



Advancing Medication Safety in the Delivery of High Alert Medications in Paediatrics

A National Collaborative Initiative

Phase 1 Report

Jan 28, 2009

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CAPHC

The Canadian Association of Paediatric Hospitals was co-founded in 1968 by the leaders of children's hospitals across Canada. In 2001, the Canadian Association of Paediatric Health Centres (CAPHC) was created to better respond to emerging healthcare challenges and the shifting landscape of child and youth health service delivery in Canada. CAPHC is a national organization with forty-two member organizations, representing multidisciplinary health professionals that provide health service delivery to children, youth and their families within acute care hospitals, community health centres, rehabilitation centres and home care provider agencies across Canada. All children's hospitals and their respective children's hospital foundations in Canada are members of CAPHC, providing strong linkages to clinical care, education and research.

CAPHC supports a communication network that enables knowledge transfer of leading-edge research from contributors across the globe. Along with its members and partners, CAPHC is a strong national advocate for change and quality improvement to enhance the healthcare of all children and youth. As a national organization representing health professionals and organizations across the continuum of care, CAPHC is uniquely positioned to influence system-wide change at the national level by advocating for child and youth health service delivery. In addition, because a large part of CAPHC's membership is at the grass roots level, the organization is able to effect change at the point of service delivery.

Patient safety and quality improvement are among CAPHC's national priorities. Under the leadership of CAPHC's Patient Safety Collaborative, a framework for partnership and communication supports national paediatric patient safety and quality improvement programs. Examples of these programs include the CAPHC-Paediatric Trigger Tool, the CAPHC Paediatric

Medication Reconciliation Collaborative and High-Risk Medication Delivery in Paediatrics – Implementing Leading Practice.

Among the six Safer Healthcare Now! (SHN!) Phase 1 interventions, the Patient Safety Collaborative identified Medication Reconciliation as their national priority. The CAPHC Paediatric Medication Reconciliation Collaborative, in collaboration with SHN! has provided support to paediatric health care centres and related organizations across Canada to facilitate implementation of medication reconciliation.

ISMP Canada

The Institute for Safe Medication Practices Canada is an independent national not-for-profit agency committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

ISMP Canada's mandate includes collection, review and analysis of medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents. Information on safe medication practices for knowledge translation is published and disseminated.

Additional information about ISMP Canada, and its products and services, is available on the website: www.ismp-canada.org

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Advancing Medication Safety in the Delivery of High Alert Medication in Paediatrics

Executive Summary

Paediatric healthcare institutions face unique challenges in the delivery of care. It is well known that various patient and system factors place paediatric patients at greater risk of experiencing harm from medication errors, and that certain medications have a higher potential to cause harm when used in error. Many adult health centres have successfully adopted medication delivery processes to improve patient safety, but fundamental differences in the delivery of medications in paediatrics, particularly weight-based dosing, have hindered the adoption of some practices in paediatric care.

CAPHC and ISMP Canada have established an important partnership intended to advance medication system safety in the delivery of high alert medications in Canadian paediatric facilities. An Advisory Committee, with representation from across Canada, is providing direction to the project and assisting with the interpretation of findings. This report describes the first phase of this collaborative project.

The goals of the first phase of the project included the identifications of the top medications reported as causing harm or potential harm in Canadian paediatric healthcare settings, the identification of existing leading practices and the analysis of the information obtained to develop solutions to form the basis of a medication safety intervention.

The goals of the first phase were addressed in part by an analysis of medication incident data submitted to ISMP Canada by selected paediatric healthcare facilities, to determine the medications most commonly associated with harmful medication incidents and to categorize the types of incidents and contributing factors. Close to one quarter of all medication incidents reported as causing harm were associated with five medications, two of which were opiates. This suggests that a small number of medications account for a disproportionately large number of incidents and these medications may represent opportunities for targeted interventions.

An additional analysis of harmful and non-harmful incident reports for the top five medications and for the opioid class provided information on types of incidents and contributing factors. Although the most commonly-reported incident types varied from medication to medication, "wrong dose" and "wrong drug" incidents were reported frequently. For "wrong dose" incidents, mix ups of dosage units and calculation errors were common contributing factors; while for "wrong drug" incidents, look-alike / sound-alike medications were frequently identified as a contributing factor.

A survey of selected paediatric healthcare facilities to obtain information on leading practices was also conducted. The results of the survey provide a landscape view of patient safety initiatives in place at Canadian paediatric facilities in August 2008. The analysis of the survey data helped to identify leading practices that have been implemented in many facilities, but also suggested that safe practices are not being consistently implemented. For example, certain leading practices related to safe handling of opioids that are in place in many facilities have not been adopted by other facilities.

Based on a set of predetermined criteria and with consideration given to the results of the incident report analysis and landscape survey, the National Advisory Committee has reached a consensus on the following intervention:

To create an intervention that will assist in the implementation of safe medication practice for the delivery of opioids in paediatric settings. This includes all aspects of the opioid medication system from prescribing to storage and administration.

Implementing Leading Practice for High Alert Medication Delivery in Paediatrics

A National Paediatric Medication System Quality Improvement Program

1. Introduction

Paediatric healthcare institutions face unique challenges in the delivery of care. It is well known that various patient and system factors place paediatric patients at greater risk of experiencing harm from medication errors, and that certain medications have a higher potential to cause harm when used in error. Many adult health centres have successfully adopted medication delivery processes to improve patient safety. Many of these best practices are sanctioned and supported by ISMP Canada, Accreditation Canada, The Joint Commission and other organizations focused on improving patient safety, yet fundamental differences in the delivery of medications in paediatrics, particularly weight-based dosing, have hindered the adoption of some practices in paediatric care.

The value of creating standards related to the handling of high-alert medications across all paediatric settings was identified as a priority at a patient safety symposium entitled: “Promoting Patient Safety and Best Practices in Paediatrics through Standardization of Medication Practices and Delivery Protocols”, which was held at the CAPHC October 2006 annual meeting in Vancouver.¹ Subsequently, CAPHC and ISMP Canada established an important partnership intended to advance medication system safety in the delivery of high alert medications in Canadian paediatric facilities. An Advisory Committee, with representation from across Canada, is providing direction to the project and assisting with the interpretation of findings. This report describes the first phase of this collaborative project.

¹ For final proceedings, see www.caphc.org/documents_annual/2006/patient_safety_symposium_proceedings.pdf

2. First Phase Project Goals

- To identify the top medications reported as causing harm or potential harm in Canadian paediatric healthcare settings, based on frequency and severity of reported medication incidents
- To identify existing leading practices associated with the delivery of high alert medications in Canadian paediatric health care facilities; and
- To analyze the information obtained to develop solutions that will form the basis of a medication safety intervention.

The goals of the first phase were addressed in part by the completion of two distinct projects:

- An analysis of medication incident data submitted to ISMP Canada by selected paediatric healthcare facilities, to determine the medications most commonly associated with harmful medication incidents. A further analysis of types of errors and contributing factors for these medications and opioid analgesics was also conducted.
- A survey of selected paediatric healthcare facilities to obtain information on leading practices.

The results of these projects are provided in sections 3 and 4 of this report.

3. Medication Incident Analysis- Learning from Reports of Harmful Medication Incidents in Paediatric Healthcare Settings

3.1 Objectives

Primary Objective

To identify the top five medications reported as causing harm through medication incidents in Canadian paediatric healthcare settings,

Secondary Objective

To identify the types of incidents and possible contributing factors associated with incident reports (harmful and non-harmful) involving

- the top five medications reported as causing harm through medication incidents, and
- opioid analgesics

3.2 Methods

3.2.1 Recruitment of Participants

Representatives from selected CAPHC hospitals were contacted by the project lead and provided with information on the background, objectives and methods of the project. Of the 17 CAPHC hospitals who were invited to participate, 11 agreed to submit paediatric medication incident data to ISMP Canada. Each of these hospitals was provided with a letter of agreement, to be signed and returned to ISMP Canada. Medication incident data submission for each facility began following receipt of the signed letter of agreement.

3.2.2 Specifications of Medication Incident Report Submission

Due to the lack of a standardized data set for collection of paediatric medication incident data across Canadian paediatric hospitals, ISMP Canada selected key data fields for the purpose of this project, based on the Canadian Medication Incident Reporting and Prevention System (CMIRPS) core data set for individual practitioner reporting. The following **de-identified** data fields were requested, if available:

- Medication(s) involved
- Severity level
- Error type
- Event description

The participating facilities were asked to submit all medication incident reports involving paediatric patients from Jan 1st 2006 to Dec 31st 2007.

Detailed Medication Incident Reports: Medication incident reports that included the requested data fields were classified as detailed medication incident reports (as opposed to summarized medication incident reports, described below). Detailed medication incident reports were included in both the primary analysis (i.e. the identification of the top medications reported as causing harm) and the secondary analyses (i.e. categorization by type of errors and identification of contributing factors for all medication incidents involving the top five medications reported as causing harm, as identified in the primary analysis).

Summarized medication incidents: In the event that a hospital wanted to participate in the project, but for some reason could not submit data with the requested data fields, they were offered an alternative, less detailed level of data submission – to submit a frequency table of medications involved in incidents with harm (harm was defined by the NCC MERP severity level of E or above - see appendix A). Summarized medication incident data were included only for the purpose of identifying the top five medications reported as causing harm (i.e. the primary objective).

3.2.3 Data cleansing / Exclusion Criteria of Medication Incidents for Analysis

All medication incident reports submitted were imported / entered into a combined dataset. Data cleansing / exclusion of medication incident reports for analysis was done according to the following rules:

- Incident reports that did not identify the specific medication name (e.g. medication name of “antibiotic”) were excluded.
- Misspelled medication names were corrected, provided that it was clear what the intended medication name was. If the medication name was misspelled beyond recognition and if none of the other data fields of the incident report gave further information as to what the correct medication name was, the incident report was excluded.
- For combination products (e.g. acetaminophen + codeine), each ingredient was counted as an individual item. Exceptions include TPN, infant formulas (multiple ingredients, but were treated as a single item), piperacillin / tazobactam and sulfamethoxazole / trimethoprim (neither sulfamethoxazole nor tazobactam were available as individual medications).
- Incident reports that could be definitively classified as adverse drug reactions were excluded.

From the cleansed dataset, a table was created showing the frequency of incidents (with an outcome of harm or above) for each medication. This analysis was used to identify the top five medications reported as causing harm through medication incidents.

For the secondary objective, detailed medication incident data involving the top five medications reported as causing harm through medication incidents (as identified in the primary analysis) as well as all data from detailed incident reports involving opioid analgesics, were extracted. For this analysis, all incidents involving the top five medications and opioid analgesics were included, regardless of whether the incident was reported as causing harm. To enable the aggregate analysis of data from different hospitals, each incident was assigned to one of the following categories for type of incident:

-
- "Wrong IV solution"
 - "Wrong drug"
 - "Wrong route"
 - "Wrong formulation -- IR vs. SR"
 - "Dose omission"
 - "Wrong dose"
 - "Incorrect time / frequency"
 - "Wrong patient"
 - "Other"

For each of the top five medications and opioid analgesic drug categories, a frequency table was created showing the number of incidents for each type of incident.

