Canadian Paediatric High Alert Medication Delivery

Paediatric Opioid Safety - Phase 3: Education, Knowledge Translation and Implementation

Final Report
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Respectfully Submitted by
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Introduction & Background

The Canadian Association of Paediatric Health Centres (CAPHC) is a recognized leader and advocate for advancing the improvement of healthcare for Canada's children and youth.

CAPHC's mission is to support member and partner organizations through education, research, and quality improvement initiatives to improve health service delivery for Canadian children and youth.

The Institute for Safe Medication Practices Canada (ISMP) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

With partnership support from the Canadian Patient Safety Institute, Baxter Corporation, MedBuy, and HIROC, CAPHC and ISMP Canada began working together in 2008 to enhance the safety of paediatric medication use. The collaborative project, guided by a national advisory committee of content experts, practitioners, and researchers has successfully progressed through three phases.

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

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 reached a consensus on the following intervention to guide Phase 2:

"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." (Phase 1 Report)

The second phase of the project resulted in the development of a comprehensive set of recommendations to ensure safe opioid medication practice in three key areas of practice:

1. Standard IV concentrations,
2. Safe storage and labelling, and
3. Prescribing. (Phase 2 Report)

Phase 3 focused on education, knowledge exchange and implementation.

Preamble

This report represents the culmination of effort from CAPHC, ISMP Canada and CAPHC member organizations to realize the third phase of the Canadian Paediatric High Alert Medication Delivery: Opioid Safety Project. The knowledge translation, education and implementation phase began in April 2011 and continued until December 2012 with plans for 2 more webinar presentations in early 2013.

Purpose

To facilitate standardization of opioid medication safety practice across all organizations who deliver health services to infants, children and youth in Canada.

Goals & Objectives:

The overarching goal of Phase 3 of the Canadian Paediatric High Alert Medication Delivery Opioid Safety Project was to facilitate the implementation of the CAPHC/ISMPC Paediatric Opioid Safety Consensus Guidelines (Consensus Guidelines) in healthcare organizations serving infants, children and youth.

Main Objectives:

1. To assist paediatric organizations in implementing the Consensus Guidelines as identified in Phase 2;
2. To identify successful strategies to implement standard concentrations of opioid solutions;
3. To demonstrate the practical applicability of these recommendations within a variety of paediatric healthcare facilities (i.e. Quaternary, Tertiary, and Community-based);
4. To identify barriers to and enablers of practice change;
5. To develop an implementation framework that is flexible enough to be used by organizations at varying stages of readiness.

Achievements & Deliverables

The CAPHC/ISMP Canada Paediatric Opioid Safety Resource Kit is referenced in the 2013 Accreditation Canada Medication Management Standards.

The success of the first 2 phases was in large part due to the collaborative nature of the work. Phase 3 was no different and relied on national consultation through teleconferences, survey, web meetings, focus groups, workshops and education sessions. Feedback from the continuum of care as well as other stakeholder groups was integral to the revision and refinement of the Consensus Guidelines.

Achievements & Deliverables cont…

1. **Revised CAPHC/ISMPC Paediatric Opioid Safety Consensus Guidelines**
   - Through feedback from the child & youth healthcare community the Consensus Guidelines have been revised to include an Independent Double Check (IDC) recommendation
   - The Consensus Guidelines have been reformatted into a single document that highlights two different settings**: (Appendix A)**
     1. **Paediatric Specialty Hospitals**: Includes Level 3 NICU, PICU, Paediatric Intensivist on staff
     2. **Community Hospitals:** Includes General paediatric units, No PICU, Up to Level 2 NICU

2. **The Launch of an Electronic Paediatric Opioid Safety Resource Kit (the Kit):**
   - Available at http://ken.caphc.org/xwiki/bin/view/PaediatricOpioidSafetyResourceKit/ and includes:
     1. Background and rationale,
     2. Consensus Guidelines,
     3. References and recommended reading,
     4. Resources and tools.

Tools and resources on the Kit have been contributed by participating health care organizations, ISMP Canada, other stakeholder organizations, and or developed by the Steering Committee through consensus with participating organizations. All materials have been vetted by the Steering Committee and content experts prior to posting on the CAPHC Knowledge Exchange Network (KEN).

As more organizations move to the recommended standard concentrations it is anticipated that more resources and tools will be shared.

In the *References & Recommended Reading* section there are published papers, journal references, presentations, ISMP Canada bulletins and posters relating to and supporting all aspects of the Consensus Guidelines.

The *Tools & Resources* section contains contributions of order sets from paediatric specialty hospitals and community hospitals, as well as a contribution of 3 order sets using the recommended standard concentrations from PatientOrderSets.com

The Children's Hospital of Eastern Ontario (CHEO) has provided access to their electronic Dosage Calculation Tool. The tool will be revised to include the recommended standard concentrations as CHEO completes their implementation process.

There are also tips on labeling and storage; implementing standard concentrations, smart pump technology, and the Consensus Guidelines.

Much work was done on the development of an *Emergency Department Opioid Safety Toolkit for Paediatric Patients less than 40kg.* This was geared towards small community hospitals that rarely needed to run morphine infusions but found it very stressful when it became necessary. The concept is based on a successful program in the Champlain Local Health Integration Network (LHIN) where the Children's Hospital of Eastern Ontario reached out to community hospitals and helped to establish separate paediatric crash carts in their respective Emergency Departments (ED).

In response to the need expressed by the small community hospitals, strong consideration was given to the development of a physical kit including all of the items required to order, calculate, mix and run a morphine infusion and making it available in the respective EDs. There were concerns raised over the maintenance and upkeep of the kit once it was in place. Upon further discussion and field testing a decision was made to create an electronic version of the necessary elements. This would allow the organizations to download and print the documents relevant only to their specific requirements, avoiding confusion.

3. **Workshop:**

Representatives from 17 health care and stakeholder organizations met in Toronto on August 9, 2011 for a day long workshop. Nursing and pharmacy were the target audience.

The objectives were to:

- Introduce the participants to the Consensus Guidelines
    a. Background; rationale & development,
    b. Validate the usability of the Kit, and
    c. Test the tools available in the Kit.
- Use feedback provided to improve the Resource Kit and host a follow up interactive education session on October 16th, 2011 at the CAPHC Annual Conference

(**Workshop Proceedings- Appendix B**)

4. **Webinars:**
    - May 27, 2011 - *Paediatric Opioid Safety - Toward a Change in Practice* Presented in partnership with Accreditation Canada to the CAPHC Community (Posted to the KEN);
    - November 2, 2011 - *Paediatrics National Consensus Guidelines for Opioid Medication Delivery in Paediatrics* Presented at the Canadian Patient Safety Institute (CPSI) 2011 Virtual Forum;
    - December 7, 2011 - *Opioid Safety in Paediatrics National Consensus Guidelines for Opioid Medication Delivery in Paediatrics* Presented to non CAPHC members through ISMP Canada;
    - March 30, 2012 - How *to Be Smart when Implementing Smart Pump Technology* Presented to the CAPHC Community. (Posted to the KEN);
    - February 22, 2013 - Health *Sciences North – Implementing CAPHC/ISMPC Consensus Guidelines.*

5. **Education Sessions:**
    - October 16, 2011 CAPHC Conference: 10 healthcare organizations represented by patient safety and quality, directors and administrators participated in this workshop providing feedback from a different perspective and helped to focus the next steps to community hospital implementation

- Via web meetings with individual organizations where Health Sciences North shared their implementation strategy with the following community hospitals to help them design their own plan: Trillium Health Partners: Credit Valley Hospital and Mississauga Hospital; St. Joseph's Healthcare, Interior Health Authority: Kelowna General Hospital, and Ross Memorial Hospital
- October 28, 2012 CAPHC Conference: The Paediatric Opioid Resource Kit was used as a model for the demonstration of CAPHC's Knowledge Exchange Network.

