



Canadian Paediatric High Alert Medication Delivery: Opioid Safety *Toward a Change in Practice*

Phase 2 Report January 28, 2010

Introduction: Transforming Paediatric Opioid Delivery

At the 2006 Canadian Association of Paediatric Health Centres (CAPHC) Annual Conference, the CAPHC Patient Safety Collaborative initiated an exploration of national standards to increase safe delivery of high alert medications in the unique paediatric healthcare setting. **(Appendix I)** CAPHC and the Institute of Safe Medication Practice Canada (ISMP) established a partnership to undertake this work, and completed Phase 1 in 2008. Based on the Phase 1 results and a set of predetermined criteria, the focus of the initiative was narrowed to opioid delivery in paediatrics.

(Appendix II) The National Advisory Committee agreed 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.

This report describes the second phase of this collaborative initiative. In addition it also indicates clear directions for the next phase of this important work.

Phase 2 Results: An Integrated, Multi-dimensional Approach

What is unique about Phase 2 is the synergy of perspectives applied to the issues of safer opioid delivery in paediatric healthcare settings. Health professionals, human factors experts and psychologists worked together throughout Phase 2 to create a layered environment of safety.

A National Advisory Committee, with representation from across Canada, is providing direction to the project and assisting with the interpretation of findings.

The result? An integrated, multi-dimensional approach toward transforming practice in paediatric opioid delivery.

The conclusions of Phase 2 investigations support:

- Moving to standardized concentrations to reduce calculation and other errors
- Customization of standards for community and tertiary hospitals and of communications for two distinct psychological groups of health professionals; and
- The benefits of an optimal psycho-physiological state to deliver opioids.

These conclusions point to a new equation for change: *opioid safety tactics + human factors analysis + psychological insights = safer opioid delivery in paediatric healthcare settings.*

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The promise of the Phase 2 results will now require testing and validation. Going forward, workshops, training modules and pilot implementation in approximately twenty CAPHC member organizations will provide opportunities to confirm our Phase 2 conclusions.

Phase 2: Finding What Works

Following a well-charted path to medication delivery safety in paediatrics

Project origins set direction

Phase 2 of The Canadian Paediatric High Alert Medication Delivery Opioid Safety Project has moved substantially forward on the path originated by the 2006 CAPHC *Patient Safety Collaborative Annual Symposium*. The participants at the Symposium agreed that standardization in paediatric healthcare settings is crucial. They recommended that CAPHC explore strategies to build standards for medication administration techniques from prescription to delivery.

Phase I established the context

Phase 1 of the Project, developed and delivered in partnership by CAPHC and ISMP Canada, provided the necessary context to develop best practice strategies. Through a comprehensive *Medication Incident Analysis*, Phase 1 identified the top five medications reported as causing or potentially causing, harm to paediatric patients. Two of the five are opioids. This analysis also identified that the two most common types of medication incidents reported as causing harm were "wrong drug" and "wrong dose" incidents.

A *Paediatric Best Practice Landscape Survey* of paediatric healthcare facilities provided additional contextual information. The survey identified leading practices that have been implemented in many facilities, but also suggested that safe practices are not being consistently implemented.

The decision to focus on opioid agents in Phase 2 was based on a set of predetermined criteria and the results of the incident report analysis and landscape survey, the National Advisory Committee 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.



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Phase 2 Objectives: Focus On Clarification and Consultation

Primary objectives:

- To develop a comprehensive set of intervention recommendations and tools to ensure safe opioid medication practice including, but not limited to, methods of standardization of prescribing and administration, calculation tools, contracting and storage.
- To utilize an innovative approach by applying human factors expertise and psychological theory and practice, to design strategies for developing support for professionals in safe medication delivery practice. This included developing collateral strategies for the safe recommendations described in the Objective above.

Additional objectives:

- To develop a Paediatric Opioid Safety "Resource Guide Toolkit"
- To coordinate and host training session/workshop to engage and ensure buy-in from the Canadian paediatric healthcare community.