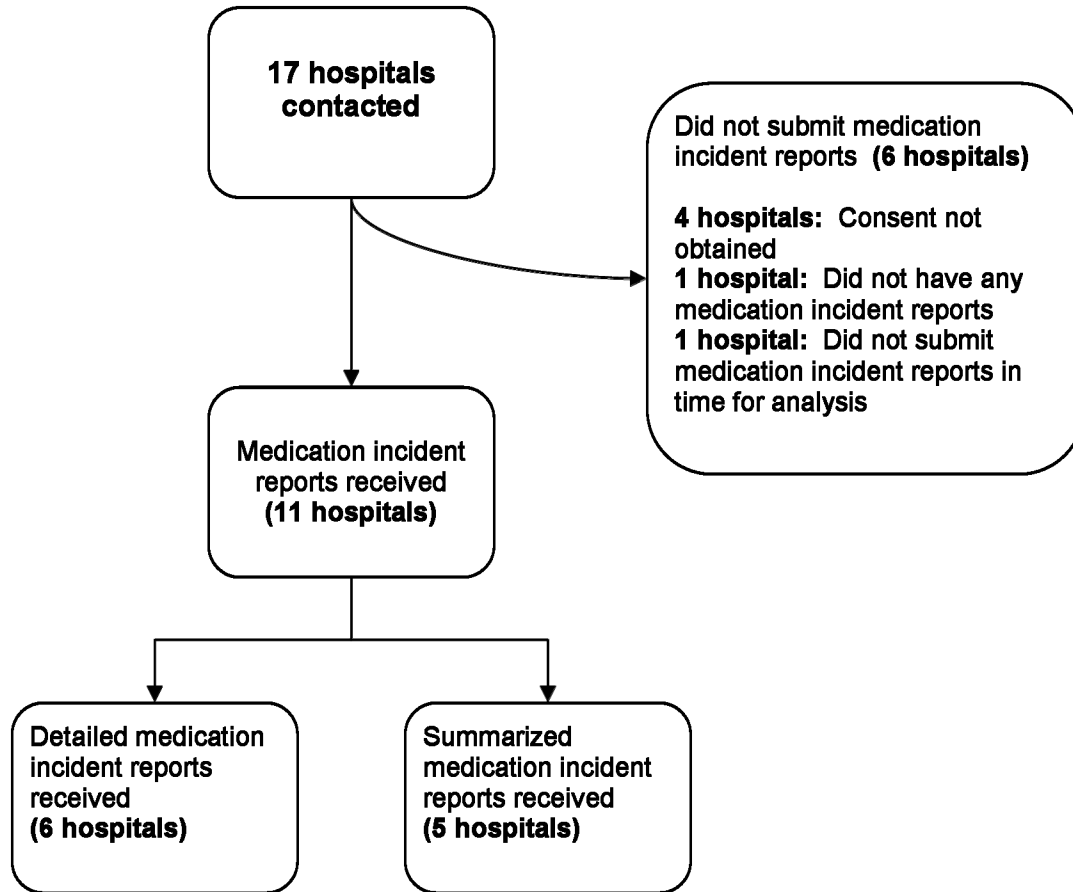
To identify the possible factors contributing to the medication incidents, the extracted dataset was examined and each event description data field (a narrative data field which allows the reporter to type in a summary of the medication incident) was analyzed in a qualitative manner to gain more in-depth insights regarding the underlying factors contributing to each type of medication incident.

The subset of detailed incident reports involving harm was also analysed to determine whether differences in the type of incident and contributing factors existed.

3.3 Results

Of the 11 participating hospitals, six submitted detailed medication incident reports. The remaining five hospitals submitted medication incident frequency summary tables (See Figure 1). Most hospitals submitted medication incidents that had occurred within the specified time-frame of Jan 1st 2006 to Dec 31st 2007. However, some hospitals were not able to do so (e.g. reporting system established after Dec 31st 2007). The final date range of the received data was from Oct 2005 to June 2008.

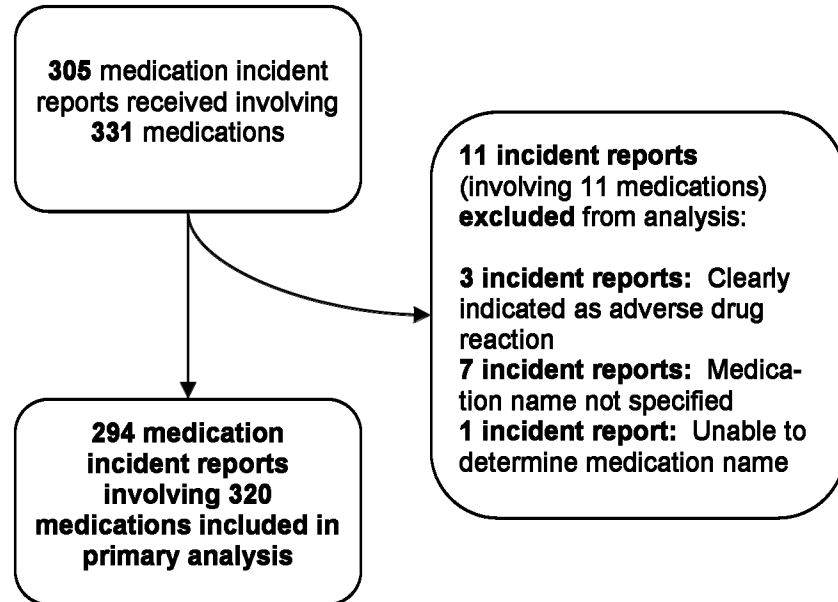
Figure 1. Data Collection from hospitals



3.3.1 Primary Analysis Results

Overall, 305 medication incident reports with an outcome of harm or above were received from 11 hospitals, involving 331 medications (one incident may involve more than one medication). Of these, 11 incident reports were excluded from analysis; three because they were clearly adverse drug reactions; seven because the medication name was not specified and one because the medication name was misspelled beyond recognition. The remaining 294 incident reports, involving 320 medications, were included in the primary analysis (See Figure 2).

Figure 2. Data cleansing process / inclusion of medication incidents for primary analysis



The top medications reported as causing harm are summarized in Table 1.

Table 1. Top Five Medications Involved in Incidents Reported as Causing Harm

Medication	Number of Reports	Overall Percentage (%) n=294 incidents
morphine	26	8.8%
potassium chloride	14	4.8%
insulin	11	3.7%
fentanyl	10	3.4%
salbutamol	10	3.4%
Total (top 5 medications)	71	24.1%

3.3.2 Secondary Analysis Results for Top Five Medications

Detailed medication incident report data were received from six hospitals. A total of 595 detailed medication incident reports involving the top five medications and opioid analgesics were included in the secondary analysis. Medication incidents of all severities were included in the secondary analysis (as opposed to incidents with a severity level of harm or above in the primary analysis) in order to include near miss incidents, which often provide valuable insights to potential contributing factors.

Table 2 summarizes the number of medication incident reports (all severities and harmful) included in the secondary analysis for each of the top five medications.

Table 2. Medication Incident Reports Included in the Secondary Analyses (Top Five Medications Reported as Causing Harm Through Medication Incidents)

Medication	Number of Detailed Medication Incident Reports (Harm)	Number of Detailed Medication Incident Reports (All Severities)
Morphine	20	176
Potassium chloride	7	204
Insulin	8	41
Fentanyl	5	30
Salbutamol	5	30
Total	45	481

3.3.2.1 Types of Incidents and Contributing Factors – Morphine

Table 3. Detailed Incident Reports involving Morphine-Type of Incident

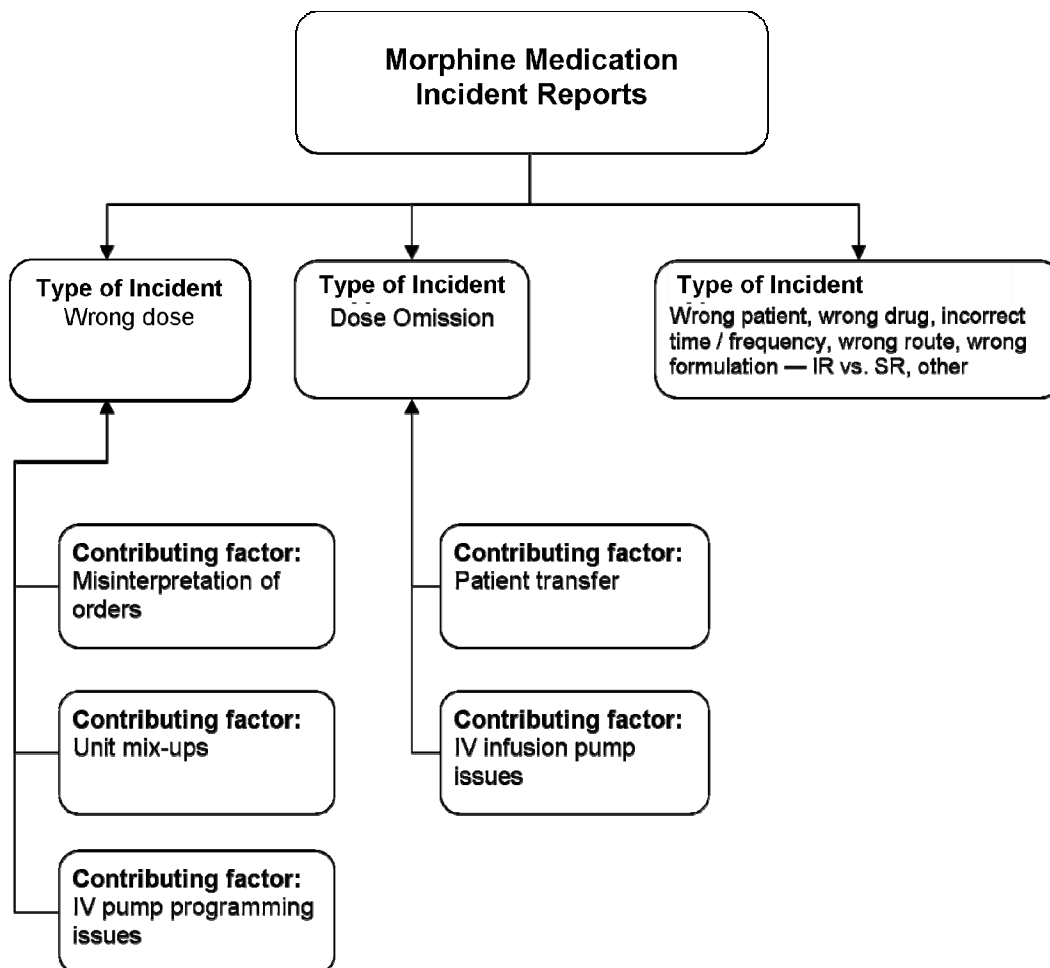
Type of incident (Morphine)	Number of Reports	Percentage (n=176)
Wrong dose	97	55.1%
Other	31	17.6%
Dose omission	25	14.2%
Wrong patient	7	4.0%
Wrong drug	5	2.8%
Incorrect time / frequency	4	2.3%
Wrong route	4	2.3%
Wrong formulation -- IR vs. SR	3	1.7%
Grand Total	176	100.0%

- Wrong dose incidents:** Wrong dose incidents accounted for more than 50% of morphine incidents in this analysis. Most of these incidents involved morphine IV (intermittent doses and continuous infusions) or morphine PCA. A number of contributing factors of these incidents were identified (see Figure 3).

 - Misinterpretations of orders: Misinterpretation of orders was associated with a high number of multi-fold overdose incidents. For example, in many instances the misinterpretation of the decimal place had resulted in 10 fold overdoses, which often led to patient harm. In two cases, morphine IV 1.5mg was ordered but morphine IV 7.5mg was administered (presumably due to misinterpretation of the handwritten order), resulting in a 5 fold overdose.
 - Unit mix-ups: Unit mix-ups have been reported to be a contributing factor for morphine overdose incidents. In 3 cases, morphine IV infusion was ordered in mcg/kg/hr, but was programmed into the IV pump as mcg/kg/min, resulting in a 60 fold overdose. In addition, mix-ups between mg and mcg were also reported.
 - IV pump programming issues: IV pump programming issues were also identified as a contributing factor. For instance, there was a case where a morphine infusion was ordered to be infused at 0.7cc/hr, but the pump was accidentally set at 7cc/hr, resulting in a 10 fold overdose.

- **Dose omission incidents:** Dose omission incidents accounted for 14% of morphine medication incidents. Morphine dose omission not only results in potential loss of patient’s pain control, but may lead to opioid withdrawal symptoms. Two contributing factors were identified:
 - Patient transfer: A number of incident reports identified patient transfer as a contributing factor for omission of morphine doses or orders.
 - IV infusion pump issues: A number of cases cited contributing factors related to IV pump problems such as leakage at pump connectors, incorrect PCA tubing and incorrect infusion pump set-up.

Figure 3. Morphine incidents: Type of incident and contributing factors



Analysis of the harm reports subset (n=20): Wrong dose (12 reports) and dose omission (5 reports) were also the most common type of incidents in the subset of incidents where harm was reported (refer to corresponding sections above for details). Of note, there was a wrong drug incident where hydromorphone was administered instead of morphine; this resulted in mild harm to the patient.

