Long
	2F	Develop a process that evaluates the effectiveness of implemented recommendations to prevent reoccurrence of the adverse event.	HF-C R	C	Medium	Long
	2G	Establish a reporting structure and accountability process that oversees recommendation implementation.	HF-C R	C	High	Long
3	While respecting the family's wishes to not disturb their baby, the infusion lines were not tracked back to source to ensure that oral medications intended for enteral delivery would be given through the enteral line and not the IV line.					
	3A	Develop a decision making process that enables the nurse to provide safe care within a family-centered care environment and integrates the following: • Management and front-line nursing staff understand	HF-C HF-T	C	Medium	Long

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**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
		and apply nursing regulatory practice standards. o Consider engaging CARNA in the educational process. • Management leads and supports regulatory practice standards. • Management is aware of current-practice and addresses deviations from nursing regulatory practice standards. • Performance appraisals are done regularly using a tool that is based upon regulatory practice standards.	R			
	3B	Educate patients and/or families to understand that patient safety is used as a criteria in applying a family-centered care philosophy.	HF-C HF-T R	C	Medium	Long

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**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	3C	Assist nurses in dealing with pressures from the family to provide care that does not compromise patient safety. Consider the following: • Establish a process whereby safety issues related to family-centered care identified by individual staff members are addressed locally in a timely fashion. o Form a working group to determine how the principles of family-centered care will be implemented whilst ensuring adherence to nursing practice standards that includes patient safety. (e.g. Discuss how to assess the sleeping patient.)	HF-C HF-T R	C	Medium	Long
4	There was a last minute change in the patient assignment followed by failure to gain full familiarity with the patient's current treatment regimens that would have revealed the changed regimen for the enteral feeds and the addition of a new infusion pump.					
	4A	Conduct a literature search on the best practices to ensure safe and effective patient handover in various scenarios. (e.g. at shift change report, when transferring between services).	HF-C HF-T R	C	Medium	Long

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**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	4B	Implement a standardized approach using best practice communication techniques (e.g. SBAR language) and check lists to provide complete and consistent information at the time of patient handovers.[13]	HF-C HF-T R	C	Medium	Long
	4C	Create and implement a system and tool(s) that enables nurses to provide and access care plan information in a timely manner facilitating handover of patients on an ongoing basis.	HF-C HF-T R	C	Medium	Long
5	Infusion lines were not labeled identifying the route and contents of the infusion which would have differentiated the enteral line from the intravenous lines.					
	5A	See 2A				
6	Pressure to administer multiple medications, along with many competing priorities at the beginning of the shift, decreased the attention to detail in selecting the correct infusion pump.					
	6A	Consider non-standardized times for administration of complex medication therapies to reduce the number of concurrent administrations.	HF-C	C	Low	Long

[13] Schaedig R, Bloom M. Safer Patient Handoff – The Shift to Shift Report. *Journal of Pediatric Nursing.* 23:2:e5, 2008.

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Medications Intended to be Given Through a Gastrostomy Tube Were Given Intravenously						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	6B	Utilize a collaborative interdisciplinary approach to resolve or address complex medication administration issues.	HF-C	C	Low	Long

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Appendix IB – Recommendations -- Fentanyl Overdose

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
1	A telephoned order for an analgesic to relieve acute pain was ineffectively communicated between the physician prescriber and the nurse accepting the order.					
	1A	Senior medical leadership to develop and implement a code of conduct with criteria for what constitutes disruptive behaviours by physicians that interfere with the provision of safe patient care.	HF-C R	C	High	Short
	1B	Senior medical leadership to develop and implement policies, by-laws, and employment or contractual agreements to address disruptive behaviour by physicians that includes: • Zero tolerance for disruptive behaviour. • Processes to address disruptive behaviour that include a written plan outlining expectations and the escalating consequences of repetition of disruptive behaviour; the plan is agreed to and signed by the physician. Ensure responses are prompt, constructive and sustained. • Active support and advice by senior medical leadership to assist the department or division head if he/she is unable to deal with the physician exhibiting disruptive behaviour.	HF-C HF-T R	C	High	Short