The Toolkit is developed and ready for testing, and the first projected activity for future work will be a workshop to test and refine some of the proposed interventions.

Three linked activities characterize Phase 2

A cross-disciplinary working group met via teleconference on a monthly basis throughout Phase 2 to co-ordinate three concurrent activities:

- 1. The development of Opioid safety tactics
- 2. A human factors analysis
- 3. A psychological analysis.

In consultation with the national advisory committee, the work in each area informed the work in the other two, as the project progressed. An all-day 'in person' meeting at the project's midpoint also provided an opportunity to share first findings, further identify linkages and address how to weave the three 'strands' of activity together.

1. Opioid Safety Tactics

A multidisciplinary team from ISMP Canada and CAPHC member hospitals developed and provided standardized approaches to opioid safety tactics.

The eleven tactics encompass three groups of activities, providing an optimal 'ladder' of safety:

- 1. Fundamental System Safety Elements
- 2. Prescribing Standardization Elements
- 3. Dose Administration Standardization Elements.



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The team's ultimate recommendations reflect the iterative, consultative process that they used to arrive at a pan-Canadian consensus on each tactic.

Survey results underscore differences between tertiary and community hospitals

A defining feature of Phase 2 is the recognition of the different needs of community and tertiary hospitals. This distinction will inform all action going forward, an approach that covers a significant portion of the 'continuum of care', recognizing that approximately 65% of paediatric care is delivered in community hospitals (Canadian Institute of Health Information (CIHI), F2007 Canadian Paediatric Hospitalizations).

The Opioid Safety Tactics Team conducted a series of surveys to determine how hospitals currently use and administer opioids to paediatric patients and to investigate the differences between community and tertiary hospitals' practice of paediatric opioids. (Appendix III)

A summary of survey results reveals the following information:

• Survey Results – Tertiary Hospitals

- $\circ~$ Less than half of respondents have adopted standard IV opioid infusion concentrations but all are supportive of the idea.
- $\circ\,$ Almost all respondents would purchase commercially available standard IV opioid infusion concentrations.
- Half of the respondents require an independent double check on all opioid infusions and pump rate changes for opioids.
- Slightly less than half have calculation tools for frontline nurses with respect to dose checking, mixing and administering opioids or calculating infusion rates.

• Survey Results – Community Hospitals

Community hospitals that provide significantly high volumes of healthcare services to children and youth often lack standardization and clinical procedures specific to this vulnerable population.

- Many have already implemented standard concentrations.
- The majority would be willing to adopt standard concentrations.
- Almost all respondents do not routinely label oral opioid syringes prior to transporting them from the medication room/medication cart to the bedside. (But some respondents have pre-labelled syringes from pharmacy).
- Almost all respondents have a pharmacist review all paediatric opioid prescriptions within the first 24 hours of treatment in general medicine.
- In mixed adult/paediatrics environments, a vast majority of respondents do not separate adult and paediatric opioids in ER or general storage.
- Independent Double Check with opioid medications occurs regularly in the community hospital setting.



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- The community hospitals providing paediatric services appear to be able to standardize to a fewer number of opioids and fewer concentrations of opioids for standard infusions.
- Community hospitals have greater oral opioids usage and are concerned about the recent controversies surrounding the use of oral codeine in paediatric patients.
- National standard concentrations are helpful to support community hospital nurses who work at more than one organization.

As the Opioid Safety Tactics work proceeded toward recommendations, a focus group of directors of pharmacy and frontline nurses in tertiary and community hospitals met with the project team to: (Appendix IV)

- 1. Increase the understanding of the differences between specialized paediatric sites and community hospitals serving paediatric patients.
- 2. Identify the top three tactics that they would consider a priority and/or would implement in the next 12 months. (Appendix V)

The results:

- i. Standard IV Concentrations
- ii. Safe Storage and Labelling
- iii. Prescribing Standardization.