3.3.2.2 Types of Incidents and Contributing Factors - Potassium Chloride

Table 4 summarizes detailed incident reports involving potassium chloride. **Of note, none of these incidents involved concentrated potassium chloride vials**

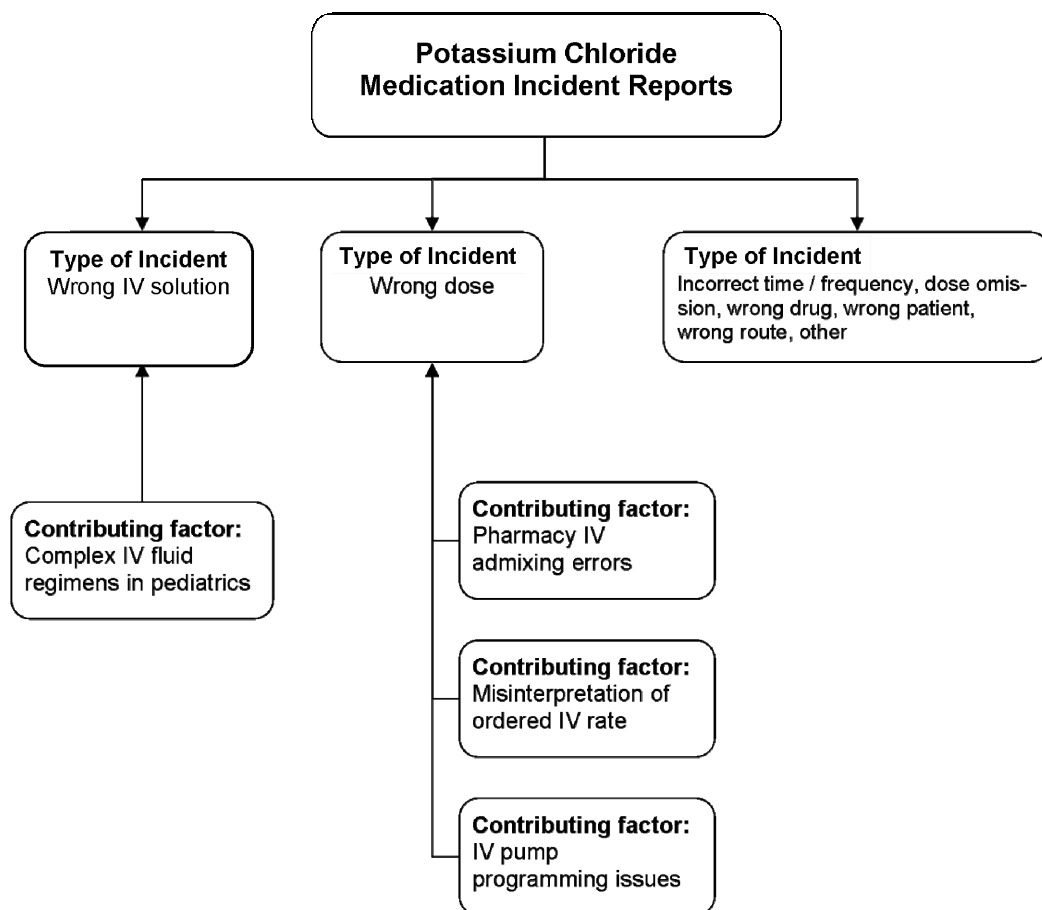
Table 4. Detailed Incident Reports involving Potassium Chloride - Type of Incident

Type of incident (KCl)	Number of Reports	Percentage
Wrong IV solution	91	44.6%
Wrong dose	47	23.0%
Other	26	12.7%
Incorrect time / frequency	16	7.8%
Dose omission	13	6.4%
Wrong drug	5	2.5%
Wrong patient	3	1.5%
Wrong route	3	1.5%
Grand Total	204	100.0%

- Wrong IV solution:** Wrong IV solution accounted for 44.6% of potassium chloride incidents. One example of this type of incident was D5W / 0.2% sodium chloride + potassium chloride 20mmol/L ordered but D10W / 0.2% sodium chloride + potassium chloride 20mmol/L given (wrong IV fluid). One of the main contributing factors to these incidents is the complex IV fluid regimens utilized in paediatrics. With numerous variables (i.e. different concentrations of dextrose, sodium chloride and potassium chloride) resulting in a high number of possible combinations, the likelihood of incident in the dispensing / administration stage is increased, especially if these IV solutions are placed in close proximity to each other in the stock area.

- **Wrong dose incidents:** Wrong dose incidents accounted for 23% of the potassium chloride medication incidents. The following are some of the contributing factors identified:
 - Pharmacy IV admixing incidents: A number of potassium chloride wrong dose incidents involved pharmacy compounding of potassium chloride containing solutions. For instance, in one incident extra potassium chloride was ordered to be added to TPN to a total of 120meq/L, this was not added which resulted in the patient receiving a much lower dose of potassium chloride (20meq/L) through TPN.
 - Other contributing factors: Other contributing factors identified were the misinterpretation of ordered IV rate as well as IV pump programming issues.

Figure 4. Potassium Chloride Incidents: Type of incident and contributing factors



Analysis of the harm reports subset (n=7): In the subset of potassium chloride incidents where harm was reported, the types of incidents were dose omission (2 reports), wrong dose (1 report), wrong IV solution (1 reports) and “other” (3 reports) (refer to corresponding sections above for details).

3.3.2.3 Type of Incidents and Contributing factors - Insulin

Table 5. Detailed Incident Reports Involving Insulin- Type of Incident

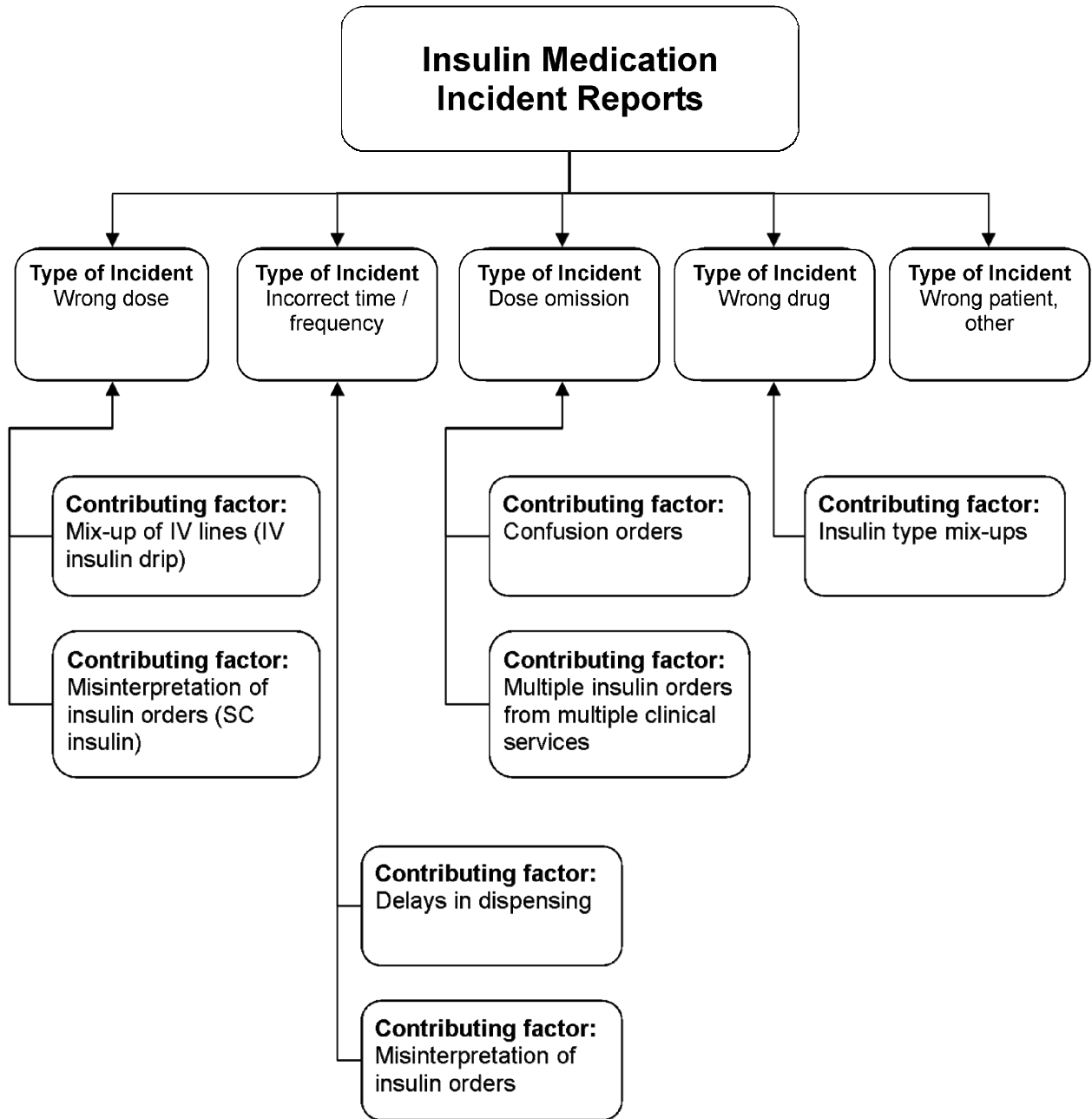
Type of incident (Insulin)	Number of Reports	Percentage
Wrong dose	18	43.9%
Incorrect time / frequency	9	22.0%
Dose omission	6	14.6%
Wrong drug	4	9.8%
Other	3	7.3%
Wrong patient	1	2.4%
Grand Total	41	100.0%

- **Wrong dose incidents:** Wrong dose incidents (41.9% of insulin medication incidents) could be divided into two main groups, intravenous (IV) insulin drip incidents and subcutaneous (SC) insulin incidents.
 - **Wrong dose – IV insulin drip:**
 - Mix-up of IV lines: The received reports suggest that mix-ups of IV lines are a significant contributing factor for IV insulin drip incidents. For example, a report indicated that an insulin drip was run at 1.6mL/hr instead of 0.1mL/hr as ordered (resulting in a 16 fold insulin overdose), while the maintenance IV, which was supposed to be run at 1.6mL/hr, was run at 0.1mL/hr. Similarly, another report also indicated that a line mix-up contributed to an IV insulin drip overdose.
 - **Wrong dose – SC insulin:**
 - Misinterpretation of insulin orders: Contributing factors to SC insulin incidents included the misinterpretation of insulin orders, which can lead to over-dose or under-dose being administered. For example, misinterpretation of insulin dose in another case led to the administration of 5 units of humalog sc and 40 units of insulin NPH sc, while the order

was for 0.5 units of humalog sc and 4 units of insulin NPH sc. This 10 fold incident resulted in patient harm.

- **Incorrect time / frequency incidents:** Potential contributing factors identified include delays in dispensing insulin and the misinterpretation of insulin orders (e.g. insulin NPH was ordered qhs, but was given with dinner).
- **Dose omission incidents:** Insulin dose omission incidents could potentially lead to patient harm. For example, a dose omission incident with sc insulin led to a patient's serum glucose rising to above 40. Moreover, omission incidents with IV insulin drips may also lead to patient harm. In one case, an IV insulin drip was omitted because the IV line was clamped in error, resulting in patient harm. Contributing factors identified were confusing orders (e.g. confusing sliding scale orders) and multiple insulin orders from multiple clinical services.
- **Wrong drug incidents:** Wrong drug incidents accounted for 9.8% of insulin incidents and may potentially lead to patient harm. The main contributing factor identified was the mix-up between different types of insulin.
 - Insulin type mix-ups: Mix-ups between different types of insulin have been reported, especially between short acting and long acting insulin. This could happen when prescribing insulin (e.g. insulin N STAT was ordered while presumably a short acting insulin was intended) as well as during dispensing and administration of insulin (e.g. insulin R was ordered, but insulin N was dispensed and administered).

Figure 5. Insulin incidents: Type of incident and contributing factors



Analysis of the harm / death reports subset (n=8): Wrong dose (6 reports) and dose omission (2 reports) accounted for the insulin reports with harm (refer to corresponding sections above for details).