6. Implementation

Consensus Guideline Implementation

Through consultation with the child and youth healthcare community it was agreed that initial implementation efforts should be focused on the community hospital setting. Discussions with community hospitals of varying sizes took place to determine how CAPHC and ISMP Canada could best support guideline implementation. It was recognized that hospitals were in various stages of readiness to implement and it became evident that competing priorities were a challenge. As Health Sciences North was preparing for Accreditation, they felt it was a perfect opportunity to implement the Consensus Guidelines. As stated above, their implementation strategy was shared as a model with other organizations.

Health Sciences North, in Sudbury Ontario, developed a self assessment tool to determine their own state of readiness. This consisted of a series of questions relating to each recommendation. This template is now shared on the KEN and is available for other centres to use as their starting point. **(Appendix C)** This adult teaching hospital also delivers health services to a large number of infants, children and youth and through this process is now developing/or has developed, paediatric specific monographs, order sets, and physician orders. They will be presenting their experience to a larger audience via webinar on February 22, 2013. As their new tools are approved within their organization they will be shared in the Paediatric Opioid Safety Resource Kit on the CAPHC KEN.

Standard Concentrations Implementation

The use of standard concentrations is the basis for many of the CAPHC/ISMP recommendations. Many organizations have implemented standard concentrations already but not those recommended through this process.

The standard concentrations were recommended by a Paediatric Clinical Expert Workgroup who met in Edmonton in October 2008 with the purpose of achieving consensus on a list of high-alert parenteral medications used within their practices, and for these listed medications, to propose:

- A relative harm ranking,
- Safety measures for their clinical practice areas and,
- Recommendations for Canadian standard IV concentrations.

Where there is national consensus on standard concentrations and the usage is high, it was also proposed that the Clinical Expert Workgroup would approach commercial IV admixture companies to produce these products to further enhance safety. (**Meeting Notes – Appendix D)**

In August 2010 a consensus statement was drafted by The Canadian Directors of Pharmacy of Paediatric Institutions and other Paediatric Pharmacy Practice Leaders that endorsed the following concentrations. It is recognized that additional concentrations of opioids for continuous intravenous infusion may be required by hospitals that care for very-low-birth-weight babies and by hospitals that do not have pumps with the ability to deliver volumes to 0.01 mL/hr accuracy. **(Consensus Statement - Appendix E)**

Recommended Standard Concentrations for Opioid Continuous Infusions

Morphine:	Hydromorphone:	Fentanyl:
0.2 mg/mL and 1 mg/mL	40 mcg/mL and 250 mcg/mL	50 mcg/mL

Another survey of Paediatric Specialty Hospitals was conducted in April 2012 to determine the progress of these organizations in implementing the Consensus Guidelines. It was determined that most of these organizations had at the very least had formal discussions and were considering implementation or had partially or fully implemented the guidelines.

Children's Hospital of Eastern Ontario is implementing the recommended standard concentrations for morphine, fentanyl and hydromorphone. This tertiary hospital already uses standard concentrations and smart pump technology but strongly agrees with the principles behind these choices. This change requires many resources of man hours to program pump libraries and settings; design and validate new pre-printed orders; develop admixing guidelines; train staff on the changes; removal of concentrations no longer appropriate for the care areas; changes to calculation tools; etc. As the new CHEO tools are validated and approved they will be added to the Kit.

BC Children's Hospital has also moved to the recommended standard concentration for morphine. They have included a third concentration to accommodate their needs. The BC experience is available as a resource in the Kit. They will also be sharing their experience to a wide paediatric audience via webinar in January 2013.

Interior Health in British Columbia is a geographically based health authority that includes 16 community hospitals, 4 service area hospitals, 2 tertiary referral hospitals and 6,275 residential care and assisted living beds. Morphine standard concentrations have been introduced at Kelowna General Hospital and are being implemented across the health authority. This work is pharmacy led and came as a response to an adverse event.

Challenges

The scope of this phase did not allow for any data collection for comparison purposes. Without quantitative data it is more challenging for organizations to present a business case to support practice change. While there is research in place to support standardization of practice, there is only anecdotal evidence and tacit knowledge to support the implementation of the CAPHC/ISMP Canada Paediatric Opioid Safety Consensus Guidelines.

Barriers to practice change exist at many levels:

- Leadership,
- Organizational/system-level barriers,
- Healthcare Team/social-level barriers, and
- Patient level barriers.

The organizational or system level barriers were seen to be the major barriers to implementing the Consensus Guidelines. Practice change is resource intensive and all healthcare organizations have competing priorities. The move to standard concentrations is the foundation for all of the consensus guidelines, and standard concentrations are most safely accompanied by the implementation of smart pump technology. The move to this technology is expensive and requires many human and monetary resources.

The team or social level barriers were reflected in a reluctance of individual nurses to change practice from the Rule of Six to standard concentrations. There was not a good enough understanding of the risks and benefits. There was an impression that mixing a standard concentration from which to make a morphine infusion was an unnecessary extra step.

There were minimal resources available for tool development. The recommended standard concentrations were not fully implemented by any of the CAPHC member organizations prior to this phase so there were no tools developed that reflected those concentrations. There was a great reliance on member organizations to share their tools as they were validated. **Reflecting on the collaborative nature of this work, the willingness of organizations to share can be seen as an enabler.**

Conclusions

It is widely accepted that standardization of practice can improve healthcare efficiencies and outcomes and there appears to be agreement in principle with the CAPHC/ISMP Canada Consensus Guidelines across Paediatric Specialty and Community Hospitals.

Healthcare organizations are at various stages of readiness and ability to implement practice change. As more healthcare organizations are able to apply smart pump technology, the implementation of the guidelines will be easier. As they create drug libraries and preprinted orders there will be additional resources and references added to the Kit to facilitate the process.

To further facilitate the implementation of the guidelines it will be important for organizations to have access to the Paediatric Opioid Safety Resource Kit and understand how to use the resources most effectively.

Next Steps

1. Development of train the trainer education modules for small community hospitals:
    - Using think aloud approach learn how to calculate and run a morphine infusion;
    - Situational awareness/mindfulness;
    - Why standard concentrations are important; and
    - How to use the available tools & resources.

2. Continued update of material on Paediatric Opioid Safety Resource Kit; and
3. Continue providing opportunities to share and learn from implementation experiences across the paediatric community.

Acknowledgements

CAPHC and ISMP Canada would like to take this opportunity to thank the Canadian Patient Safety Institute, Medbuy, the Baxter Corporation and HIROC for their ongoing support, and commitment to improve patient safety. We look forward to continued partnerships as we work together to standardize opioid medication safety practice across all organizations who deliver health services to infants, children and youth in Canada.

We would also like to thank all of the healthcare organizations who contributed to this process through their participation in surveys, focus groups, web meetings and teleconferences and who continue to contribute by sharing their implementation experiences with the larger child and youth healthcare community.

We would also like to acknowledge and thank Lisa Stromquist, National Coordinator Patient Safety and Quality, CAPHC, and Alice Watt, Medication Safety Specialist, ISMP Canada, for the leadership and commitment to this national program.

Paediatric
Opioid Safety Consensus Guidelines
Appendix A

<table>
<tr><th colspan="2">Recommendations</th><th>Guideline</th></tr>
<tr><td colspan="2">ADOPT STANDARD CONCENTRATIONS of opioid solutions intended for continuous intravenous infusion, as noted below, and use these standard concentrations in combination with smart pumps for maximum safety and/or infusion dosing charts where smart pump technology is not available</td><td rowspan="3">Standard concentrations of opioid solutions intended for continuous infusion should ideally be adopted in conjunction with maximal use of Drug Error Reduction Software (DERS) within smart pump technology. In the absence of DERS, it is imperative to ensure that other strategies, including infusion pump flow limits and dosing charts, are available to support the use of standard concentrations.

Use commercially prepared premixed intravenous solutions if available from the manufacturer.

If premixed IV solutions are not available commercially, prepare them in the pharmacy whenever possible. (Provide admixing guidelines for nursing staff for use when premixed, standard-concentration opioid solutions are not available.)

Exceptions: It is recognized that, hydromorphone or fentanyl may be required in certain situations.