Opioid safety recommendations support standardization that is customized for community and tertiary hospitals

The needs of tertiary hospitals and community hospitals are different and the recommendations reflect these differing needs. **(Appendix VI)**

The Phase 2 Opioid Safety recommendations align with Accreditation Canada's Required Organizational Standards as indicated on the following charts. All hospitals that provide paediatric services support the relevance of the proposed tactics and consider them to have a positive impact on patient safety.



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ISMP Canada/CAPHC Recommendations: For Pediatric Opioids in TERTIARY Hospitals

Recommendation	Tactic	Aligned with Accreditation Canada	Aligned with HIROC
EVALUATE the use of oral codeine liquid based on recent literature. Consider the use of oral morphine 1 mg/mL liquid as the oral opioid of choice.	1.3	1	1
ADOPT STANDARD CONCENTRATIONS of continuous opioid infusions to : Morphine: 0.2 mg/mL and 1 mg/mL Hydromorphone: 250 mcg/mL and 40 mcg/mL Fentanyl: 50 mcg/mL and 25 mcg/mL **additional concentrations may be required for hospitals with extremely premature babies and hospitals without two decimal pumps**	2.1 3.2	V	Y
STORE all oral opioids in pre-filled oral syringes.	1.4	\checkmark	
LABEL EVERY dose of injectable or oral opioid prepared by nurses away from the bedside (e.g. in med room, anteroom etc.)	1.4	\checkmark	1
ALL opioid orders for paediatric patients who weigh 50 kg or less must include the dosage by weight in: - (mg or mcg)/kg/hr or (mg or mcg)/kg/dose	2.2	1	1
DEVELOP and DISSEMINATE institution wide dosing guidelines for commonly used opioids in pediatrics, including initial dose recommendations and initial max adult doses for opioid naive patients.	2.2		V



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ISMP Canada/CAPHC Recommendations:				
For Paediatric Opioids In COMMUNITY Hospitals				

Recommendation	Tactic	Aligned With Accreditation Canada	Aligned With HIROC
SEGREGATE paediatric opioids from adult opioids In mixed units where adult and paediatric patients are being treated in the same area (e.g. Emergency Department, ambulatory care clinics), sequester pediatric opioids (narcotics) from adult opioid (narcotics).	1.4	٦	V
LIMIT the opioid injectable agent to morphine	1.3	1	٦
 RESTRICT ACCESS to fentanyl injectable. Exceptions: If fentanyl is needed then provide guidelines for use including dosing. (For example: Rapid Sequence Intubation). Hospitals with a NICU may require fentanyl 50 mcg/mL for admixing infusions. 	1.3	1	
RESTRICT ACCESS to hydromorphone injectable to palliative care areas.	1.3	\checkmark	\checkmark
EVALUATE the use of oral codeine liquid based on recent literature. Consider the use of oral morphine 1 mg/ml liquid as the opioid of choice.	1.3	4	1
LIMIT the available concentration of morphine to : ORAL: Morphine oral liquid 1 mg/mL INJECTABLE: Morphine 2 mg/mL INFUSION: Morphine 0.2 mg/mL and 1 mg/mL	2.1 3.2	٦	7
STORE all oral opioids in pre-filled oral syringes.	1.4	1	
LABEL EVERY dose of injectable or oral opioid prepared by nurses away from the bedside (e.g. in med room, anteroom etc.)	1.4	٦	1
ALL opioid orders for pediatric patients who weigh 50 kg or less must include the dosage by weight in: - (mg or mcg)/kg/hr or (mg or mcg)/kg/dose	2.2	1	1
DEVELOP and DISSEMINATE institution wide dosing guidelines for commonly used opioids in paediatrics, including initial dose recommendations and initial max adult doses for opioid naive patients.	2.2		~



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2. Human Factors

Human factors is concerned with the design of equipment, systems or organizations to match human capabilities and requirements.

One of the Opioid Safety recommendations is to adopt standard concentrations of continuous opioid infusions. The goal of standardization is to remove ambiguity in the processes and to eliminate the need for nurses to perform calculations and prepare solutions for opioid infusions.

A human factors analysis was conducted in Phase 2 to evaluate the effectiveness of moving from non-standard concentrations to standard concentrations. The analysis focused on the preparation of morphine solutions for infusions.