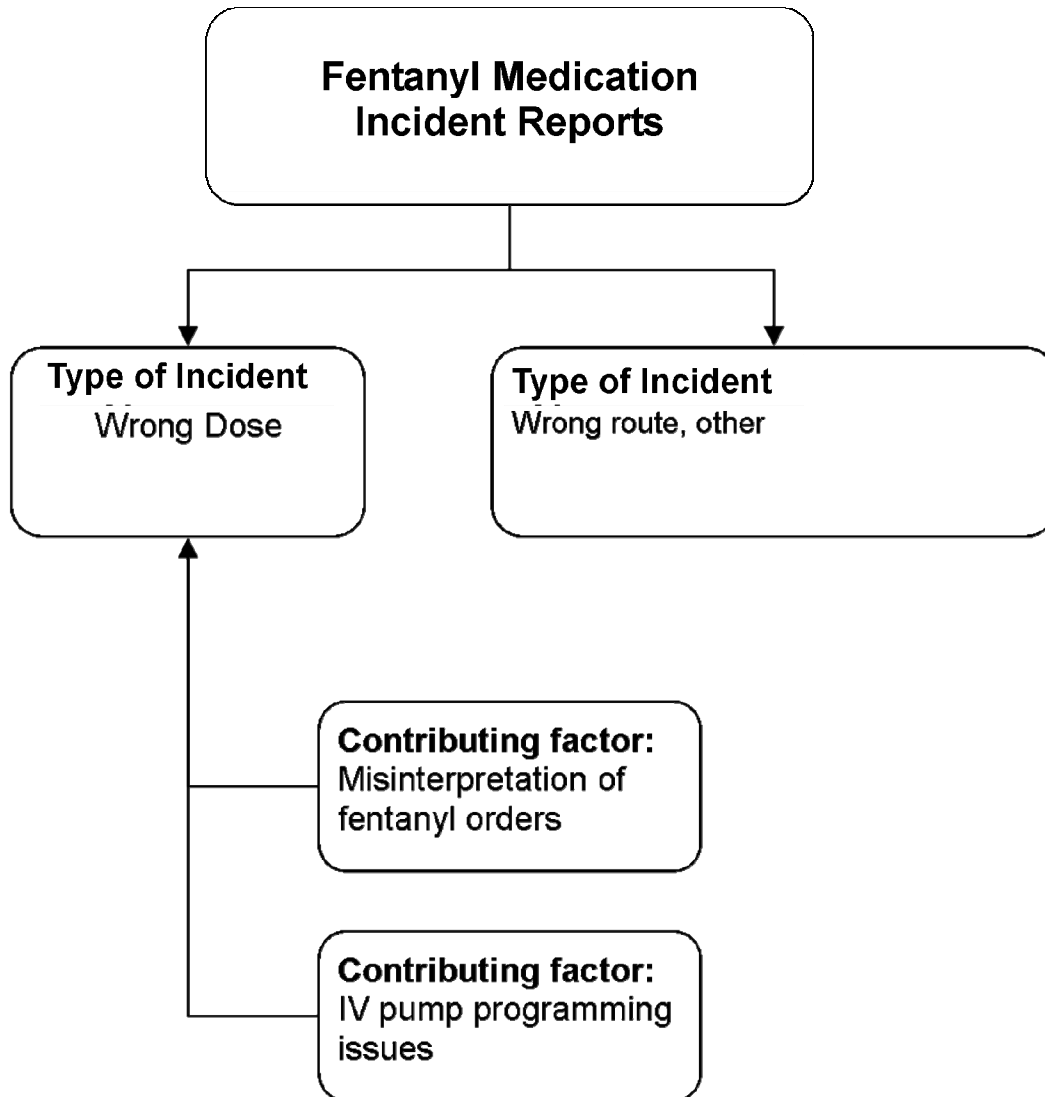
3.3.2.4 Type of Incidents and Contributing factors- Fentanyl

Table 6. Detailed Incident Reports Involving Fentanyl-Type of Incidents

Type of incident (Fentanyl)	Number of Reports	Percentage
Wrong dose	26	86.7%
Other	3	10.0%
Wrong route	1	3.3%
Grand Total	30	100.0%

- **Wrong dose incidents:** Wrong dose incidents accounted for the majority of fentanyl medication incidents reported (86%). Contributing factors identified include misinterpretation of fentanyl orders and IV pump programming issues.
 - Misinterpretation of fentanyl orders: A number of fentanyl wrong dose incidents cited the misreading of the decimal place in the order during dispensing or administration of fentanyl as a contributing factor. For example, a 0.55mg fentanyl order was received, but 0.05mg was administered, resulting in a 10 fold under dose. In addition to the dispensing and administration stage, 10 fold dosing incidents during the prescribing stage have also been reported (fentanyl 0.6mg intended for the patient, but a calculation incident lead to the prescriber ordering 0.06mg for the patient instead).
 - Various IV pump programming issues have been reported to contribute to fentanyl over dose incidents.

Figure 6. Fentanyl incidents: Type of incident and contributing factors



Analysis of the harm reports subset (n=5): All incidents within the subset of fentanyl incidents where harm was reported involved wrong dose. See corresponding sections above for details.

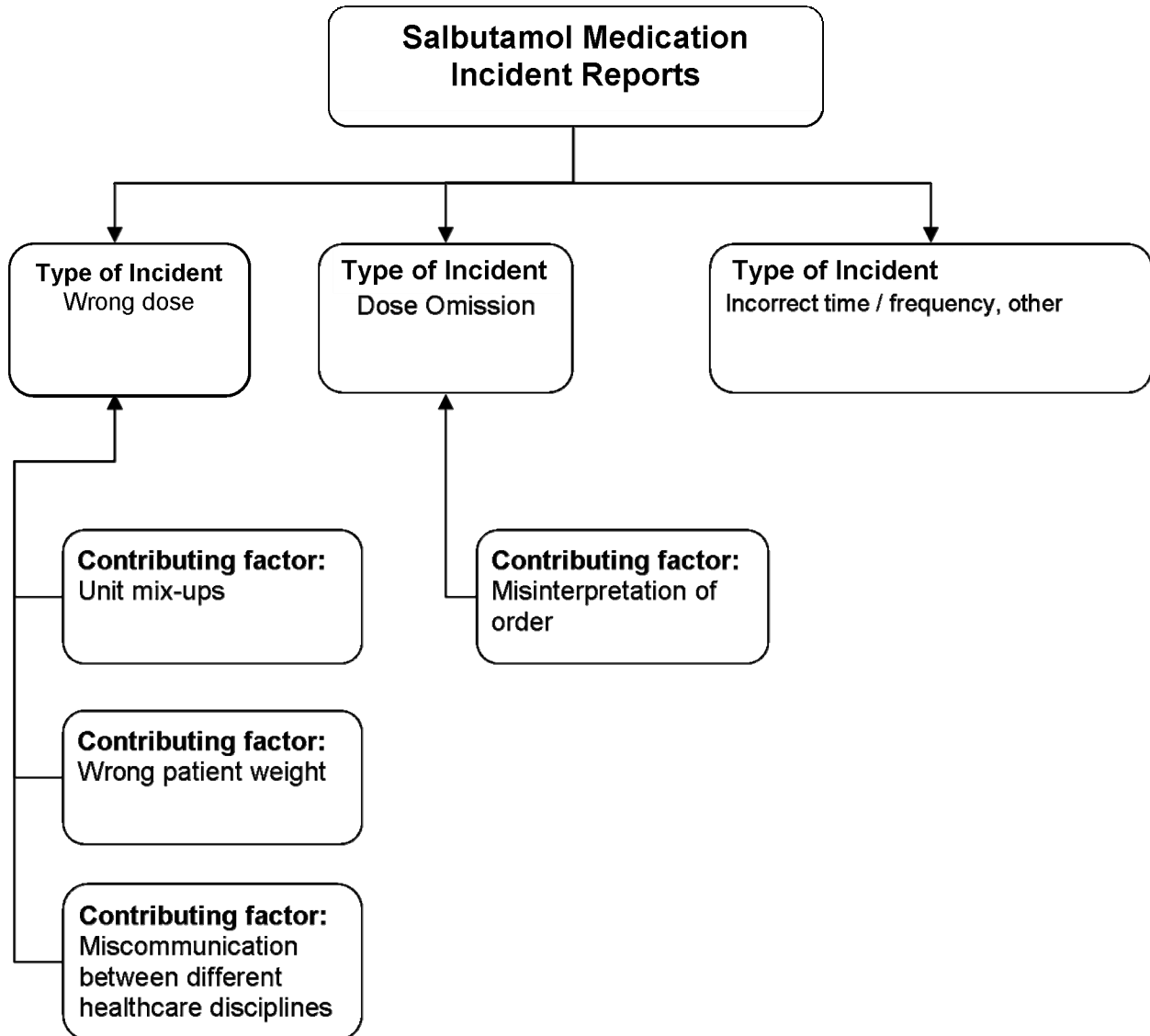
3.3.2.5 Types of Incidents and Contributing Factors- Salbutamol

Table 7. Detailed Incident Reports Involving Salbutamol- Type of Incidents

Type of incident (Salbutamol)	Number of Reports	Percentage (n=31)
Wrong dose	15	48.4%
Dose omission	12	38.7%
Incorrect time / frequency	3	9.7%
Other	1	3.2%
Total	31	100.0%

- Wrong dose incidents:** Wrong dose incidents accounted for 48.4% of salbutamol incidents. Contributing factors leading to wrong dose salbutamol incidents included mix-ups between units (e.g. 5mL vs. 5mg); dose miscalculation due to the wrong patient's weight used and miscommunication between different healthcare disciplines (e.g. lack of communication between RN and RT led to the independent administration of patient's salbutamol inhaler, resulting in salbutamol overdose).
- Dose omission:** The fact that salbutamol is frequently used as a rescue medication for asthma exacerbations means that salbutamol dose omission incidents may result in significant patient harm. In a number of reports, misinterpretation of the order was a significant contributing factor for salbutamol dose omission incidents (e.g. order misinterpreted leading to the omission of salbutamol masks q2h prn, which led to patient harm).

Figure 7. Salbutamol incidents: Type of incident and contributing factors



Analysis of the harm / death reports subset (n=5): For incidents within the subset of salbutamol incidents where harm was reported, the types of incidents were dose omissions (3 reports) and wrong dose (2 reports).

3.3.3 Secondary Analysis-Opioid Analgesics

Table 8 summarizes the number of medication incidents included in the secondary analysis for each opioid medication category:

**Table 8. Medication Incident Reports Included in the Secondary Analysis
(Opioid Analgesics)**

Medication	Number of Detailed Medication Incident Reports (Harm)	Number of Detailed Medication Incident Reports (All Severities)
Morphine	20	176
Oral Opioids*	4	78
Hydromorphone	7	31
Fentanyl	5	30
Miscellaneous**	0	5
Total	36	320

* Includes opioid analgesics mostly used orally. In this analysis, incidents involving codeine (and combinations), oxycodone (and combinations), methadone and diphenoxylate -atropine were classified in this category.

** Includes incidents involving medications which did not fit in the categories above. In this analysis, incidents involving sufentanil, remifentanil and Opium & Belladonna suppositories were classified under the “miscellaneous” category. Due to the small sample size (n=5) and the fact that very little or no details were included with these incidents, no further analysis was conducted for this category.

Each of these top medications was summarized according to the type of incidents and of the possible factors contributing to the medication incidents.

For analysis results for morphine, please refer to Section 3.3.2.1, page 10.