RESTRICT ACCESS to hydromorphone to units where this drug is needed for specific paediatric patients or situations (e.g., for palliative care).

RESTRICT ACCESS to injectable fentanyl to units where this drug is needed for specific paediatric patients or situations (e.g., for rapid-sequence intubation of neonates in the neonatal intensive care unit).</td></tr>
<tr><td>Paediatric Specialty Hospitals

Includes: Level 3 NICU, PICU, Paediatric Intensivist on staff

Morphine:
0.2 mg/mL and 1 mg/mL

Hydromorphone:
40 mcg/mL and 250mcg/mL

Fentanyl:
10 mcg/mL and 50 mcg/mL</td><td>Community Hospitals

Includes:
General paediatric units, No PICU,
Up to Level 2 NICU

LIMIT the parenteral administration of opioids for paediatric patients to morphine.

Morphine:
0.2 mg/mL and 1 mg/mL

LIMIT the availability of injectable morphine to 2 mg/mL ampoules in paediatric care areas. (Currently the lowest dose of morphine ampoule available in Canada)</td></tr>
<tr><td colspan="2">Exception:
It is recognized that additional concentrations of opioids for continuous intravenous infusion may be required by hospitals that care for very-low-birth-weight babies and by hospitals that do not have pumps with the ability to deliver volumes to 0.01 mL/hr accuracy.</td></tr>
</table>

Paediatric
Opioid Safety Consensus Guidelines
Appendix A

Recommendations	Guideline
ADOPT STANDARD METHODS for preparing and administering intermittent bolus doses of opioid.	Develop admixing guidelines and calculation aids for use by nursing and pharmacy staff when preparing bolus opioid doses, and make these tools available at the point of care, as appropriate to practice. Ensure that procedures for administration of intermittent bolus doses are developed by the organization.
INCLUDE the dosage by weight for **ALL** opioid orders for paediatric patients weighing 40 kg or less, expressed as: - mg (or mcg)/kg/dose or - mg (or mcg)/kg/hr	For paediatric patients weighing less than 40 kg, prescribers' orders should include the weight-based dose, as mg/kg or mcg/kg, along with the patient-specific dose. Standard order sets (either electronic or preprinted) should express opioid doses for IV infusion in terms of the standard concentration(s) used by the organization and in a manner (e.g., mg/kg, mcg/kg/hr) and sequence that matches entries in medication administration records and programming choices on infusion pumps. Use consistent terminology (e.g., for dosing units) when communicating drug information (via labels, handwritten or pre-printed orders, medication administration records, chart notations, and documents in electronic formats, including computer screens
LABEL EVERY DOSE of opioid intended for oral or parenteral administration	Label all containers for opioid medications (e.g., oral syringes, parenteral syringes and infusion bags). This includes opioids prepared on nursing units. Ensure that, at a minimum, labels include the drug name and strength or total dose/total volume i.e morphine 1 mg/mL or 20 mg/20 mL

Recommendations	Guideline
DEVELOP and **DISSEMINATE** institution-wide dosing and monitoring guidelines for opioids used in paediatrics, including recommendations for the initial dose and maximum doses for opioid-naive patients	Ensure that current protocols, guidelines, dosing charts (including equianalgesic charts for oral, Parenteral and transdermal (e.g.,by patch), and/or checklists for opioids are readily accessible to prescribers, pharmacists, and nurses, and ensure that these aids are used whenever opioids are prescribed, dispensed, administered, and monitored. Initial maximum weight-based doses of opioids for paediatric patients (e.g., in mg/kg or mcg/kg per hour) should NOT exceed the usual starting dose for opioid-naive adults. Ensure that the reversal agent naloxone (and guidelines for its use) is readily available wherever opioids are administered.
In mixed units, where adult and paediatric patients are being treated in the same area (e.g., emergency department, ambulatory care clinics, inpatient units), **SEGREGATE** paediatric formulations of opioids from adult formulations	**For hospitals without automated dispensing cabinets** In mixed units, where adult and paediatric patients are being treated in the same area (e.g., emergency department, ambulatory care clinics, inpatient units), ensure that opioids intended for paediatric patients are physically separated from opioids intended for adult patients. For example, store paediatric opioids in a separate cupboard, similar to the use of separate crash carts for this patient population

Recommendations	Guideline
SEGREGATE, SEPARATE, and **DIFFERENTIATE** admixed opioid solutions intended for parenteral infusion from all other solutions intended for intravenous use.	Use a variety of differentiation strategies to prevent selection errors. For example, opioids intended for continuous infusion (which will have a large total dose in each container) should have a different appearance from other opioids to prevent inadvertent administration as an intermittent bolus dose. Strategies to be considered include size of container, colour or other aspects of labelling, and use of auxiliary labels, as well as physical separation in the storage location. To prevent mix-ups, the concentrations for hydromorphone and morphine suggested in the guideline for tertiary care are intentionally dissimilar. Additional differentiation strategies may be necessary for settings where both morphine and hydromorphone are needed, to prevent mix-ups between these medications, which have look-alike, sound-alike names
USE prefilled oral syringes for all liquid opioids for enteral administration	Package liquid opioids for enteral administration in patient-specific unit doses or in standard doses appropriate for paediatric patients and the particular clinical setting. Use only oral syringes that cannot be connected to parenteral systems (e.g., IV tubing).

Recommendations	Guideline
ADOPT INDEPENDENT DOUBLE CHECKS for prescribing, preparing and administering oral opioids (e.g. liquid), intravenous (continuous and intermittent) or epidural opioid medications.	Develop a policy requiring two clinicians (e.g., nurse, pharmacist, physician) independently verify the appropriateness of the prescription based on weight and indication), dose calculations, pump programming (e.g., initial set up and rate/dose changes, scheduled solution and tubing change, and patient transfers). Pharmacy opioid independent check process should include appropriateness of the prescription dose based on weight and calculations, calculations of doses, sterile compounding, stocking of medications in Automated Dispensing Cabinets or narcotic drawers/cupboards Ensure that education on the independent double check process is provided to nursing, medicine and pharmacy staff Consider use of checklists or tools that that support independent checks on critical information including documentation

Appendix B

Paediatric Opioid Safety Resource Kit Validation Workshop August 9, 2011

Proceedings

Canadian Paediatric High Alert Medication Delivery: Opioid Safety Phase 3

Participating Organizations

SickKids
Children's Hospital of Eastern Ontario (CHEO)
McMaster Children's Hospital
Credit Valley Hospital
Halton Healthcare Services
North York General
Rouge Valley Health System
Toronto East General Hospital
St. Joseph's Health Centre
William Osler Health Centre
Markham Stouffville Hospital
Humber River Regional
Institute for Safe Medication Practices (ISMP) Canada
Canadian Association of Paediatric Health Centres (CAPHC)
Healthcare Insurance Reciprocal of Canada (HIROC)
Medbuy
Baxter

Objectives

1. Introduce the participants to the Consensus Guidelines
    a. Background; rationale & development
    b. Validate the usability of the on-line Paediatric Opioid Safety Resource Kit http://ken.caphc.org
    c. Test the tools
2. Use feedback provided to improve the Resource Kit and host a follow up interactive education session on October 16th, 2011 at the CAPHC Annual Conference

Welcome & Introductions:

Elaine Orrbine, President and CEO of CAPHC, welcomed all participants to the workshop and provided a brief background of the work to date, goals and objectives and vision going forward.

CAPHC's mission is to support member and partner organizations through education, research, and quality improvement initiatives to improve health service delivery for Canadian children and youth.

At CAPHC's 2006 Annual Conference Patient Safety Symposium, the need to establish system-wide national standards for high risk medication practices across all paediatric settings was identified as a national priority.

Phase 1 – January – December 2008: The top 5 medications causing harm and/or potential harm in paediatric settings were identified through an analysis of 4,000 incident reports; as part of Phase 1, data from a national landscape survey revealed varied standards of practice nationally. A decision was taken at the end of Phase 1, to focus on opioid safety in paediatric settings across Canada - "**Create an intervention that would assist in the implementation of safe medication practices for the delivery of Opioids in paediatric settings"**.

