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ISMP Canada Safety Bulletin

Volume 14 • Issue 3 • March 19, 2014

Advancing Opioid Safety for Children in Hospitals

Introduction

The provision of medications to paediatric patients involves challenges distinct from those associated with medication administration to adult patients. These challenges arise for all paediatric age groups (infants, children, and youth) in every care setting, from community hospitals to specialty tertiary care facilities. Management of high-alert medications[1], such as opioids, poses additional risks. Opioids constitute the medication class most commonly represented in harmful medication incidents in paediatric hospitals.[2-4] Since 2006, ISMP Canada has been collaborating with the Canadian Association of Paediatric Health Centres (CAPHC) to enhance medication safety in paediatrics, with a particular focus on opioids. This bulletin provides an update on a national initiative to improve paediatric opioid safety and introduces national guidelines and associated resources to support hospitals in implementing safe opioid practices in paediatrics.

Incident Example

A paediatric patient in a community hospital was ordered HYDROmorphone via continuous intravenous (IV) infusion to manage post-operative pain. The order also included provision for additional doses of HYDROmorphone for breakthrough pain as needed. The infusion was initiated in the postanaesthetic care unit, and the patient was subsequently transferred to the inpatient paediatric unit. Several hours later, the child required a dose of HYDROmorphone for breakthrough pain. Shortly after the extra dose was administered via manual IV push, the child became unresponsive, apneic, and cyanotic. Resuscitation efforts, including administration of the opioid antagonist naloxone, were successful. It was later determined that the child had received 2 mg HYDROmorphone by manual IV push, instead of the intended 0.02 mg (20 mcg).

A root cause analysis conducted by the hospital where the incident occurred identified a number of factors that potentially contributed to the incident, including the following:

- Lack of predefined order sets for management of postoperative pain in paediatric patients
- Selection of HYDROmorphone for this patient because of a perception that its side effect profile was better than that of morphine
- Lack of familiarity with HYDROmorphone on the part of the nursing staff, because morphine was the opioid usually used on the paediatric unit
- Availability of HYDROmorphone in ward stock for the paediatric unit, despite infrequent use of this drug
- Lack of a mechanism on the infusion pump for delivery of additional "as needed" doses, which led the nurse to manually draw up the breakthrough dose from the ward stock supply

- Inconsistency of independent verification of high-alert medications before administration, because of workflow challenges

- Lack of flexibility in the pharmacy information system for entries into the medication administration record (MAR), resulting in MAR instructions that were confusing to the nurses caring for the child

- Inadequate communication processes between and among the various disciplines and departments for exchange and hand-off of important information related to patient care

It is likely that vulnerabilities similar to those illustrated by this incident are present in other hospitals caring for paediatric patients in Canada. This is supported by the findings of a recently published retrospective analysis of 14 incidents associated with parenteral opioid infusions that occurred over a 5-year period in a tertiary care paediatric hospital.[5] The root causes most frequently identified in the published analysis were deficiencies in preprinted order sheets; lack of nursing guidelines for adjustment of opioid infusion rate and weaning; inadequate policies and guidelines for monitoring and recording pain, vital signs, and arousal score.

Since 2006, ISMP Canada, CAPHC and CAPHC member organizations have been working on a national initiative to identify intervention opportunities and develop standardized approaches and resources to support practitioners and hospitals in promoting the safe management of opioids for paediatric patients in the hospital setting. The following sections describe the 3 phases of this multi-year project.

National Initiative to Improve Paediatric Opioid Safety

Phase I: Identification of the top medications reported as causing harm through medication error for paediatric patients and initiation of a new intervention (2006–2008)

The project began with an analysis of more than 4000 incident reports voluntarily submitted by 11 facilities. This analysis showed that close to one quarter of all medication incidents reported as causing harm were associated with 5 medications, 2 of which were opioids: morphine and fentanyl.[4] The 2 most common types of medication incidents were "wrong drug" and "wrong dose" incidents. In follow-up to this analysis, the national advisory committee for the project determined that recommendations and tools were needed to assist in implementing and sustaining safe medication practices at all stages of delivery of opioids in paediatric settings; i.e., prescribing, order processing, dispensing, storage, administration, and monitoring. An assessment of current status was made through a survey of Canadian paediatric facilities in August 2008. The results identified that leading practices had been implemented across the country but confirmed that there was variability in practice.