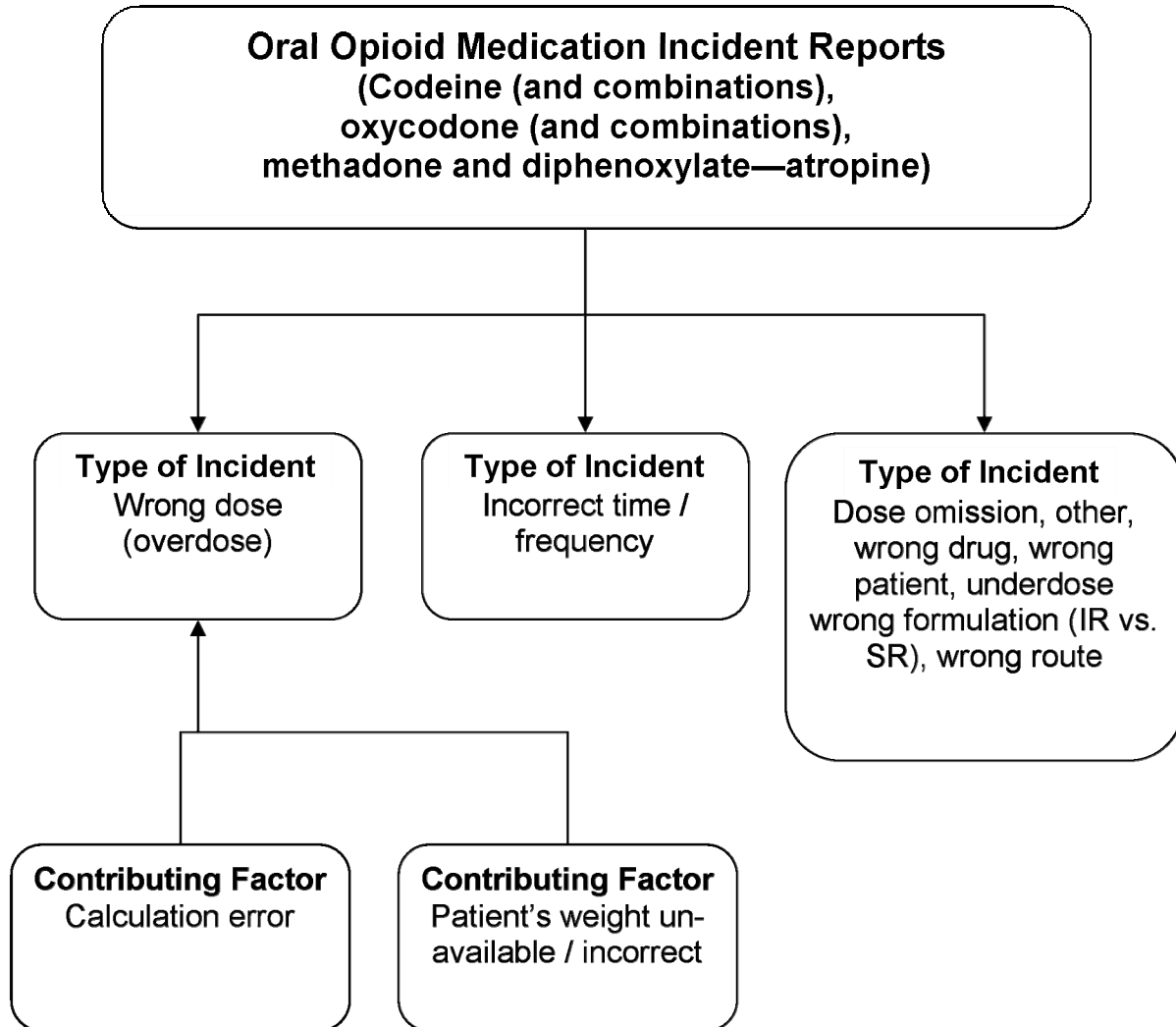
3.3.3.1 Types of Incidents and Contributing factors- Opioid Analgesics (Oral Opioids)

Table 9. Detailed Incident Reports Involving Oral Opioids- Type of Incidents

Type of incident-Oral Opioids	Total	Percentage
Wrong dose -- Overdose	18	23.4%
Incorrect time / frequency	15	19.5%
Dose omission	10	13.0%
Other	9	11.7%
Wrong drug	9	11.7%
Wrong dose	6	7.8%
Wrong patient	6	7.8%
Wrong dose -- Under dose	2	2.6%
Wrong formulation -- IR vs. SR	1	1.3%
Wrong route	1	1.3%
Total	77	100.0%

- Wrong dose incidents:** Wrong dose (overdose) incidents accounted for 23.4% of the incidents in the “oral opioid” category. In most of the incidents, a calculation error led to the ordered dose being too high. Furthermore, the unavailability of the patient’s weight or the use of an incorrect patient weight have also been cited as potential contributing factors for wrong dose incidents.
- Incorrect time / frequency:** Incidents involving Incorrect time / frequency of administration accounted for 19.5% of the incidents in the “oral opioid” category. Typical examples include codeine “q6h ordered, q4h given” or codeine q4h ordered but administered q8h. None of these incidents resulted in patient harm.

Figure 8. Oral Opioid Incidents: Type of incident and contributing factors



Analysis of the harm reports subset (n=3): Sample size too small for further analysis.

3.3.3.2 Type of Incidents and Contributing Factors-Hydromorphone

Table 10. Detailed Incident Reports Involving Hydromorphone- Type of Incidents

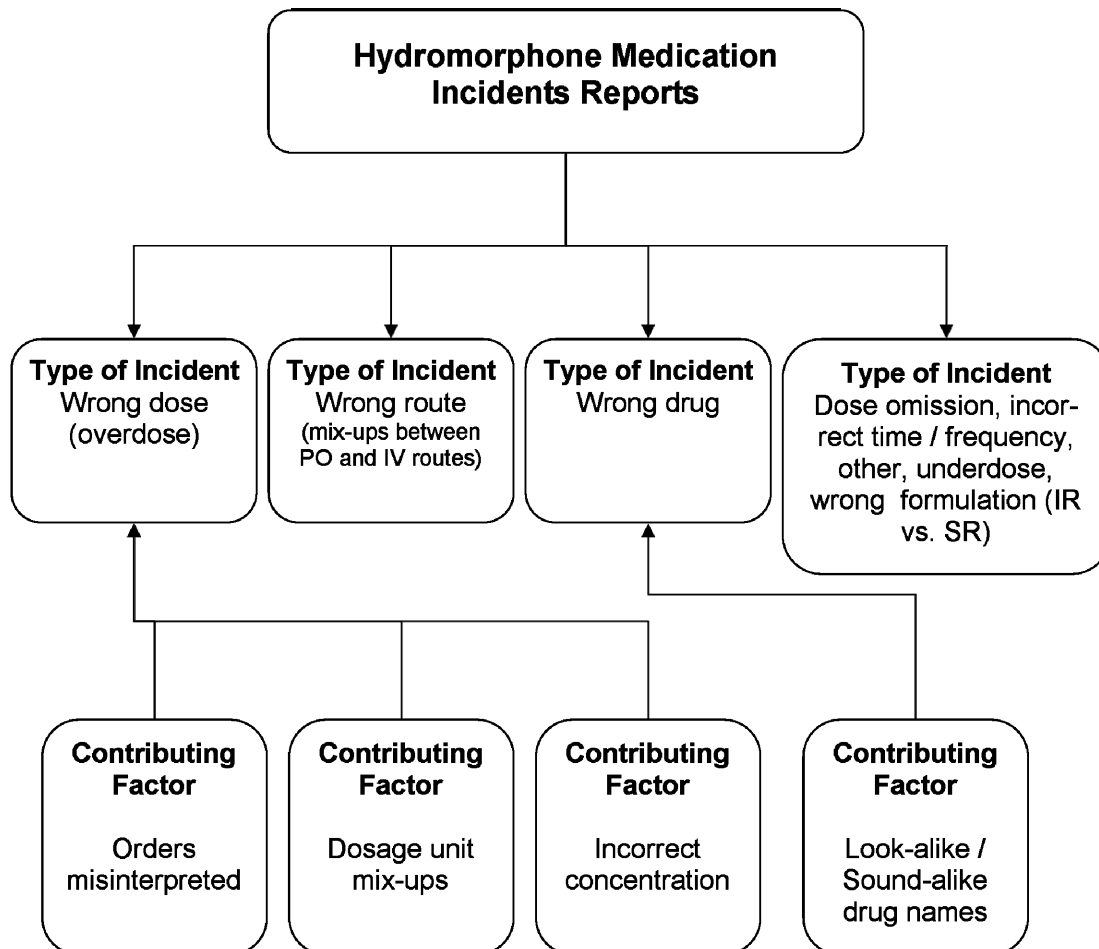
Type of incident	Frequency	Percentage
Wrong dose -- Overdose	8	25.8%
Wrong route	5	16.1%
Dose omission	4	12.9%
Wrong drug	4	12.9%
Wrong dose	3	9.7%
Incorrect time / frequency	2	6.5%
Other	2	6.5%
Wrong formulation -- IR vs. SR	2	6.5%
Wrong dose -- Under dose	1	3.2%
Total	31	100.0%

- Wrong dose:** Wrong dose (overdose) incidents accounted for 25.8% of hydromorphone incidents in this analysis. Most of these incidents involve hydromorphone IV continuous infusion or PCA. Misinterpretation of orders, dosage unit mix-ups and incorrect drug concentrations have been identified as potential contributing factors to these incidents:

 - Misinterpretation of orders: A significant number of incidents received mentioned the misinterpretation of decimal places leading to 10 fold hydromorphone overdoses. In another case, hydromorphone PCA was ordered with a dose of 300mcg/bolus (**1.5mL**) q6min, however, 1500mcg (**7.5mL**) q6min was administered (presumably due to misinterpretation of the handwritten order) resulting in a 5 fold overdose.
 - Dosage unit mix-ups: Mix-ups between “mg” and “mcg” were identified as a potential contributing factor to hydromorphone wrong dose incidents. In a report, “450mcg hydromorphone IV q2h prn was ordered”, but hydromorphone 4.5mg (4500mcg) was administered, resulting in a 10 fold overdose.
 - Incorrect hydromorphone concentration: In a case example, a PCA bag with the wrong hydromorphone concentration (2000mcg/mL instead of the ordered concentration of 200mcg/mL) was administered to the patient, resulting in a 10 fold overdose.
- Wrong route:** Most of the wrong route incidents involved mix-ups between oral and IV routes. Some of these incidents resulted in serious harm to the patient.

- Wrong drug:** Wrong drug incidents accounted for 12.9% of incident reports involving hydromorphone . The most common medication mixed-up with hydromorphone was morphine. This is likely due to the look-alike (and sound alike) issue of the drug names “hydromorphone” and “morphine”.

Figure 9. Hydromorphone incidents: Type of incidents and contributing factors



Analysis of the harm reports subset (n=7): Wrong dose (3 reports) and wrong route (3 reports) were the most common type of incidents (refer to corresponding sections above for details).

For analysis results for fentanyl, please refer to section 3.3.2.4, page 17.

3.3.4 Limitations

A number of limitations to the data / data analysis needed to be considered for proper interpretation of the results:

- Due to the voluntary nature of reporting, the frequencies of incidents in this analysis likely represent an underestimation of the true incidence rate.
- The contributing factors identified in the secondary analysis were derived solely from the event description fields in the received medication incidents. No interviews were conducted with the individuals involved in these incidents to confirm whether these contributing factors are accurate.
- The contributing factors are identified via qualitative methodology and thus this analysis does not give information as to their relative importance in context of the medication use system.
- The number of participating hospitals and therefore the number of reports analyzed was relatively low. Additional data collection and analysis is required to confirm that these results can be broadly assumed to apply in all Canadian paediatric settings.

3.4 Conclusions

Close to one quarter of all medication incidents reported as causing harm were associated with five medications, two of which were opiates. This suggests that a small number of medications account for a disproportionately large number of incidents and these medications may represent opportunities for targeted interventions.

An additional analysis of harmful and non-harmful incident reports for the top five medications and for the opioid class provided information on types of incidents and contributing factors. Although the most commonly-reported incident types varied from medication to medication, "wrong dose" and "wrong drug" incidents were reported frequently. For "wrong dose" incidents, mix ups of dosage units and calculation errors were common contributing factors; while for "wrong drug" incidents, look-alike / sound-alike medications were frequently identified as a contributing factor.

4. Paediatric Best Practice Landscape Survey

A paediatric specific survey was developed to identify leading medication system safety practices in Canadian paediatric centres. The survey tool was developed with input from the National Advisory Committee and pilot-tested with two different paediatric sites.

A total of 20 CAPHC members were invited to participate in this survey; 15 sites participated, resulting in a **75%** response rate.