Phase 2 - January 2009 – January 2010: Achieved national consultation and consensus via multiple focus groups, surveys and national meetings. Human factors and psychological theory were also employed as part of this process. Draft guidelines/national standards were subsequently established.

Responding to the specific needs of both tertiary and community hospitals serving children and youth, these recommendations are focused on safe storage, labeling, prescribing and standard IV concentrations. (See attached presentation).

Workshop Keynote Speaker - Dr. Conor McDonnell – The Hospital for Sick Children
"Opioids in pediatric practice: safe as houses or just safety in numbers?"

Dr. McDonnell presented on his recent work examining over 6,000 medication-related safety reports that were voluntarily submitted at SickKids between July 2004 and June 2009. It was noted that although reporting is on the increase, opioid related incidents remain a steady percentage. It is hoped that through continued study the ability to address the issues of harm proactively will be learned.

The objectives of this study were to answer the following:

- Where are we with opioid safety?
- What issues can we address?
- How?

The study and presentation helped to highlight the pervasiveness of the problem of medication errors in general and the significant risks to the paediatric population. Because of the wide variations in weight, dosing ranges, drug dilutions and off label practices, the risk of adverse events and potential harm still exists in spite of many safety practices that are in place.

Almost 4% of the medication errors examined were tenfold errors with opioids being the most common class of drug. Of these errors, approximately 70% were overdoses while 30% were underdoses. Although patient harm was noted in 22 of the reports, none of these errors resulted in long term morbidity or death. It was noted that an underdose can be as dangerous as an overdose. There were 18 one hundred fold errors reported.

Calculations are often being made in high stress situations with multiple distractions. The most frequent causes of error were related to calculation, ten involving decimal points and multiple zeros. Dr. McDonnell commented that as an anesthesiologist he is able to focus on one patient, one drug at a time with minimal distraction, nurses at the bedside do not have that luxury.

The use of Computerized Physician Order Entry (CPOE) and smart pump technology does not appear to have a significant impact on the frequency of tenfold errors. It was suggested that there is a need to design paediatric modules, as they are currently designed for an adult population. A hospital Opioid Committee with members from IT and pharmacy will help to address errors related to the equipment and programming.

It is important to identify the risk/benefit of opioid usage.

Through his study on medication errors Dr. McDonnell found it very important to dialogue with those involved in errors as soon as possible after the incident. Asking the question “what were you doing just before...” helped to identify factors contributing to the event and to focus the discussion. Providing support to those involved in any adverse event is essential.

Presentation: Margaret Colquhoun, Project Leader, Institute for Safe Medication Practices Canada
"Opioid Safety in Paediatrics - Implementing Consensus Guidelines for Opioid Medication Delivery in Paediatrics"

Margaret provided background information on ISMP Canada and their goal to bring awareness to system vulnerabilities to facilitate system improvements. She highlighted ISMP's capacity for practitioner and consumer reporting of medication incidents.
The purpose of Marg's presentation was to introduce the Consensus Guidelines and determine if there were any major challenges identified by workshop participants.

The Consensus Guidelines include fundamental system safety elements; prescribing elements; and dose standardization elements. There are separate guidelines for tertiary and community hospitals that include many similarities, as well as some significant differences. It was important to note that 60% of all hospitalized children are treated in community hospitals. This is a major reason for focusing much attention on community hospitals who often see only a few patients on an annual basis requiring an opioid infusion.

Adopting standard concentrations was the first recommendation. This recommendation is in line with Accreditation Canada ROPs but goes a step further by recommending the specific concentrations. Consensus on the specific concentrations came through a meeting of a clinical expert committee. In developing the standard parenteral concentrations the expert group focused on many human factors principles:

1. Avoidance of decimal errors as much as possible (e.g. avoid 100 mcg and 1000 mcg);
2. Use of solution concentrations that span the fluid requirements of neonatal to 16 year-old patients;
3. Avoidance of existing adult concentration, where possible;
4. Being cognizant of significant potency differences between category agents, and avoid "potency" errors (e.g. morphine vs. hydromorphone); and
5. Ultimately, to align standards concentrations with smart pump drug library settings.

Using this report and further consultation from community hospitals it was decided to limit the parenteral opioid agent used for paediatric patients in community hospitals to morphine only.

It was also recognized that additional concentrations of opioids for continuous infusions may be required for hospitals caring for very low birth weight babies, as well as for hospitals without pumps who deliver volumes to 0.01mL/hr accuracy.

The absence of a recommendation dealing with Independent Double Check (IDC) was questioned by workshop participants. Marg explained that initially it was part of the guidelines but was removed because of an inability to create an implementation plan for IDC. IDC was acknowledged to be an important process and a policy that should be in place at all organizations. There was recognition however that it is very difficult for nurses to follow and IDC and that auditing of the process is often inaccurate. It was agreed that IDC would be put back into the recommendations and further work would be done with organizations to develop guidelines to support the required processes.

There was discussion about differentiation strategies. It was noted that ISMP Canada does not support colour coding on labels. Some organizations use different colour tubing for IV lines but there is no industry standard.

There was agreement in principle on the recommendations presented. Many of the participants acknowledged that they are working towards an opioid safety plan and appreciate the guidance provided through the Consensus Guidelines and intend to bring theses recommendation back to their respective organizations for further consultation.

Presentation – Elaine Wong, PICU Pharmacist, Children's Hospital of Eastern Ontario *"Calculations in the O zone"*

Through a case based presentation, Elaine Wong provided an opportunity for workshop participants to calculate bolus doses and continuous infusions using the recommended standard concentrations. Questions on how to label the doses were also asked. As part of a "mock exercise", distractions were made by other members in the room to illustrate how difficult it is to perform the tasks in the chaotic environment of PICU, NICU, Emergency Department, as well as many other units.

Participants indicated that they had often performed calculations on paper towels, margins of an order in their hands and other random spaces.

Not everyone was successful in completing the calculations or the labeling exercises. A tenfold error was made during the exercise.

The issue of labeling medications prepared by nurses away from the bedside was also discussed. It was agreed that it is common practice for syringes to be prepared and not labelled. It was also agreed that this is a dangerous practice.

Examples of labels for bolus doses and infusions were provided. It was illustrated that it is possible to get a lot of information on a small label that is designed to be attached to syringes without covering the gradations. Everyone was supplied an example of the CHEO labels.

An ideal scenario was provided where commercially produced syringes or bags in the desired concentrations were available. All organizations had infusion pumps with dose error reduction software. Dose and rate confirmation with individualized weight based charts were provided.

Presentation – Lisa Stromquist, National Coordinator Patient Safety and Quality, CAPHC
"Welcome to the Knowledge Exchange Network"

Lisa introduced the participants to the CAPHC Knowledge Exchange Network (KEN). **http://ken.caphc.org** The KEN was described as a wiki based interactive on line community, originally created for the continuity and coordination of care of children with complex needs. It has expanded to include many categories and supports information exchange for different communities. The CAPHC - KEN was developed with a focus on sharing, growing, and expanding knowledge for the child and youth healthcare community. Its purpose is to facilitate the identification and sharing of leading practices in different areas of child & youth heath.

To become a member of the KEN you must click the REGISTER button in the top right hand corner and follow the instructions.

The KEN was chosen as an appropriate site to house the CAPHC - ISMP National Paediatric Opioid Safety Resource Kit because it can be accessible wherever there is internet connection. The KEN allows for timely revisions to content and allows users to comment and interact in "real-time". The resources that are available on the KEN can be easily downloaded for use at different organizations. Members of the KEN will be able to add information to the Kit through a secure process.

The Kit is organized into several main pages that provide background information, acknowledgements, the Consensus Guidelines, references, and resources.

The Resource and Tools pages have information from many CAPHC member organizations. Elaine Wong demonstrated the CHEO Drug Calculation Program. This tool is based on the standard concentrations and dosages used at that institution.