Phase 2: Transformation of opioid delivery in paediatrics (2009–2010)

Two objectives were identified to support transformation of opioid delivery in paediatrics:

- Develop a comprehensive set of recommendations and tools to ensure safe medication practices for opioids, including, but not limited to, methods for standardization of prescribing and administration, calculation tools, and recommendations for purchasing and storage.

- Apply human factors expertise, including psychological theory and practice, to design strategies to support professionals in the safe delivery of medications.

It was recognized that a national consensus would be needed to meet these objectives. Collaborative consultation was undertaken via focus groups and surveys disseminated across CAPHC member organizations and community hospitals. Information obtained through this consultation, as well as a review of national and international guidelines for pain management in paediatrics, led to the development of a set of recommendations and guidelines[6]. A key focus of these recommendations and guidelines is the adoption of standard concentrations of opioids for continuous infusions

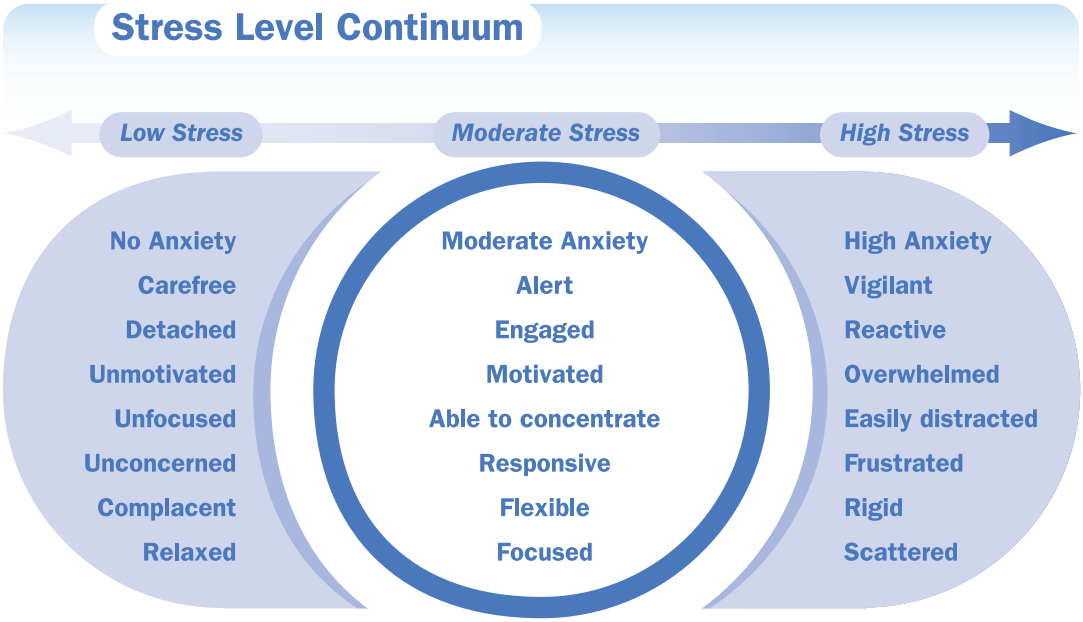
and the use of these standard concentrations in combination with smart pumps to maximize patient safety. The recommended standard concentrations for continuous opioid infusions were established by an interdisciplinary working group of paediatric clinical experts and have been endorsed through a consensus statement approved by paediatric academic health sciences centres in Canada.[7-8] The guidelines also include recommendations for intermittent opioid dosing, preparation and labelling of oral and parenteral opioids, development and dissemination of institution-wide opioid dosing and monitoring guidelines, appropriate storage and segregation of opioids, and implementation of independent double checks before administration of opioids to paediatric patients.