Two activities investigated the implications of changing to standard concentrations

- 1. A comparison of task analyses for the current practice of using non-standard concentrations of morphine with the proposed method of using standard concentrations.
- 2. Identification of the types of errors healthcare workers make when calculating an infusion, using both the current and proposed process.

Task Analyses

The task analyses were compiled through literature reviews and telephone interviews with pharmacists and other healthcare workers to make a comparison between the existing process (producing individualized opioid concentrations for each patient using the *rule of six*) and the proposed process (selecting one of a limited number of standard concentrations and calculating the infusion rate).

• Standardized calculations have fewer steps and the calculations are less complex than using the *rule of six*. One of the challenges is that healthcare workers who were familiar with preparing individualized concentrations use different variants of the *rule of six*.

Calculation Task

The Task Analysis showed that calculation error was the most frequent error identified with preparing an infusion, either using the *rule of six* or using standard concentrations. A small study compared the complexity and error frequency of the current individualized concentration with that of using standard concentrations.



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The study was conducted at CAPHC's Annual Conference in October, 2009. It involved 67 participants, predominantly from the healthcare field, the majority with experience in delivering direct patient care. (Appendix VII)

There were three components to the calculation task:

1. Calculation

Participants were asked to calculate infusion rates and morphine concentrations based on a fictional prescription and patient. One calculation was modeled on the *rule of six*, the calculation technique favoured by healthcare employees who have to prepare individualized morphine solutions.

The second calculation was based on the method that pharmacists and nurses would have to follow given standardized concentrations of morphine. All participants completed both calculations, and the order of completion was counterbalanced to remove any order effects.

Step-by-step instructions for each calculation were provided. All participants used the supplied calculators. There are fewer (and less complicated) steps involved in the standardized concentration calculation, and it was hypothesized that this calculation would result in fewer errors, and more correct responses.

2. Effects of Distraction

A second component of the project was to investigate whether being distracted during the calculations had an effect on error rates. The rationale was that the research team wanted to replicate a real life situation as closely as possible, so a distraction condition was implemented in the experiment.

Half of the participants were asked questions about the fictional patient at various times during the experiment, and participants had to answer the question by locating the correct information on the patient order form before they could continue.

3. Effects of Time Pressures

All participants were timed with a stopwatch to add a time pressure component to the situation, again to make the experiment more life-like. To add weight to the timing, participants were informed before beginning the study that a \$50 gift certificate would be awarded to the person who completed both calculations accurately in the quickest time.



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Human factors results support the transition to standard concentrations to reduce errors

Results of both the task analyses and the calculation test support Phase 1 conclusions about the potential for calculation error when preparing opioid infusions: **(Appendix VIII)**

- The task analyses showed that introduction of standard concentrations simplifies the calculations required.
- Calculation test participants made more errors when using the *rule of six* method than they did using the standard concentrations method.
- 67% of the participants indicated that they found the standardized calculation easier. Since they answered this question before they were told whether or not their calculations were performed correctly, their answers should be free of bias from information concerning their actual performance.
- The distraction manipulation did not work as intended, as it did not increase error rate or time to complete the task. This is likely because the distraction used was not powerful enough.

Because this was a high level prospective analysis, it is not possible to identify all the factors that influence error rates, and while prospective human factors analysis is useful, it is not a substitute for field-testing proposed interventions. Therefore before wide-scale adoption, it would be important to pilot test the introduction of standard concentrations to systematically assess the impacts of the change in operational environments.

3. Psychological Profiles

The environments in which opioids are administered are highly stressful settings where work involves multiple, precise and time-sensitive tasks. These environments are often understaffed.

This component of Phase 2 work used psychological theory and methodology to gather data to support practitioners involved in the delivery of paediatric opioids. The purposes were to:

- Gain a psychological understanding and perspective of practitioners involved in administering opioids
- Create a psychological profile of paediatric nurses that integrates both the personal and the professional
- Develop a targeted communications approach
- Define the psychological state that supports focused, conscious decision-making.