Patient specific dosages and infusions rates are calculated by entering a patient weight into the appropriate entry fields. The tool serves as a resource in the medication safety process to help verify accuracy of paediatric drug calculations.

There was discussion about the sharing of tools and liability. There is a disclaimer on the KEN that states CAPHC, ISMP Canada and the contributing hospitals are not responsible or liable for the use of the information provided. It was also noted that the CHEO Calculation Program is currently being shared with CHEO's Local Health Integration Network (LHIN).

As more organizations begin to use the recommended standard concentrations more specific tools will become available. Draft dosing charts have been developed but need to be validated before being shared on the KENe.

There was a discussion about the viability of commercial availability of the standard concentrations. Hospitals can currently outsource admixing services to various vendors. There are many factors that would influence the decision to outsource this service; usage, cost, stability, etc. Many of the children's hospitals in Canada have the capability to prepare syringes and bags for infusion in the pharmacy. However, the stability of these products, like the outsourced products, is limited. There is still admixing happening at the bedside in many community and tertiary hospitals. There are studies that show a great variance between ordered and delivered concentrations of opiate infusions.

Implementation Guidelines – Kate Mahon, President, Canadian Association of Critical Care Nurses

Speaking from her experience with practice change through the implementation of smart pump technology and standard concentrations at the IWK in Halifax, Kate walked participants through a draft implementation plan for the guidelines. Recognizing that organizations are in various stages of standardization, the discussion focused on starting with the basics.

When creating a multi-disciplinary implementation team it is important to create Terms of Reference that will respect the differences and expertise that each member of the team will have. Identifying local (unit) champions has proven to be very effective in keeping the momentum and interest.

Making the implementation of opioid safety standards personal and relevant to all professions is important and will lead to greater buy in and success. Include articles and the experience of the organization in all orientation sessions.

Recognizing that financial resources will need to be allocated to allow for staff time and training, will mean less problem solving throughout the implementation process. Depending on the size of an organization, the rollout may take place unit by unit, or hospital wide. If implementing one unit at a time, it is imperative to proactively address the issues that will arise from different equipment and processes. In addition, partnering with schools of nursing, medicine and pharmacy was seen as a benefit to the implementation process.

The units or programs need to identify their drug utilization. It is also important to understand that practice may highlight opportunities to completely remove certain medications from the floors. Using appreciative inquiry can be helpful to determine what part of a system is working well and where changes need to occur.

Education opportunities for nursing staff in the use of all new equipment and processes must be available and audited. Staff must be supported in their ability to follow through on all of the recommendations.

As nurses access the medications frequently and are responsible for the narcotic counts on their units, they must have input into designing storage solutions.

The implementation guidelines will be revised to reflect the conversation and posted to the KEN.

Moving Forward

Marg Colquhoun led a discussion on next steps and asked what the organizations need from ISMP and CAPHC to help to implement the recommended changes in practice.

- The tertiary centres represented have all switched to standard concentrations, although not the recommended concentrations;
- There was however a consensus statement from the directors of pharmacy at the 16 academic health sciences centres to adopt the recommended opioid concentrations for use in paediatrics;
- Some of the community hospitals have switched to standard concentrations;
- There are still organizations that use the Rule of Six;
- Pumps are being used in most centres with a large variation on the usage of Drug Error Reduction Technology.

Auditing the data that is collected by the pumps can be valuable in understanding practice and usage on units and across organizations. It can lead to a better understanding of hard and soft limits and when there may be a need to review these limits. Baxter has a program on Clinical Informatics and that can help to collect and analyze data. Other pump manufacturers likely have a similar program.

SickKids reported that looking at their data showed that soft limits are often overridden and they are looking at creating new hard limits for low dose morphine and a separate limit for high dose morphine.

It was noted that the information collected from the pumps can be used in support of legal/forensic circumstances.

Participants agreed that admixing guidelines for the standard concentrations would be helpful.

Baxter Corporation will consider doing stability testing to extend the shelf life of the admixed products if they are provided with the concentrations, pack size, packaging and diluent. If a longer shelf life is possible it may make it more likely that smaller centres would order the products. If all hospitals serving paediatrics move to these standard concentrations it would create a situation where it would be viable for a manufacturer to produce and sell the products. This could be a benefit to hospitals, industry and most importantly to the patient who would be receiving consistent dosing.

HIROC suggested that they have background information to share that supports the implementation of standards and about professional accountability.

Webinars with a variety of foci will be scheduled for the fall of 2011 and winter of 2012. Some of the suggested topics included but are not limited to:

1. Smart pumps
    a. Implementation
    b. Programming
    c. Auditing & Data
2. Leadership
3. Monitoring
4. Storage & labeling
5. Independent Double Check
6. Implementation of Standard Concentrations

It was suggested that shorter vignette type videos could also be posted to the toolkit in support of some of these recommendations. Not every topic will require a 60 minute presentation and staff will have limited ability to attend all sessions.

A 90 minute workshop will be held on Sunday, October 16 at the CAPHC Conference where the calculation exercise will be highlighted with an on-line demonstration of the Resource Kit.

ACTION:

1. Work will be ongoing on the CAPHC - Knowledge Exchange Network to update the Resource Kit;
2. Admixing guidelines and dosing charts will be created and validated;
3. A proposal will be made to Baxter for stability testing for the standard concentrations;
4. An Independent Double Check guideline will be added; and
5. An education schedule will be created and disseminated across the CAPHC Network.

REFERENCES:

Proceedings 2006 CAPHC Patient Safety Collaborative Symposium
Phase 1 Report
Phase 2 Report
ISMP Canada Bulletin
CAPHC ISMP Canada Paediatric Opioid Safety Resource Kit
http://ken.caphc.org/xwiki/bin/view/PaediatricOpioidSafetyResourceKit/

Paediatric Opioid Safety Consensus Guidelines
Self Assessment Tool
Appendix C

<table>
<tr><th colspan="2">Recommendations</th><th>Guideline</th></tr>
<tr><td colspan="2">ADOPT STANDARD CONCENTRATIONS of opioid solutions intended for continuous intravenous infusion, as noted below, and use these standard concentrations in combination with smart pumps for maximum safety and/or infusion dosing charts where smart pump technology is not available</td><td rowspan="2">Standard concentrations of opioid solutions intended for continuous infusion should ideally be adopted in conjunction with maximal use of Drug Error Reduction Software (DERS) within smart pump technology. In the absence of DERS, it is imperative to ensure that other strategies, including infusion pump flow limits and dosing charts, are available to support the use of standard concentrations.

Use commercially prepared premixed intravenous solutions if available from the manufacturer.

If premixed IV solutions are not available commercially, prepare them in the pharmacy whenever possible. (Provide admixing guidelines for nursing staff for use when premixed, standard-concentration opioid solutions are not available.)

Exceptions: It is recognized that, hydromorphone or fentanyl may be required in certain situations.

RESTRICT ACCESS to hydromorphone to units where this drug is needed for specific paediatric patients or situations (e.g., for palliative care).

RESTRICT ACCESS to injectable fentanyl to units where this drug is needed for specific paediatric patients or situations (e.g., for rapid-sequence intubation of neonates in the neonatal intensive care unit).</td></tr>
<tr><td>Paediatric Specialty Hospitals

Includes: Level 3 NICU, PICU, Paediatric Intensivist on staff

Morphine:
0.2 mg/mL and 1 mg/mL

Hydromorphone:
40 mcg/mL and 250mcg/mL

Fentanyl:
10 mcg/mL and 50 mcg/mL</td><td>Community Hospitals

Includes:
General paediatric units, No PICU,
Up to Level 2 NICU

LIMIT the parenteral administration of opioids for paediatric patients to morphine.