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	1C	Senior medical leadership to perform an environmental scan of practices and the literature to identify best practices in the management of disruptive physician behaviour.	HF-C HF-T R	C	High	Short
	1D	Provide Division Chiefs and Department Heads with resources to recognize and deal with physicians exhibiting disruptive behaviour including, but not limited to, didactic materials, leadership courses, and mentoring. Consider the College of Physicians and Surgeons "Managing Disruptive Behaviour in the Health Care Workplace, *Expectations of Professionalism",* 2009 and the accompanying "Toolkit Package".	HF-C HF-T R	C	High	Long
	1E	Educate direct health care providers on strategies to manage physicians with disruptive behaviour.	HF-T R	C	High	Long
	1F	Ensure a process is in place to facilitate reporting of incidents of disruptive behaviour by physicians and clearly communicate to staff.	HF-T	C	High	Short
	1G	When physician disruptive behaviour is identified as a contributing factor to an adverse event, the appropriate department or division head is to be notified to address the behaviour.	HF-T R	C	High	Short

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	1H	Monitor compliance to policy, procedures and by-laws regarding disruptive physician behaviour through the reporting mechanism and other surveillance techniques.	HF-C HF-T R	C	High	Long
	1I	Alberta Health Services to invest in programs that can help all physicians develop the skills they need in a rapidly changing environment that supports positive, effective interactions and teamwork.	HF-C HF-T R	C	High	Long
2	An accurate description of an independent double check and instructions on how to conduct same were absent in the organization's policy and procedure and a true independent double check of the dose was not conducted.					
	2A	Describe the independent double check process[14],[15],[16] in policy and procedure, including: • Calculation of the dose based upon weight. • When the check is used. • How the check is done. • Who may perform the double check. • How an "independent double check" differs from a "double check".	HF-T R	C	High	Short

[14] Independent Double Check / Double Check Verification for High Alert Medication, Children's Hospital of Eastern Ontario, Policy and Procedure, July 2008
[15] Medication Administration. The Hospital for Sick Children, Toronto, Ontario. Policy and Procedure September 14, 2007
[16] ISMP Medication Safety Alert, Independent double check of a high alert medication, May 31, 2007

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****Timeline:** Immediate – 3 months Short – 6 months Long – 12 months

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	2B	Educate medicine, nursing and pharmacy personnel on conducting an independent double check : Consider the following: • Process to be included in orientation of pharmacy and nursing students and new staff. • Process to be included in education sessions for physician orientees. In-service to be provided to all current pharmacy and nursing staff.	HF-T R	C	High	Short
	2C	Measure and monitor compliance to independent double check process with follow up to improve compliance if necessary.	HF-T R	C	High	Short
	2D	Include information on independent double checks in the annual review of nursing competencies and skills.	HF-T R	C	Medium	Long

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**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
3	Information from the adult monograph, located in close proximity on the computer screen to the pediatric/neonatal monograph, was used to verify the pediatric dose.					
	3A	Make access to the adult parenteral monograph by neonatal and paediatric units to available electronically only after specific steps are completed to ensure the ADULT monograph is being requested; utilize human factors consultation to determine process. (e.g. For consideration - Include prompt after selection of monograph - "Are you sure you want the ADULT monograph?")	E, B	C	High	Short
	3B	Clearly identify and differentiate adult and neonatal/paediatric drug monographs throughout the text electronically and in hard copy form.	E	C	High	Short
	3C	Separate the location of the adult drug monographs from neonatal/paediatric drug monographs on the computer screen.	E	C	High	Short
	3D	Revise the format of the drug monographs to easily identify critical information elements (see adult monograph as an example of safer formatting).	E, R	C	High	Long
	3E	Implement a formal process for development and approval of neonatal/paediatric parenteral monographs.	HF-C R	C	High	Long

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Fentanyl Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	3F	Standardize the terminology used to describe the administration of a medication directly from a syringe into the bloodstream through the skin or via parenteral tubing; currently the following terms are used interchangeably – IV push, IV direct, tube direct, bolus.	HF-C R	C	Medium	Long

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Appendix IC – Recommendations -- Azathioprine Overdose

Azathioprine Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
1	A medication reconciliation process was not used to establish an accurate medication history.					
	1A	Implement medication reconciliation as an integral part of a process to obtain a comprehensive medical history.	HF-C HF-T R	C	High	Immediate (to start process)
	1B	Teach and encourage prescribers and pharmacy staff to use the Pharmaceutical Information Network (PIN, a component of NetCare®) as a tool to assess a patient's current medication profile.	HF-C HF-T R	C	High	Immediate
2	A safe dose per weight check was not performed by physicians and physician trainees writing or reviewing the prescribing order.					
	2A	Reinforce the principle and requirement of safe dose per weight checks by physicians and physician trainees during their training and on-going performance assessment of physicians and physician trainees.	HF-T R	C	High	Immediate
	2B	Utilize robust clinical decision support technology[17] to validate dose based upon patient's weight and/or body surface area at the time of order writing and/or entry.	HF-T E, R	C	High	Long