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This research had three main elements to determine underlying values, attitudes, beliefs and behaviours:

- 1. BarMar Traits Inventory[™]
- 2. Emotional Response Imagery Cards[™] Exercise
- 3. One-to-one interviews

Participants were paediatric practitioners at three Ontario hospitals – 12 frontline paediatric nurses (6 in ICU, 2 in Oncology, 4 in Infant-Toddler/Surgical Recovery), a physician, pharmacist, team leader and director of nursing. (Appendix IX)

Findings delineate important distinctions for communications

The findings were correlated and cross-referenced from an analytical psychological perspective, and identified the following:

- There are two groups with distinct and different ways of taking in and processing information -- one more factual (*doers*) one more conceptual (*theorists*).
- ICU nurses tend to be *theorists*, other paediatric nurses were *doers*.
 - ICU nurses are a distinct group among nurses.
 - Function as team players and are also independent thinkers.
 - Respect traditional methods but are open to change and innovation.
- These two groups have differing needs for structure and flexibility.
 - Doers tend to need more structure and are planners
 - *Theorists* tend to need more flexibility and are more open-ended.
- Both groups base decisions on logic, but are strongly influenced by values.

Customized communications increase potential for safe opioid delivery

Because of the different ways that the two identified groups take in and process information; to be effective, communications need to address the psychology of both. For the *doers*, who are practical and concrete:

• Facts and details should be presented in a structured, sequential way.

For the *theorists*, who are conceptual and abstract:

• Facts and details should be presented with symbolic language, in the context of the 'big picture.'

For both groups, communications materials need to address generational differences. 'Fear' messaging will not work – it reinforces high anxiety. All say that humour is essential to be effective at work. The need for support in their work is critical to both groups – all report that lack of support leads to loss of morale and increases stress. **(Appendix X)**



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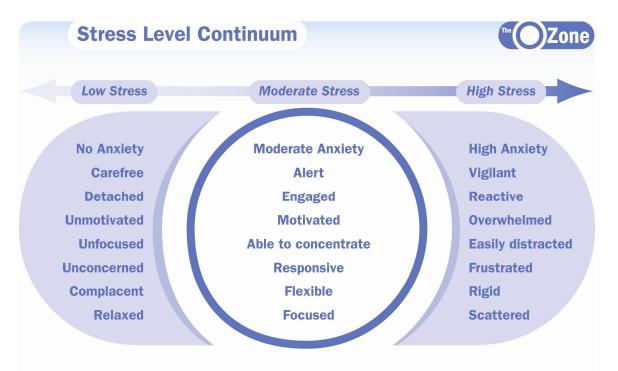
Findings indicate an optimal psycho-physiological state to deliver opioids

The majority of participants estimate their stress levels on an average day are "7 out of 10" on a scale of 1-10, 10 being the most stressful. Depending on their distinct psychology, individuals either withdraw or over-compensate when under high stress.

Either withdrawal or over-compensation compromise safety. Optimal opioid delivery requires a *moderate stress level* –or 'managed stress'.

Too much anxiety leads to feeling out of control and too little anxiety leads to diminished motivation. The ultimate performance goal is to move the individual along the stress continuum to where he or she feels psychologically capable of handling a degree of uncertainty.

In a state of moderate – or managed – stress, the person is alert, engaged and focused, but not overwhelmed. This psycho-physiological state is the ideal protective space for the safe delivery of opioids for both patients and practitioners – an 'opioid zone' – to be known as **The O Zone.**





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About The O Zone

The O Zone concept is based on psychological interview findings and follow-up discussions with other healthcare professionals. It identifies a state described by many as a particular kind of space they know they're in when they are working most attentively and effectively.

The O Zone is a name for that space.



The hypothesis is that by naming a space already familiar to many healthcare practitioners, we can help them access it in a deliberate way for safer delivery of opioids.

The O Zone incorporates the key elements of managing stressful situations:

- The ability to acknowledge a state of stress
 - Ability to perceive a risk
- Good training and self-efficacy
 - o Perception that one has the skills to deal with it
- Confidence that supports are available as back up
 - Ability to ask for help.