Morphine:
0.2 mg/mL and 1 mg/mL

LIMIT the availability of injectable morphine to 2 mg/mL ampoules in paediatric care areas. (Currently the lowest dose of morphine ampoule available in Canada)</td></tr>
</table>

Recommendations	Guideline
Exception: It is recognized that additional concentrations of opioids for continuous intravenous infusion may be required by hospitals that care for very-low-birth-weight babies and by hospitals that do not have pumps with the ability to deliver volumes to 0.01 mL/hr accuracy**.**	

Questions to Ask

1. What other locations could paediatric patients be treated? For example, ED, Surgical Day Care, OR, PACU, Ambulatory Clinics (fracture clinic)
2. What morphine concentrations are currently used?
3. What is the compliance rate with pumps?
4. What is the lowest volume that can be delivered via our pumps?
5. What are the settings for the IV pump library in Peds/NICU/Peds-ICU for continuous infusions?
6. Do we use premixed solutions in pharmacy or is it batched?
7. Do we have IV monographs? Are they paediatric specific or contain all dosing information?
8. What strengths of morphine are stocked for paediatric patients?
9. Is HYDROmorphone used anywhere and if so, is it restricted?
10. Is FentaNYL used anywhere and if so, is access restricted?
11. Does the organization have P&P addressing the safeguard of narcotics?

Recommendations	Guideline
ADOPT STANDARD METHODS for preparing and administering intermittent bolus doses of opioid.	Develop admixing guidelines and calculation aids for use by nursing and pharmacy staff when preparing bolus opioid doses, and make these tools available at the point of care, as appropriate to practice. Ensure that procedures for administration of intermittent bolus doses are developed by the organization.

Questions to Ask

1. Do we have guidelines and calculation aids to use by nursing and pharmacy staff when preparing bolus opioid doses? Where are they kept?
2. Do we have pump settings for opioid bolus doses?
3. Do we have guidelines for the administration of opioid bolus doses?
4. Is there an Independent Double Check policy in place?
5. Is this process audited?
6. Is there a designated chart area for documentation that an independent double-check has been performed?
7. Is ongoing education available for new staff, those returning from MLOA, or transferring units?

Recommendations	Guideline
INCLUDE the dosage by weight for **ALL** opioid orders for paediatric patients weighing 40 kg or less, expressed as: - mg (or mcg)/kg/dose or - mg (or mcg)/kg/hr	For paediatric patients weighing less than 40 kg, prescribers' orders should include the weight-based dose, as mg/kg or mcg/kg, along with the patient-specific dose. Standard order sets (either electronic or preprinted) should express opioid doses for IV infusion in terms of the standard concentration(s) used by the organization and in a manner (e.g., mg/kg, mcg/kg/hr) and sequence that matches entries in medication administration records and programming choices on infusion pumps. Use consistent terminology (e.g., for dosing units) when communicating drug information (via labels, handwritten or pre-printed orders, medication administration records, chart notations, and documents in electronic formats, including computer screens

Questions to Ask

1. How compliant are we with mg/kg/dose dosing?
2. Is our terminology consistent when communicating drug information?
3. Is CPOE used? If not, are there opportunities to create pre-printed orders?

Recommendations	Guideline
LABEL EVERY DOSE of opioid intended for oral or parenteral administration	Label all containers for opioid medications (e.g., oral syringes, parenteral syringes and infusion bags). This includes opioids prepared on nursing units. Ensure that, at a minimum, labels include the drug name and strength or total dose/total volume i.e morphine 1 mg/mL or 20 mg/20 mL

Questions to Ask

1. Do we have a policy on how the drug should be labelled? If so, where is it available and do staff have easy access to it?
2. How are labels displayed in pharmacy, on the nursing unit?

Recommendations	Guideline
DEVELOP and **DISSEMINATE** institution-wide dosing and monitoring guidelines for opioids used in paediatrics, including recommendations for the initial dose and maximum doses for opioid-naive patients	Ensure that current protocols, guidelines, dosing charts (including equianalgesic charts for oral, Parenteral and transdermal (e.g.,by patch), and/or checklists for opioids are readily accessible to prescribers, pharmacists, and nurses, and ensure that these aids are used whenever opioids are prescribed, dispensed, administered, and monitored. Initial maximum weight-based doses of opioids for paediatric patients (e.g., in mg/kg or mcg/kg per hour) should NOT exceed the usual starting dose for opioid-naive adults. Ensure that the reversal agent naloxone (and guidelines for its use) is readily available wherever opioids are administered.
Questions to Ask	
1. Do we have a checklist (double-check process) 2. Where is naloxone stored? Any issues with accessibility?	

Recommendations	Guideline
In mixed units, where adult and paediatric patients are being treated in the same area (e.g., emergency department, ambulatory care clinics, inpatient units), **SEGREGATE** paediatric formulations of opioids from adult formulations	**For hospitals without automated dispensing cabinets** In mixed units, where adult and paediatric patients are being treated in the same area (e.g., emergency department, ambulatory care clinics, inpatient units), ensure that opioids intended for paediatric patients are physically separated from opioids intended for adult patients. For example, store paediatric opioids in a separate cupboard, similar to the use of separate crash carts for this patient population

Questions to Ask

1. Is there a separate storage area for paediatric formulations?
2. If not, how are they identified?

Recommendations	Guideline
SEGREGATE, SEPARATE, and **DIFFERENTIATE** admixed opioid solutions intended for parenteral infusion from all other solutions intended for intravenous use.	Use a variety of differentiation strategies to prevent selection errors. For example, opioids intended for continuous infusion (which will have a large total dose in each container) should have a different appearance from other opioids to prevent inadvertent administration as an intermittent bolus dose. Strategies to be considered include size of container, colour or other aspects of labelling, and use of auxiliary labels, as well as physical separation in the storage location. To prevent mix-ups, the concentrations for hydromorphone and morphine suggested in the guideline for tertiary care are intentionally dissimilar. Additional differentiation strategies may be necessary for settings where both morphine and hydromorphone are needed, to prevent mix-ups between these medications, which have look-alike, sound-alike names

Questions to Ask

1. Are opioids intended for continuous infusion different in appearance from opioids intended for intermittent bolus dose?
2. Do we make a differentiation in product labelling and presentation?
3. Dose the product label (pre-mixed, pharmacy prepared) match our order entry, pre-printed order forms, IV pump screen/library?
4. If applicable, how do we display our morphine and HYDROmorphone concentrations?

Recommendations	Guideline
USE prefilled oral syringes for all liquid opioids for enteral administration	Package liquid opioids for enteral administration in patient-specific unit doses or in standard doses appropriate for paediatric patients and the particular clinical setting. Use only oral syringes that cannot be connected to parenteral systems (e.g., IV tubing).

Questions to Ask

1. How do we package oral liquid morphine?
2. What strength/size is available on each unit?
3. Do we use oral syringes?
4. How are they labelled and differentiated?

Recommendations	Guideline
ADOPT INDEPENDENT DOUBLE CHECKS for prescribing, preparing and administering oral opioids (e.g. liquid), intravenous (continuous and intermittent) or epidural opioid medications.	Develop a policy requiring two clinicians (e.g., nurse, pharmacist, physician) independently verify the appropriateness of the prescription based on weight and indication), dose calculations, pump programming (e.g., initial set up and rate/dose changes, scheduled solution and tubing change, and patient transfers). Pharmacy opioid independent check process should include appropriateness of the prescription dose based on weight and calculations, calculations of doses, sterile compounding, stocking of medications in Automated Dispensing Cabinets or narcotic drawers/cupboards Ensure that education on the independent double check process is provided to nursing, medicine and pharmacy staff Consider use of checklists or tools that that support independent checks on critical information including documentation
Questions to Ask	
1. Do we have a double check policy and process for high alert medication? 2. Is the process audited?	