[17] Kuperman GJ, Bobb A, Payne TH, et al. Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc* 2007:14;29-40

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Azathioprine Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	2C	Implement a standard for writing medication that facilitates a safe dose check and includes the total dose, dose per weight or body surface area, and frequency of administration.	HF-T R	C	High	Short
	2D	Audit medication order writing in charts to determine if standards for writing paediatric orders are met; provide feedback and/or change the educational programs as necessary of various levels of trainees/staff.	HF-T R	C	High	Long
	2E	Differentiate the concept of trusting another health care provider's confirmation of a dose from the physician's professional responsibility to check a safe dose per weight.	HF-C HF-T R	C	High	Short
3	A current medication profile (drug name, dose, frequency, duration) had not been made available to the family to assist them in providing an accurate medication history.					
	3A	Inpatient and outpatient pharmacies to provide a current medication profile for patients discharged from inpatient or ambulatory care and when drug dispensing services are accessed from the outpatient pharmacy.	HF-C R	C	Medium	Short
	3B	Educate parents on the importance of keeping an active medication profile for their child(ren) and of providing it to health care providers when accessing health care services.	HF-C R	C	Medium	Long

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HF–FS = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Azathioprine Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
4	A safe dose per weight check was not conducted by nursing before administration of the drug.					
	4A	Implement a standard that requires that "the right dose" part of the traditional 5 rights of medication administration includes a safe dose by weight check by nursing.	HF-T R	C	High	Immediate
	4B	Update the policies on medication that refer to the "5 rights" of medication administration to include the requirement to perform a safe dose by weight check by nursing.	HF-T R	C	High	Immediate
	4C	Utilize robust clinical decision support technology[18] to validate dose based upon patient's weight and/or body surface area at the time of order entry.	HF-T E, R	C	High	Long
	4D	Audit compliance to safe dose check by nurses routinely and take corrective action as necessary.	HF-T R	C	High	Long
5	A potential language barrier was not recognized in communicating with the parents to obtain an accurate medication history.					

[18] Kuperman GJ, Bobb A, Payne TH, et al. Medication-related clinical decision support in computerized provider order entry systems: a review. *J Am Med Inform Assoc* 2007:14;29-40

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Azathioprine Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	5A	Ensure health care providers maintain a heightened awareness and assess comprehension of English for patients or parents whose first language is not English; consider consulting interpretative services for strategies on how to conduct meaningful conversations with families who may not have English as their primary language, i.e. assessing and overcoming language barriers.	HF-C	C	High	Long
	5B	Encourage health care providers to offer interpreter services when in doubt about clear comprehension of the English language by the patient or parent(s).	HF-C	C	High	Long
	5C	Advertise in public areas, in several different languages, the availability of interpretive services.	HF-C	C	High	Immediate
6	A safe dose check was not conducted by pharmacy before dispensing the drug.					
	6A	Reinforce the principle and requirement of safe dose per weight checks by pharmacists during their orientation and on-going performance assessment.	HF-T R	C	High	Immediate
	6B	See recommendation 4C	HF-T E, R	C	High	Long
	6C	Audit compliance to safe dose check by pharmacists routinely and take corrective action as necessary.	HF-T R	C	High	Long

***Systemic Factors:** **HF-C** = human factor - communication **HF-T** = human factor – training **E** = environment / equipment
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****Timeline:** Immediate – 3 months Short – 6 months Long – 12 months

Azathioprine Overdose						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	6D	Review and change as necessary records management requirements for storage of pharmacy copies of patient medication orders to ensure documentation of safe dose and other clinical monitoring notations are available for reference when required.	HF-C R	C	High	Short

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HF–FS = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Appendix ID – Recommendations -- Expressed Breast Milk Mix Up