Including new approaches to bolster the human elements of care can improve safe medication delivery in acute care environments. The psychological perspective adds a new dimension to engage and support practitioners involved in the delivery of paediatric opioids.

The two attached draft posters were developed to introduce *The O Zone* in future work. (Appendices XIa and XIb)



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Future Work: Findings into Action

The Phase 2 work addressed critical issues identified in Phase 1 and made recommendations for action accordingly. Future work will be to test, validate and build support for these recommendations across the paediatric community.

With reference to the development model of the opioid safety tactics, the process should be an iterative, consultative and responsive one that incorporates the experience and expertise of the end-users.

The need to assess the impact and outcomes of Phase 2 recommendations on safety and on organizations' resources is an essential next step.

Before moving to a wide-scale change of practice with full implementation in tertiary and community hospitals providing paediatric care across the country, it is vital to demonstrate the effectiveness of the tactics in practice.

CAPHC would also work in partnership with Accreditation Canada to explore uptake and implementation of paediatric standards in the delivery of high alert medications.

Three activities to consolidate the interventions

1. Workshop

- Engagement with twenty participating paediatric health centres to include a mixture of tertiary and community sites from within the CAPHC community
- Provide an opportunity to test these recommendations across the paediatric community of practice and identify challenges within the proposed interventions
- Develop case study examples (incidents) which could provide evidence about why to adopt specific practices (e.g. labelling)
- Assess the impact of *The O Zone* concept and communications.

2. Training modules

Create an e-community of practice via training and interactive communications:

- Use online tools such as the CAPHC Knowledge Exchange Network (K.E.N),
- Develop instructions/calculation aids for using standard concentrations.
- Provide training and orientation on how to enter "The O Zone".



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3. Measurement

Goal is to change practice and develop national standards:

- Assess the impact of the intervention on healthcare provider practice:
 - Conduct pre and post intervention survey to assess healthcare provider attitudes towards the intervention practices
 - Observe healthcare provider behaviours before and after the intervention
 - Conduct compliance audit to assess the extent to which there is evidence that the practices are in place before and after the intervention.

Conclusion: Building on Promise

The success of both Phase 1 and 2 has been the result of the synergistic activities of nurses, pharmacists, physicians and other healthcare professionals, human factors experts and psychologists. Together, they have created a multi-dimensional approach committed to transforming practice in paediatric opioid delivery.

Phase 2 employed a new equation for change:

opioid safety tactics + human factors analysis + psychological insights = safer opioid delivery

The work of Phase 2 establishes a benchmark in the quest for safer paediatric opioid delivery through the development and innovative implementation of standardized best practices. Building on the Phase 2 findings and its unique approach promises to advance the paediatric healthcare community's goal to improve safe medication delivery.

CAPHC and ISMP are very grateful to the Canadian Patient Safety Institute, Medbuy and the Baxter Corporation for their ongoing support, and commitment to improve patient safety. We look forward to our continued collaboration as we work together to build the final Phase of this national initiative.



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The Institute for Safe Medication Practices Canada (ISMP)

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national not-for-profit agency committed to the advancement of medication safety in all health care 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 collecting, reviewing, and analyzing medication incident and near-miss reports, identifying contributing factors and causes, and making recommendations for the prevention of harmful medication incidents.

www.ismp-canada.org

The Canadian Association of Paediatric Health Centres (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.

Today, 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 and safety 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 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 is one of CAPHC's national priorities. CAPHC's Patient Safety Collaborative provides a framework for partnership and communication that supports national paediatric patient safety and quality improvement programs. <u>www.caphc.org</u>



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Credit Valley Hospital Mississauga, Ontario

Hospital for Sick Children (SickKids) Toronto, Ontario

IWK Health Centre Halifax, Nova Scotia

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Kingston General Hospital Kingston, Ontario

Laval Hospital Quebec, Quebec

Children's Hospital London Health Sciences Centre London, Ontario

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