Appendix D

PEDIATRIC CLINICAL EXPERT WORKGROUP
ON
PEDIATRIC HIGH-ALERT MEDICATION
MEETING NOTES
Date: Saturday, October 18, 2008
Location: CAPHC Annual AGM, Westin Hotel, Edmonton, Alberta

Attendees:

Jeanne Smith (Halifax, IWK), Marcel Romanick (Edmonton, Stollery), Sandy Campbell (London, HSC), Danica Irwin (Ottawa, CHEO), Anne Longo (Toronto, Sick Kids), Terri Hamlin (Calgary, Alberta Children's), Barb Sproll (Winnipeg, HSC) , Heather Jepsen (Calgary, Alberta Children's)

Corresponding Members: JF Bussieres (Montreal, St. Justine's), Paul Bambrik (St. John's, Eastern Health), Marg Colquhoun (ISMP-Canada), Ian Sheppard (ISMP-Canada)

Workshop Leader: Roxane Carr, (Vancouver, B.C. Children's and Women's)

This workshop was convened as part of the CAPHC/ISMP national initiative to identify high-alert medications used in pediatrics and Neonatology, and to develop potential strategies to mitigate potential for harm within these care environments. Clinical experts from a number of Canadian pediatric and neonatal centres were invited to attend a one-day workshop, held in conjunction with the Canadian Association of Pediatric Health Centre's (CAPHC) annual general meeting, in Edmonton, October 18, 2008.

The group sought a consensus on a list of high-alert parenteral medications used within their practices. And, for these listed medications, to propose;

- a relative harm ranking,
- safety measures for their clinical practice areas and,
- Recommendations for Canadian standard IV concentrations.

Where both consensus and combined volumes of usage are large, it is further proposed that the Group will approach commercial IV admixture companies to produce these products to future enhance safety.

1.0 Introductions

The group conducted an introduction of members in attendance.

2.0 High-Alert Parenteral Medications

After reviewing the 2002-2006 Medmarx survey of the top 20 parenteral products involved in harmful pediatric ADEs, and after considering their own practices, the relative ranking of the high-alert medications were considered to be;

- **Opioids**
  - morphine,
  - hydromorphone
  - fentanyl
- **Insulin Products**
- **Heparin and Low molecular Weight Heparins (LMWH)**
- **Electrolytes**, including KCl, MgSO4, Na/K Phosphates, Hypertonic NaCl
- **Neuromuscular Blocking Agents**
  (Pancuronium, rocuronium, vecuronium, atracurium, cisatr)
- **Benzodiazepines** (Midazolam)
- **Epidural agents** (bupivacaine, ropivacaine, epidural fentanyl)
- **Vasopressor/Inotropes**
  - Dopamine, Dobutamine
  - milrinone
  - Epinephrine, norepinephrine

- **Other Agents**
    - Vasopressin
    - Amiodarone
    - Ketamine
    - Epoprostenol
    - Alprostadil
    - Esmolol
    - Digxin

3.0 Standardize Parenteral Practice Priorities

The workshop Group was asked to determine if national standardization of some parenteral practices would be useful in reducing harm, through simplification of systems and concentrations. The following sections summarize their collective opinion.

3.1 Standard Pediatric Parenteral Concentration Priorities

(See Appendix A: Standard Concentration Table)

In developing standard parenteral concentration recommendations the expert group focused on several human factors principles:

a) Avoidance of decimal errors as much as possible
   (e.g. avoid 100 mcg and 1000 mcg)
b) Use solution concentrations that span the fluid requirements of neonatal to 16 year-old patients
c) avoid the use of existing adult concentration, where possible
d) Be cognizant of significant potency differences between category agents, and avoid "potency" errors (e.g. morphine vs. hydromorphone)
e) Later, to align standards concentrations with smart pump drug library settings

3.1.1 Morphine

a) Avoid usually adult concentrations (e.g. 2000 mcg/mL)
b) Reduction in decimal point errors (e.g. 100 vs. 1000 look-alike)
    - Reduced picking errors
    - Reduced mathematical complexity
    - Greater differentiation between units of dosage
    - **1000 mcg/mL**
    - **500 mcg/mL**
    - **200 mcg/mL (neonates)**

3.1.2 Hydromorphone

a) Avoid potency confusion with morphine molecule, due to confusion between names (look-alike, sound-alike), and
b) Choose concentrations which are equi-analgesic to morphine (in case an error is made).
    - **250 mcg/mL**
    - **40 mcg/mL**

3.1.3 Fentanyl

a) Avoid concentrations similar to hydromorphone or morphine.
    - **50 mcg/mL (in syringes, preferred format)**
    - **25 mcg/mL (in syringes, preferred format)**

3.1.4 Insulin (Human Regular)

a) align with Canadian Diabetes Guidelines
b) Avoid decimal look-alike (ie 1 versus 0.1)
    - **1 unit/mL for diabetic ketoacidosis**
    - **0.2 unit/mL**

3.1.5 Heparin

a) use commercial products
- **100 units/mL**
- **50 units/mL**

For arterial line patency
- **1 unit/ mL NS**
- **1 unit/mL D5W**
- **2 unit/mL D5W**

3.1.6 Electrolytes

3.1.6.1 Potassium Chloride

a) Utilize SI units in ordering, if possible: millimoles per litre (mmol/L)
In addition to current commercially available concentrations
- **For Continuous IV**
  - 20 mmol/L D10W-1/2 NS
  - 40 mmol/L D10W-1/2 NS

3.1.6.2 Calcium Gluconate
- 20 mg/mL (? 50 mg/mL)

3.1.6.3 Calcium Chloride
- 20 mg/mL (CRRT Patients)

3.1.6.4 Magnesium Sulphate

a) Ordering issues may require more discussion and education (40 mg/mL = 4 g/100 mL = 16 mmol/100 mL)
b) Problems with calculations: mg to mmol conversion

3.1.7 Midazolam
- **5 mg/mL**
- **1 mg/mL**
- **0.2 mg/mL**

3.1.8 Epinephrine
- **100 mcg/mL (also used in adults)**
- **50 mcg/mL**
- **25 mcg/mL**

3.1.9 Dopamine

a) Use Commercial concentrations
b) Prefer syringes (50 mL) to bags
- **800 mcg/mL**
- **1600 mcg/mL**

3.1.10 Milrinone
- **400 mcg/mL**
- **200 mcg/mL**

3.1.11 Epidural Agents

a) Appropriate storage and labeling of bupivacaine spinal is an issue
b) Confusion between fentanyl epidural and IV routes
c) Multiple similar strengths
   - **Bupivacaine only**
     - **0.125%**
     - **0.08%**
     - **0.1 % (1 mg/mL)**
     - **0.05%**
   - **Fentanyl only**
     - **2 mcg/mL**
     - **1 mcg/mL**
   - **Epinephrine**
     - **2 mcg/mL**
   - **Ropivicaine**
     - **TBD**
     - **TBD**
   - **Combined Bupivacaine/Fentanyl**
     - **Bupivcaine 0.1% with Fentanyl 2 mcg/mL, or**
     - **Bupivcaine 0.1% with Fentanyl 1 mcg/mL**
     - **Bupivcaine 0.05% with Fentanyl 2 mcg/mL, or**
     - **Bupivcaine 0.05% with Fentanyl 1 mcg/mL**

3.2 General Standard IV Practices

3.2.1 Ordering Electrolytes
- Consistency of units (mg, mEq, mmol)

3.2.2 Labeling of bags and syringes (units of dose per units of volume)

3.2.3 Manufacturing Labeling standards

3.2.4 Consistency required for safe RN Pump Entry
- Prescription number and barcode scanning of Pharmacy doses
- Standard national Hard limits within drug library for automatic safety checks.

3.2.5 Continuous IV Infusions should be;
- Drugs….. in X units (mg or units) per mL
- Electrolytes….. X units per Litre

3.2.6 Utilize separate pump systems for INTERMITTENT infusions vs CONTINUOUS infusions.

3.2.7 Nurses to review and remove buretrol use

3.2.8 Patient care areas using high alert drugs should review the use of "rescue" drugs (antidotes) as a routine agenda item at morbidity rounds (naloxone, protamine, Vitamin K, flumazenil, etc)

3.2.9 All pump systems should undergo human factors analysis before purchase decision and implementation. Ideally, this requirement should become part of an RFP requirement.