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
1	Recommendations from previous adverse events involving EBM were not implemented and other learnings from those events were not maximized to prevent future EBM adverse events.					
	1A	As part of an incident review process, assess the potential risk for serious harm or catastrophic outcome and prioritize the potential high-risk recommendations for rapid action.	HF-C R	C	High	Short
	1B	As part of an incident review process, assess the potential risk for serious harm or catastrophic outcome and prioritize the potential high-risk recommendations for rapid action.	HF-C R	C	High	Short
	1C	Develop a strategy to follow prioritized recommendations from reviews that ensures implementation in a timely manner.	HF-C R	C	High	Short
	1D	Develop audit process that assesses compliance with implemented recommendations.	HF-C R	C	Medium	Long
	1E	Develop a process that evaluates the effectiveness of implemented recommendations to prevent reoccurrence of the adverse event.	HF-C R	C	Medium	Long
	1F	Establish a reporting structure and accountability process that oversees recommendation implementation.	HF-C R	C	Medium	Long

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HF–FS = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
2	Administration of EBM was a novel procedure for the primary care provider; lack of knowledge of the risk of transmission of viral pathogens in donor breast milk contributed to not checking of the policy and procedure prior to performing this novel procedure.					
	2A	Provide compulsory education of nursing staff about the management of expressed breast milk that includes information on the collection, storage, retrieval, patient identification and risks of viral transmission including the prevalence of HIV, Hepatitis B and C.	HF-T R	C	High	Short
	2B	Establish a process that ensures all nurses understand and apply regulatory practice standards: • Management and front-line nursing staff understand and apply nursing regulatory practice standards. o Consider engaging CARNA in the educational process • Management leads and supports regulatory practice standards. • Management is aware of current-practice and addresses deviations from nursing regulatory practice standards. • Performance appraisals are done regularly using a tool that is based upon regulatory practice standards.	HF-C HF-T R	C	High	Long

*Systemic Factors: **HF-C** = human factor - communication **HF-T** = human factor – training **E** = environment / equipment
HF–FS = human factor – fatigue, schedule **R** = rules / policies / procedures **B** = barriers

**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
3	Patient identification on the label of EBM was not matched with that of the patient receiving the EBM.					
	3A	See recommendations 2A, 2B				
	3B	Investigate the potential to utilize technology (e.g. bar coding) to ensure correct patient identification and remove reliance on human recognition of label information.	E	C	Medium	Long
4	A heightened awareness of the risk of transmission of viral pathogens in donor breast milk was not present to influence the selection of the correct bottle of EBM from the fridge by the primary care provider.					
	4A	See recommendation 2A				
	4B	Conduct regular audits of EBM processes to ensure compliance to policy and address deficiencies. Consider direct observation of: • nurses informing parents of EBM collection, storage and retrieval. • validation of patient identification process. • communication of risks of transmission of viral pathogens to parent(s). Consider survey of parent(s) to assess information shared by nurse in compliance with policy.	HF-T R	C	High	Long

***Systemic Factors:** **HF-C** = human factor - communication **HF-T** = human factor – training **E** = environment / equipment
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****Timeline:** Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	4C	Create effective teaching techniques that address various learning styles and generational differences to communicate EBM processes and risks. Consider: • use of videotaped parent's testimonial about the impact of this adverse event to heighten awareness of the risks of EBM mix-up and reduce the recurrence of similar adverse events. • interactive case study discussions human simulation of managing an EBM mix up.	HF-T R	C	Medium	Long
5	Parents were not educated on the risk of transmission of viral pathogens in donor breast milk and the need to confirm that the patient information on the EBM label matched that of their child.					
	5A	Acknowledge that disclosing the risks of viral transmission in an EBM mix-up may negatively influence the parents' decision to breast feed and conduct a study to assess the impact of full disclosure on this decision.	HF-C HF-T	C	Low	Long
	5B	Provide written health information to families about EBM that includes a description of the process to ensure that their baby receives the correct EBM.	HF-C HF-T R	C	High	Short

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****Timeline:** Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
6	Lack of a standardized orientation and a comprehensive assessment of new graduates' readiness to practice increased the likelihood that a new graduate could incorrectly perform a novel procedure.					
	6A	Create an evaluation process that includes direct observation and objective evaluative criteria to ensure that new staff, including new graduates, are ready to practice and demonstrate overall competency.	HF-T	C	Medium	Long
	6B	Add EBM processes to the orientation checklist.	HF-T	C	Medium	Immediate
	6C	Consider a formal mentoring process for new graduates to identify and address their learning needs.	HF-T	C	Medium	Long
	6D	Develop forum(s) where new graduates are able to share clinical experiences, seek educational information and receive ongoing support.	HF-C HF-T	C	Medium	Long
7	A consistent requirement for two signatures documenting the confirmation of correct patient identification with the information on the EBM label in a dedicated area of the patient record was not implemented.					
	7A	Create a procedure requiring two signatures to verify patient identification that includes use of the wrist/arm band of patient identification before administration of EBM.	HF-T R	C	High	Short