The survey was conducted via telephone interview, with a pharmacist and a nurse facilitating each interview. An electronic version of the survey was sent to each participating facility prior to the scheduled telephone interview. The time to complete the interview ranged from 45 minutes to two hours. Although sites were encouraged to involve a multidisciplinary group in the telephone interview, the actual participants had a greater representation from pharmacy staff than from medical and nursing staff. There was also a greater representation from managerial staff than from front line staff.

4.1 Results

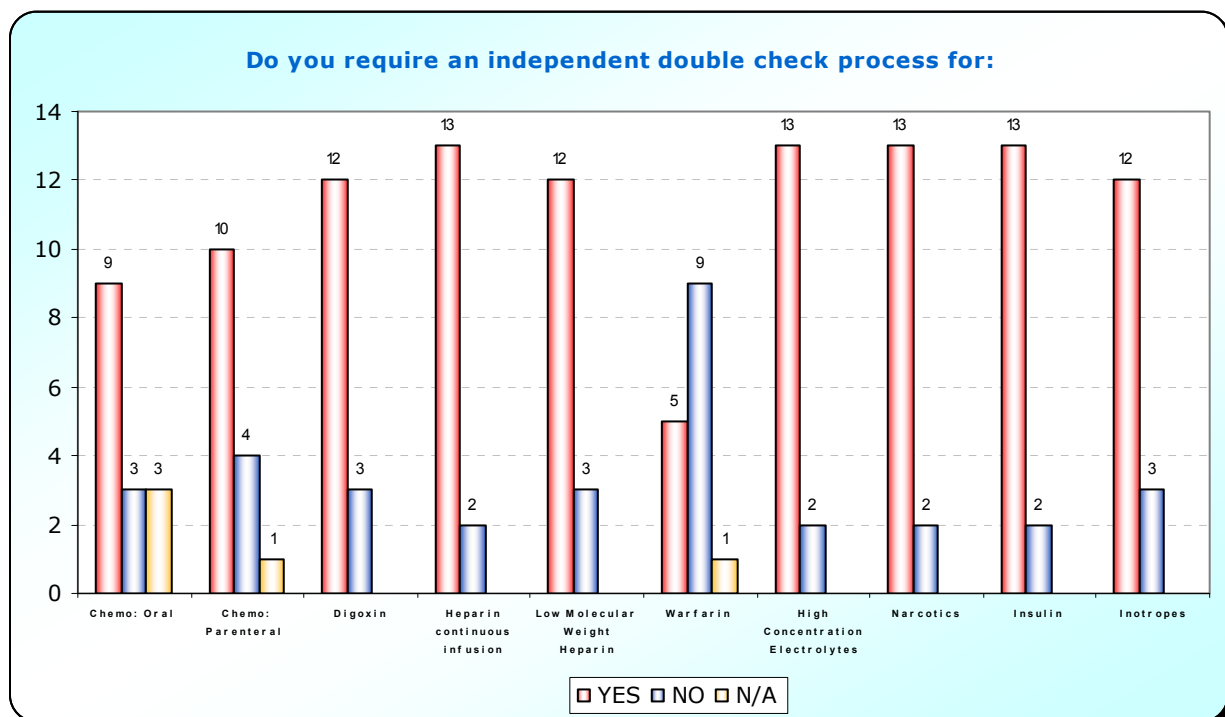
The results provide information on patient safety practices in paediatric facilities across Canada as of August 2008. The survey also captured information on initiatives that individual facilities see as necessary, and would like to plan for, in order to enhance the safety of paediatric medication systems. Some highlights of the survey responses are as follows:

4.1.1 System Safety and Incident Prevention

- Unit dose medication distribution systems were reported to be in place in 11/15 of the facilities. (Unit dose systems for oral medications were in place in 10/15 facilities and 9/15 had unit dose systems for parenteral products.) Other facilities identified implementation of a unit dose system as the highest priority in planning medication safety enhancements.

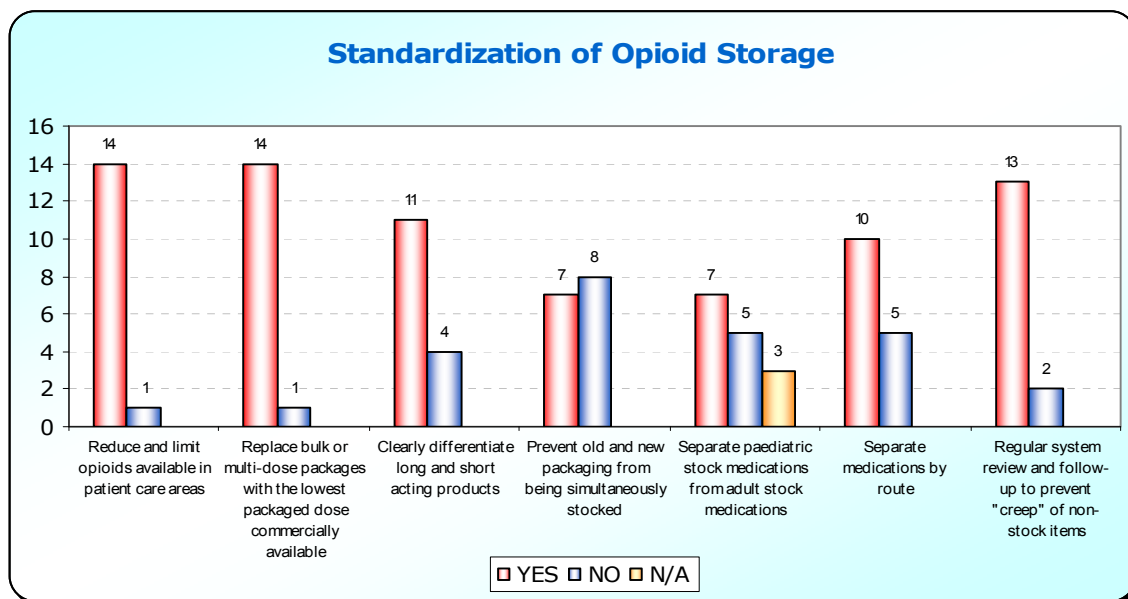
- While most facilities reported provision of clinical pharmacy services to a variety of patient care areas, only four reported that clinical pharmacy services are provided in the Emergency Room and only two reported that clinical pharmacy services are provided in the Operating Room. The areas where clinical pharmacy services were most frequently reported to be provided were haematology/oncology (13/15) NICU (11/15) and PICU (11/15).
- All but one facility reported that concentrated electrolytes had been removed from patient care areas.
- Independent double checks are widely required for high-alert drugs, with 13/15 organizations reporting use of this safety strategy. Independent double checks were most commonly reported to be required for heparin continuous infusions, high concentration electrolytes, narcotics and insulin (Figure 10). Five organizations reported that independent double checks were required for warfarin. Of interest, 4/15 organizations reported that independent double checks are not required for parenteral chemotherapy.

Figure 10. Independent Double Checks



- A majority of participants reported use of strategies related to standardization of opioid drug storage (Figure 11). Widely-implemented measures include reducing and limiting the availability of opioids in patient care areas, replacing bulk or multi-dose packages with the lowest packaged dose available commercially, clearly differentiating long and short-acting products, separating medications by route and conducting regular system review and follow-up to prevent “creep” of non-stock items. Of the 12 facilities with mixed pediatric/adult populations, seven facilities reported that paediatric stock for opioid medications is separated from adult stock. Only 7/15 facilities prevented old and new packaging from being simultaneously stocked.

Figure 11. Standardization of Opioid Storage



- Although limiting the availability of commercially prepared undiluted morphine and hydromorphone to a single strength was a commonly-reported strategy, 6/15 of responding facilities do not limit the availability of morphine and 5/15 do not limit the availability of hydromorphone (Figures 12 and 13).

Figure 12. Participants Limiting Availability of Commercially Prepared Morphine

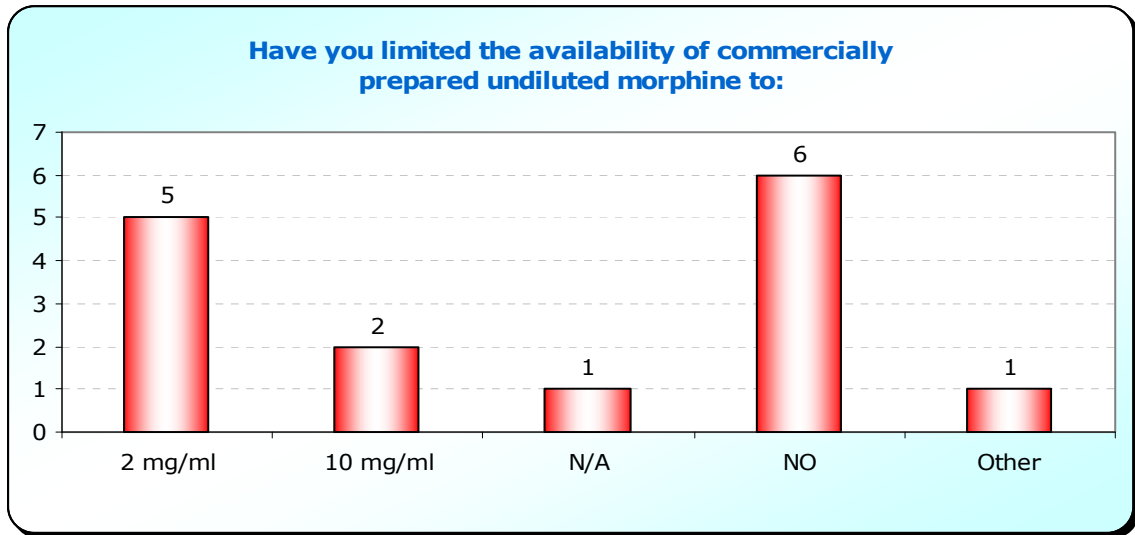
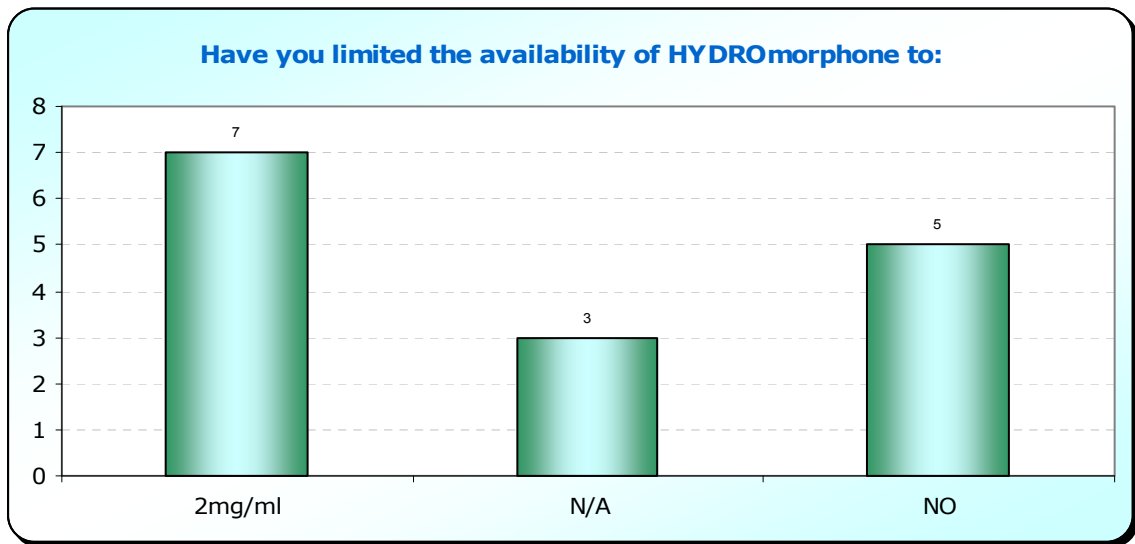