3.3 Opioid Safety Issues

3.3.1 Safety standards for IV labeling of containers
- Name and strength highlighted
- Font size
- Clarity of label (black on white)

3.3.2 Use of pre-printed orders (or computer order sets) of all IV opioid treatments

3.3.3 Avoid range dosing in orders

3.3.4 Standardized monitoring protocols to form part of order set

3.3.5 Education modules for RNs regarding differences in opioids, especially in critical care environments and Emergency Departments,

3.3.6 Prescribe hydromorphone in mcg only

3.3.7 Prescribe morphine in mg only

3.3.8 Attempt to segregate physical storage of different opioids, whenever possible

3.3.9 Keep opioids ampoules and vials in original packaging: avoid loose ampoules and vials

3.3.10 Minimize number of different strengths on formulary, and in both pharmacy and, in particular, on patient care areas.

3.3.11 Routinely monitor all trigger events as part of morbidity rounds, such as;
- Naloxone
- Protamine

3.3.12 Review, teach and implement true independent teaching methods" for RNs and pharmacy technicians

3.3.13 National standards for hard limits (warnings) on smart pumps

3.3.14 Increase pharmacy resources in critical care area, and oncology.

3.3.15 Pharmacy to prepare all high alert IV medications

3.3.16 In times of pharmacy absence, have a formalized "next best practice for prescribing, calculation, admixture and bedside dose checking.

3.3.17 Increased use of commercial pre-mixed bags and "RTA" (ready-to-administer) dose forms.

3.3.18 Clinical pharmacists to be present when standard concentrations and smart pump systems are planned and implemented.

4.0 Pediatric Expert Clinical Network

4.1.1 Develop a national ISMP or CAPHC sharing website for the following purposes;
- Standard order sets
- Standard concentration lists
- Smart pump library settings (drug libraries)
- Clinical Q&A and net-discussions
- Trigger tools

National Pediatric High Alert Concentration List
Edmonton Expert Workshop; October 2008

Intravenous

National Opiates

		Medication	Concentration	Units	Per Vol	Volume Units	Solution (mL)	Total Volume: Bulk (mL)	Preferred Solution Container	Expiry (Days)	Comments
Adult	**---**	Morphine	2000	mcg	1	mL	TBD				Commercial
	Pediatric	Morphine	1000	mcg	1	mL	TBD	250	Bag		
	Pediatric	Morphine	500	mcg	1	mL	TBD	250	Bag		
	Pediatric	Morphine	200	mcg	1	mL	TBD	150	Bag		
	Pediatric	Hydromorphone	250	mcg	1	mL	TBD	250	Bag		Equianalgesic to 1000 mcg/mL Morphine
	Pediatric	Hydromorphone	40	mcg	1	mL	TBD	150	Bag		Equianalgesic to 200 mcg/mL Morphine
	Pediatric	Fentanyl	50	mcg	1	mL	TBD	50	**Syringe**		
	Pediatric	Fentanyl	25	mcg	1	mL	TBD	50	**Syringe**		
Adult	**Pediatric**	Insulin	1	Unit	1	mL	TBD	250	Bag		
	Pediatric	Insulin	0.2	Unit	1	mL	TBD	250	Bag		
Adult	**Pediatric**	Heparin	100	Unit	1	mL	TBD	TBD	TBD		
Adult	**Pediatric**	Heparin	50	Unit	1	mL	TBD	TBD	TBD		Commercial
	Pediatric	Heparin	2	Unit	1	mL	D5W	TBD	TBD		
	Pediatric	Heparin	1	Unit	1	mL	D5W	TBD	TBD		
	Pediatric	Heparin	1	Unit	1	mL	NS	TBD	TBD		Arterial Line Patency
								TBD	TBD		
	Pediatric	Potassium Chloride	Undetermined								
	Pediatric	Potassium Chloride	20	mmol	1000	mL	D10W & 1/2 NS	500	Bag		
	Pediatric	Potassium Chloride	40	mmol	1000	mL	D10W & 1/2 NS	500	Bag		
	Pediatric	Calcium Gluconate	20	mg	1	mL	TBD	250	Bag		
	Pediatric	Calcium Chloride	20	mg	1	mL	NS				for CRRT Patients
	Pediatric	Magnesium Sulphate	16	mmol	100	mL	TBD	250	Bag		
	Pediatric	Magnesium Sulphate	8	mmol	100	mL	TBD	250	Bag		
	Pediatric	Midazolam	5	mg	1	mL	TBD	TBD	TBD		
	Pediatric	Midazolam	1	mg	1	mL	TBD	TBD	TBD		
	Pediatric	Midazolam	0.2	mg	1	mL	TBD	TBD	TBD		
Adult	**Pediatric**	Epinephrine	100	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Epinephrine	50	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Epinephrine	25	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Dopamine	1600	mcg	1	mL	TBD	50	**Syringe**		Commercial bags available
	Pediatric	Dopamine	800	mcg	1	mL	TBD	50	**Syringe**		Commercial bags available
	Pediatric	Milronone	400	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Milronone	200	mcg	1	mL	TBD	TBD	TBD		

National Pediatric High Alert Concentration List
Edmonton Expert Workshop; October 2008

National Opiate

		Medication	Concentration	Units	Per Vol	Volume Units	Solution (mL)	Total Volume: Bulk (mL)	Preferred Solution Container	Expiry (Days)	Comments
Epidural											
	Pediatric	Bupivacaine	1.25	mg	1	mL	TBD	TBD	TBD		0.125%
	Pediatric	Bupivacaine	1	mg	1	mL	TBD	TBD	TBD		0.10%
	Pediatric	Bupivacaine	0.8	mg	1	mL	TBD	TBD	TBD		0.08%
	Pediatric	Bupivacaine	0.5	mg	1	mL	TBD	TBD	TBD		0.05%
	Pediatric	Fentanyl	2	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Fentanyl	1	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Bupivacaine/Fentanyl	0.1%/ 2	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Bupivacaine/Fentanyl	0.05%/ 2	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Epinephrine	2	mcg	1	mL	TBD	TBD	TBD		
	Pediatric	Ropivicaine	1	mcg	1	mL	TBD	TBD	TBD		CHEO to Follow-up: 0.1%
	Pediatric	Ropivicaine	2	mcg	1	mL	TBD	TBD	TBD		CHEO to Follow-up: 0.2%

Consensus Statement on Opioid use in pediatric inpatients

The Canadian Directors of Pharmacy of Pediatric Institutions and other Pediatric Pharmacy Practice Leaders endorse the following statements for pediatric inpatients:

- The following Canadian national standard concentrations for continuous IV infusion in pediatric inpatients are adopted.
    - Morphine 1 mg/mL & Morphine 0.2 mg/mL
    - Fentanyl 50 mcg/mL
    - Hydromorphone 250 mcg/mL & Hydromorphone 40 mcg/mL

  These particular national standard concentrations support the principles of:
    - Avoidance of decimal point errors
    - Relative equipotency of different opioid concentrations

- Efforts will be made to decrease the use of codeine containing products in pediatric inpatients.

  This considers the pharmacogenomic variation in response to codeine leading to either lack of effect or exaggerated effect.

- Oral liquid opioids are packaged in aliquots not to exceed a single usual adult dose, unless patient specific unit doses are available

  This is aligned with industry single use products.

National consensus of these statements will lead to greater patient safety with the ability for institutions to share treatment protocols, transfer patients seamlessly and to explore commercial preparation & purchase of pediatric specific products.

This supports the ISMP/CAPHC recommendations in the 'Phase 2 Report entitled: Canadian Paediatric High Alert Medication Delivery: Opioid Safety - Toward a Change in Practice.'

Participating Centers:

Children's and Women's Health Centre of British Columbia
Alberta Health Services – Stollery Children's Hospital
Alberta Health Services – Calgary Children's Hospital
Saskatoon Regional Health Authority
Children's Hospital-Health Sciences Center Winnipeg MB
McMaster Children's Hospital/Hamilton Health Sciences
The Hospital for Sick Children – Toronto ON
Kingston General Hospital – Kingston ON
Children's Hospital of Eastern Ontario
CHU Sainte-Justine – Montreal QC
IWK Health Centre – Halifax NS
Janeway Child Health Centre – St John's NFLD

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