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****Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
	7B	Establish a dedicated section in the current documentation (e.g. 24 hour Medication Administration Record and Patient Care Information System) for required documentation of EBM administration with space and prompt for two signatures.	R	C	High	Short
	7C	Audit compliance to new procedure that requires two signatures for documentation of EBM administration.	R	C	Medium	Long
8	Pressure in managing multiple competing priorities to provide care to several patients concurrently negatively impacted the requirement for critical thinking and full attention to selecting the correct bottle of EBM from the fridge.					
	8A	Create a system/tool that helps nurses determine adequate patient assignments taking into consideration patient needs, patient acuity, and nursing level of competence and expertise.	HF-T	C	Medium	Long
	8B	Create active strategies to encourage nurses to recognize excessive competing priorities and to respond based on patient safety principles.	HF-T	C	Medium	Long

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**Timeline: Immediate – 3 months Short – 6 months Long – 12 months

Expressed Breast Milk Mix Up						
Cause or Contributing Factor	**Causal Statements and Recommended Actions**		**Systemic Factor***	**Action E= eliminate C= control A= accept**	**Priority**	**Timeline****
		Orient the new graduate to the various resources available to support safe clinical practice. For example consider the following: • Use real case studies to demonstrate management of multiple, competing priorities. • Identify supportive literature and human resources. • Link new graduate to a mentor.	HF-T	C	High	Long

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Appendix II – Glossary

ACH	Alberta Children's Hospital
Adverse event	An unexpected (unanticipated) outcome directly associated with the care provided that results in harm *(College of Physicians and Surgeons of Ontario)* An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. *(World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005).*
AHS	Alberta Health Services
AHW	Alberta Health and Wellness
Alberta Evidence Act	**(www.qp.gov.ab.ca/Documents/acts/A18.CFM)** Section 9 of the Alberta Evidence Act addresses situations involving "quality assurance activity". This activity means a planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of the quality of health care or health services, or the level of skill, knowledge and competence of health service providers. Quality assurance committee means a committee, commission, council or other body that has as its primary purpose the carrying out of quality assurance activities and that is appointed by a number of named bodies, including as of July 1, 2006, the Health Quality Council of Alberta.
CARNA	College & Association Of Registered Nurses of Alberta
Contributing factor	The reason(s), situational factor(s), or latent condition(s) that played a role in the genesis of an adverse outcome. *From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003*
EBM	Expressed Breast Milk
Enteral	A term used to describe the intestines or other portions of the digestive tract. This is contrasted with parenteral, or non-digestive, system methods of introducing drugs or substances into the body, via, for example, injection into the veins.
Harm	An unexpected (unanticipated) or normally avoidable outcome that negatively affects a patient's health, quality of life, and occurs or has occurred during the course of receiving health care or services from the Region (*Alberta Health Services – Calgary, adapted from College of Physicians and Surgeons of Ontario)*
HQCA	Health Quality Council of Alberta
Incident	Events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients *From Royal College of Physicians and Surgeons, Canadian Patient Safety*

	Dictionary, October 2003
	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events and hazards. *(World Health Organization Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005)*
IV	Intravenous Medications
NICU	Neonatal Intensive Care Unit
Patient safety	The reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices shown to lead to optimal patient outcomes *From Royal College of Physicians and Surgeons, Canadian Patient Safety Dictionary, October 2003*
Parenteral	A route of administration that involves piercing the skin or mucous membrane.
PICU	Pediatric Intensive Care Unit
RHAs	Regional Health Authorities
Root cause analysis	An analytical tool that can be used to perform a comprehensive, system based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plan *From Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, 2006*
Safety Culture	The product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and the efficacy of preventative measures. *From Advisory Committee on the Safety of Nuclear Installments 1993:23 published in: Fleming, M. Patient Safety Culture Measurement and Improvement a "How To" Guide. Health care Quarterly Vol. 8, Special Issue, October 2005.*

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