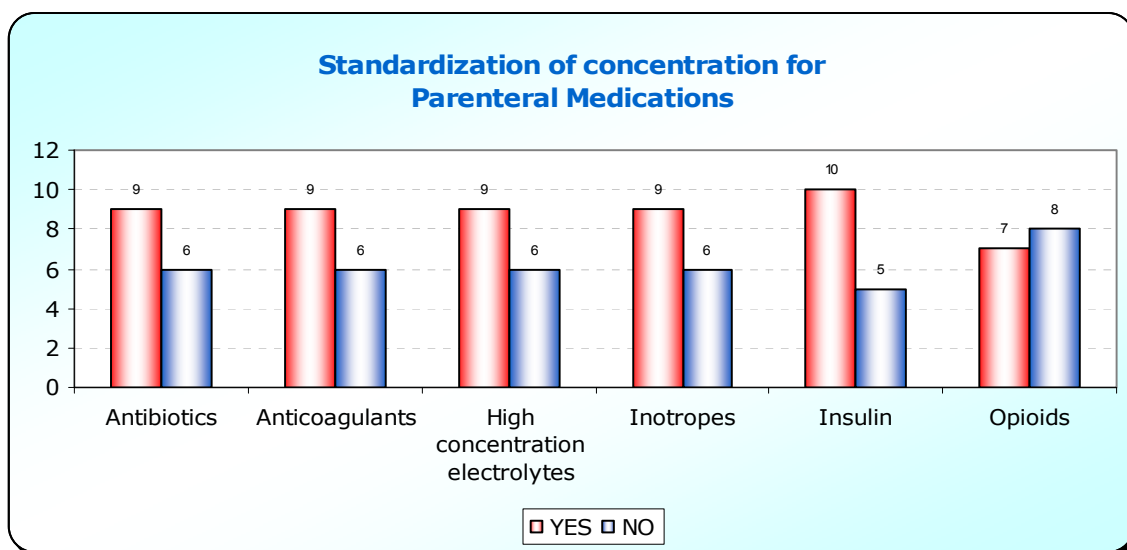
Figure 13-Participants Limiting Availability of Commercially Prepared Hydromorphone



- Four facilities reported that the availability of heparin on nursing units had been limited to the 1,000 units/mL concentration

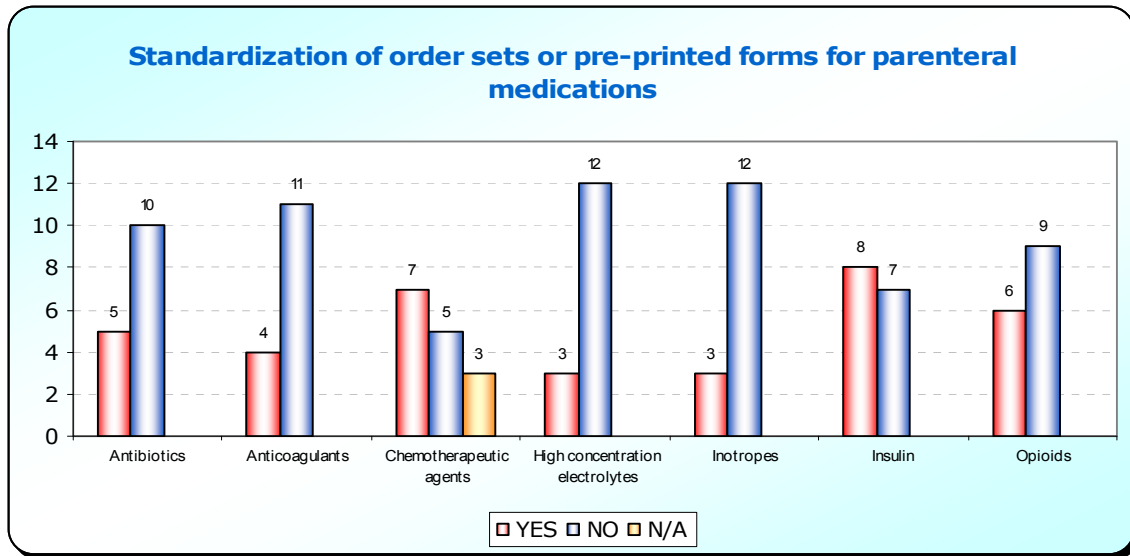
- Although the majority of responding facilities have implemented standardized concentrations for insulin, antibiotics, anticoagulants, high concentration electrolytes and inotropes (Figure 14), only 7/15 respondents have implemented standardized concentrations for opioids. Standardization of medication concentration ranked high on the list of safety interventions desired by respondents (Figure 19).

Figure 14. Standardization of Concentration for Parenteral Medications



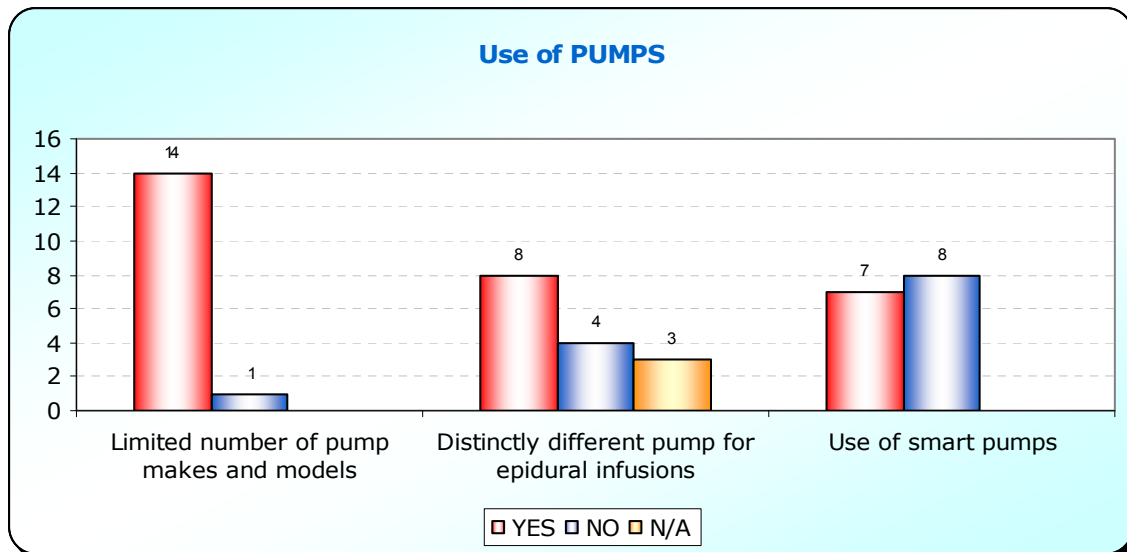
- Only 6/15 participants responded that their facilities used standardization of doses as a pediatric safety initiative.
- Seven facilities reported that use of the “Rule of Six” (a method used by some paediatric organizations to calculate the concentration required to achieve a standard rate of 1 mL/hour) has been eliminated.
- Two responding facilities reported have a pharmacist on-site 24 hours/day
- Use of standardized orders or pre-printed forms for parenteral medications was reported for a variety of agents (Figure 15). This strategy was most commonly reported for insulin and chemotherapeutic agents. Fewer than half of respondents reported use of standardized order sets or pre-printed forms for opioids, antibiotics, high concentration electrolytes and inotropes.

Figure 15. Standardization of Order Sets or Pre-Printed Order Forms for Parenteral Medications



- Various strategies related to the use of pumps, including use of Smart pumps, were reported. (Figure 16).

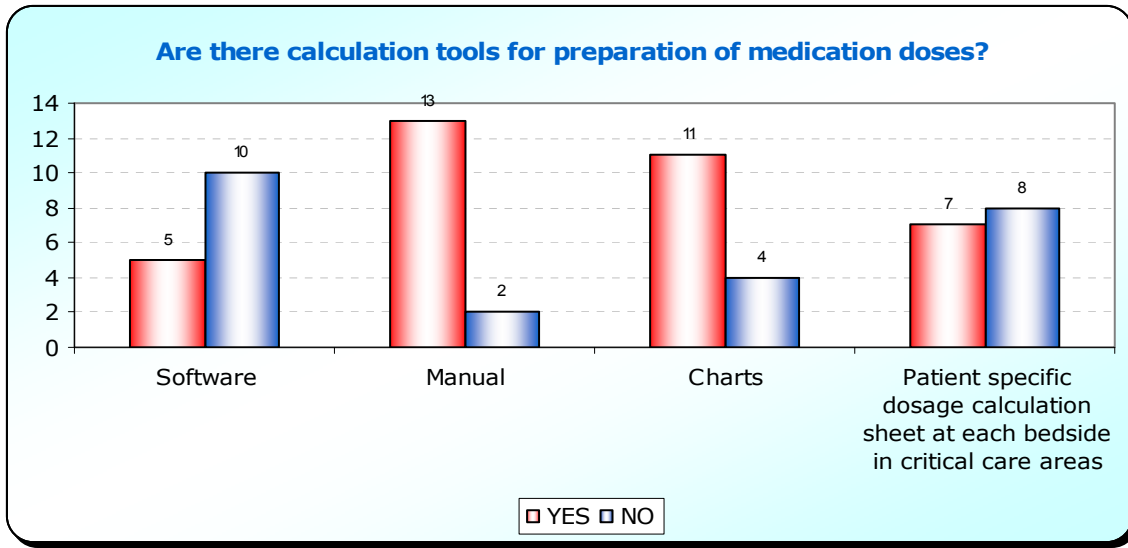
Figure 16. Use of Pumps



- Most facilities reported using calculation tools for preparation of medication doses, but only five reported having software to support this function (Figure 17). Patient-specific

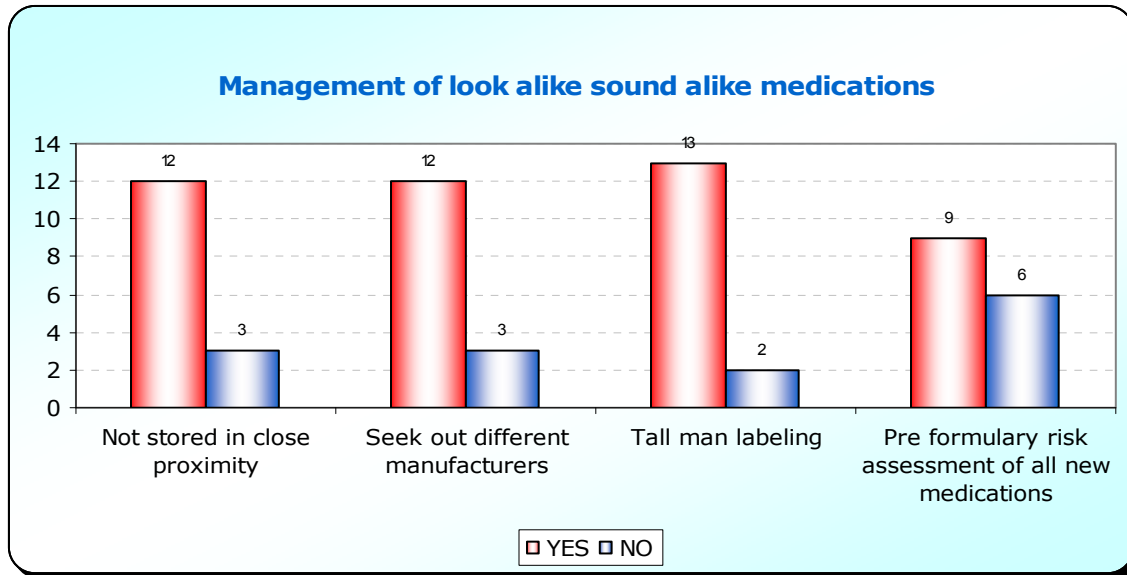
dosage calculation sheets at each bedside in critical care areas were used by nearly half of participating facilities.

Figure 17. Calculation Tools for Preparation of Medication Doses



- The strategy most commonly reported for management of look-alike/sound-alike medications was use of tall-man lettering (Figure 18). Seeking out different drug manufacturers, ensuring that look-alike/sound-alike drugs are not stored in close proximity and conducting pre-formulary risk assessments of all new medications were also reported by a majority of respondents.
- Only one facility reported use of a computerized prescriber order entry (CPOE) system and this facility reported that clinical dose checking capability is not used
- No facilities reported use of bar coding at point of care.

Figure 18. Management of Look-Alike Sound-Alike Medications



Other reported safety initiatives included use of standard paediatric dosing references (14/15), implementation of safe prescribing policies (e.g. dangerous abbreviation list, 14/15) and elimination of sliding scale insulin orders (5/15).

Overall, a higher implementation rate was noted for initiatives that rely on human resources (e.g. Independent Double Check policies and removal of high risk medications from the patient units) than for technological patient safety interventions. Initiatives that require significant fiscal resources are generally not in place.

4.1.2 Incident Reporting and Risk Assessment

The survey also included questions regarding incident reporting systems, root cause analysis and use of proactive risk-assessment tools. The responses indicated that:

- All participants had incident reporting systems that were able to identify harmful or potentially harmful incidents and collect information about contributing factors. All but one facility reported having the ability to share information from incident reports with front line staff.
- Ten participating facilities had conducted a root cause analysis on an incident involving a high alert medication.
- Eight participants indicated that an FMEA process has been used to assess a medication safety issue and one reported using a proactive risk assessment, such as a FMEA, prior to adding a drug to formulary to assess safety.

The use of Root Cause Analyses and pro-active risk assessments by many of the respondents are indications of the development of a culture of safety within pediatric organizations.

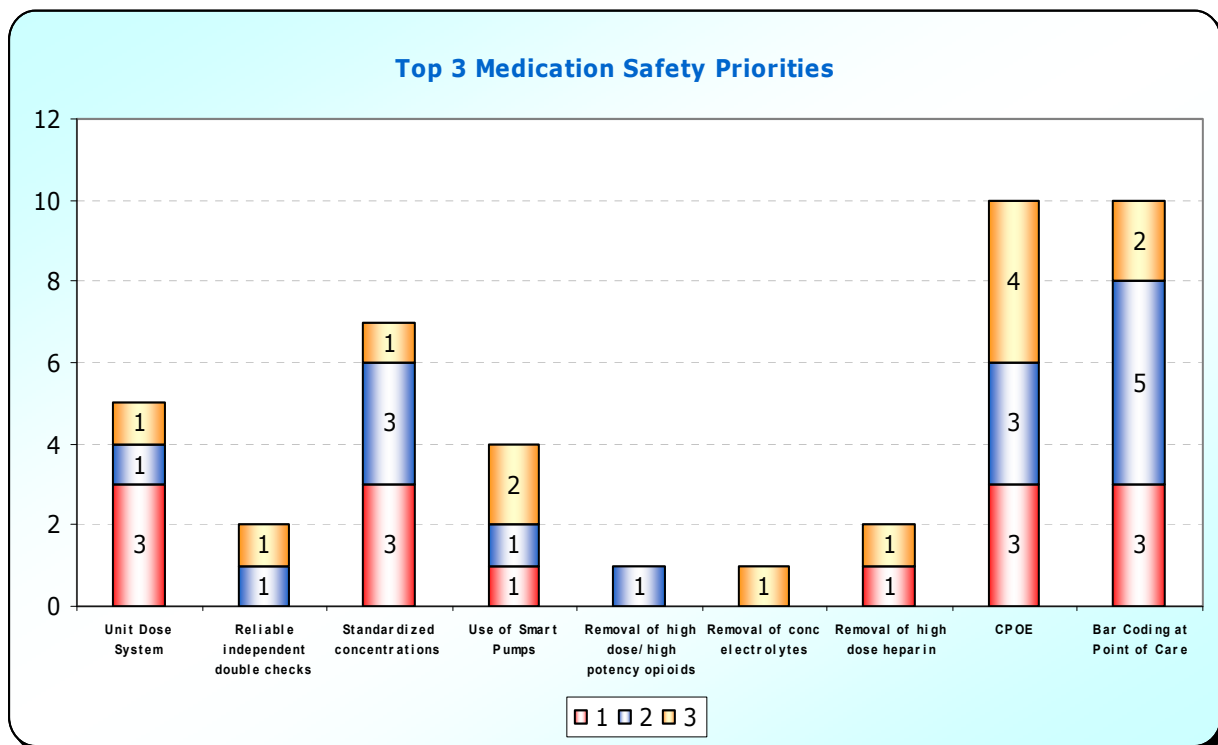
4.1.3 Priorities for Medication Safety Initiatives

Survey participants were asked to identify their top three priorities for medication safety initiatives.

- Both computerized prescriber order entry and bar coding at the point of care were included in the top three priorities for medication safety enhancements by 10/15 respondents (Figure 19)
- Implementation of unit dose systems and standardization of medication concentrations were also given high priority by many respondents.
- Certain processes or systems were high priority for respondents from organizations had not implemented systems that are widely accepted to improve safety. For example, respondents from all organizations who did not report use of a unit dose system placed this initiative in the top three priorities. Of the eight respondents who were not currently

using Smart Pumps, four placed implementation of Smart Pumps on the list of the top three priorities. Removal of concentrated electrolytes from patient care areas was the top priority for respondents from the single institution where this measure was not already in place.

Figure 19- Top Three Medication Safety Priorities



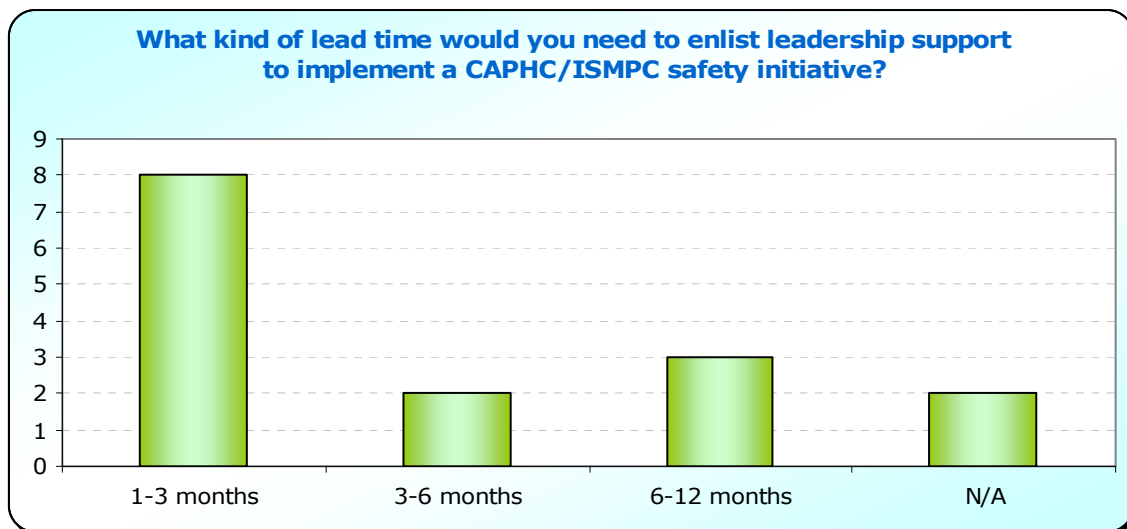
4.1.4 Priorities for CAPHC and ISMP Canada Support

When asked what CAPHC & ISMPC could provide to enhance medication system safety, responses fit into 5 distinct categories:

- Leading Practices – providing guidance with leading/safest practice; providing guidance for smaller community hospitals;
- Paediatric Database – development of a Canadian paediatric database of medication incidents with standard categorization of data;
- Indicators – specific paediatric performance indicators for benchmarking use;
- Collaboration – Accreditation Canada; Group Purchasing Organizations and Manufacturers; advocating for more research dollars; and
- Support – internet based networking environment

Most facilities indicated that a lead time of 1-3 months would be sufficient to enlist leadership support to implement a CAPHC/ISMPC safety initiative (Figure 20).

Figure 20- Required Lead Time to Enlist Leadership Support



4.1.5 Limitations

The limitations of this survey and results include

- The teams that participated in the survey process had a greater representation of managerial staff and pharmacy staff and a lesser representation of front-line staff, nursing staff and medical staff.
- The survey results were collected verbally and are based on self-reporting by responses, with the attendant possibility of inaccuracies in interpretation of questions or responses. ISMP Canada and CAPHC have not validated the accuracy of the responses.
- The assignment of priorities for medication safety initiatives were based on the personal views of the individual participants and did not necessarily reflect formally-approved organizational priorities.
- Nine of the fifteen facilities responding to the survey were based in Ontario, and the majority of the participating facilities were large teaching facilities. Consequently, the results of the survey may not fully reflect practices in certain provinces or in smaller community facilities.

4.2 Conclusions

The results of the survey provide a landscape view of patient safety initiatives in place at Canadian paediatric facilities in August 2008. This survey provided an excellent opportunity for Canadian healthcare facilities providing services to children and youth to contribute their ideas and experience to the advancement of paediatric medication system safety.

Survey responses provided data which will assist in developing solutions based on the needs of facilities providing healthcare services to Canadian children and youth. The analysis of the survey data helped to identify leading practices that have been implemented in many facilities, but also suggested that safe practices are not being consistently implemented. This is consistent with the view of the conclusions in 2006 of the CAPHC Paediatric Safety Collaborative.

The collective efforts of all participants will assist us as we begin to address medication incidents and unintentional adverse events at a system wide level.

5. Proposed Intervention

The National Advisory Committee agreed that the following criteria should be used to select a proposed intervention:

- Must address the top drugs reported as causing harm in paediatric database
- Must address the contributing factors
- Must be achievable within 2 years across the continuum of inpatient care; tertiary, community
- Must be a sustainable practice change linked to an Accreditation Canada ROP
- Must have a high impact on the hierarchy of effectiveness of incident prevention strategies
- Must be specific and measurable
- Must be meaningful to senior leadership and frontline staff

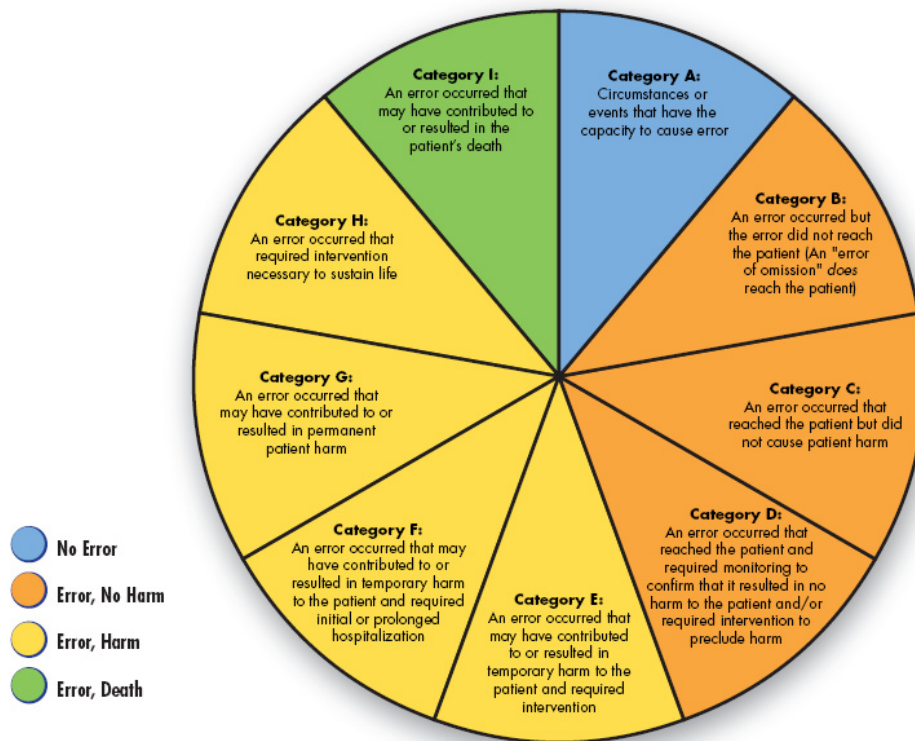
Consensus was reached on the following (intervention):

To create an intervention that will assist in the implementation of safe medication practice for the delivery of opioids in paediatric settings. This includes all aspects of the opioid medication system from prescribing to storage and administration.

The next steps include the development of a proposal for the next phase of the work, including the design and implementation of the specific intervention. Ideally, this would become an intervention of Phase 2 of the Safer Healthcare Now! (SHN!) Campaign – “Prevent Adverse Drug Events Related to High Alert Medications in Paediatrics”.

Appendix A

NCC MERP Index for Categorizing Medication Errors



Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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Advancing Medication Safety in the Delivery of High Alert Medications in Paediatrics



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