It was noted in the Canadian Paediatric Adverse Events Study[9] that more than two thirds of inpatient paediatric care is delivered in community hospitals. The advisory committee recognized that opioid guidelines would have to be customized to account for the different needs of community and tertiary hospitals. Therefore, the opioid safety recommendations support standardization that is customized for community and tertiary hospital settings. For example, the guidelines recommend that community hospitals use morphine as the opioid of choice for paediatric patients, whereas tertiary centres may use morphine, HYDROmorphone, and fentanyl.

The other component of Phase 2 explored the use of psychological theory and methods to gather data that would support practitioners who administer opioids to paediatric patients. The environments in which opioids are administered are high-stress settings, where healthcare providers' work involves multiple, precise, and time-sensitive tasks. Optimal performance of tasks in the medication management system requires a moderate stress level (Figure 1), which can be considered as "managed stress".[10] On the continuum of stress, too much anxiety can lead to feeling out of control, whereas too little anxiety may lead to diminished focus. Ideally, individuals preparing to administer medications will be able to achieve a state of moderate – or managed – stress; the person is alert, engaged, and focused, but does not feel overwhelmed.

The "O Zone" (abbreviated from "opioid zone") was coined, during the project, as the name for this psycho-physiological state; i.e., the envisioned ideal protective space for the safe management of opioids at all stages: prescription, preparation, and delivery. Additional research is needed to assess how the O Zone concept might be integrated into practice.

Figure 1. Stress level continuum



Phase 3: Knowledge translation, education, and implementation of recommendations and guidelines (2011–2012)

Practice change is complex, and individual practitioners and hospitals often lack the time and capacity to develop the policies and procedures required to support such changes. To help hospitals to implement the recommendations and guidelines, CAPHC and ISMP Canada developed an on-line Paediatric Opioid Safety Resource Kit.[6] This kit includes best practices, tools, policies, procedures, and templates that can be downloaded and tailored to meet the individual requirements of both community and tertiary hospitals. The tools and resources within the kit were developed and compiled by the advisory committee through consensus with participating organizations (see Table 1).

Table 1. Contents of the Paediatric Opioid Safety Resource Kit*

Resource	Description
Recommendations and guidelines	• Recommendations on the following topics for both tertiary paediatric centres and community hospitals providing care to paediatric patients: - Standardization of concentrations for continuous opioid infusions - Limitations on opioid selection - Limitations on availability of and access to opioids in ward stock - Adoption of standard methods for preparing and administering intermittent doses of opioids - Inclusion of dosage by weight for all paediatric opioid orders - Development of institution-wide dosing and monitoring guidelines - Segregation of paediatric opioids from formulations intended only for adult use - Segregation and differentiation of opioid formulations (by drug, by dose or concentration) - Use of prefilled oral syringes for enteral administration of opioids - Adoption of independent double checks at all stages of the medication-use process in paediatric settings - Labelling of opioids intended for oral or parenteral administration
References and recommended reading	• Published papers, presentations, ISMP Canada bulletins, and posters relating to and supporting various aspects of the recommendations and guidelines
Resources and tools	• Compendium of resources and tools shared by participating healthcare organizations, including standard concentration monographs, pump flow limits, preprinted order sets, dosing and administration instructions, calculation programs (e.g., iDoseCheck; www.idosecheck.com and drug calculation program of the Children's Hospital of Eastern Ontario; http://www.rpmcreative.com/sdc/, independent double-check policies, equianalgesia charts, monitoring guidelines, naloxone guidelines, labelling and storage recommendations • Implementation self-assessment checklist, standard concentrations checklist, opioid safety implementation checklist • Presentations describing implementation experience and leading practices from participating organizations.
The O Zone	• Background information on development of an optimal psychological state to support the safe management of opioids at all stages of the medication-use process

*The kit is available online at http://ken.caphc.org/xwiki/bin/view/PaediatricOpioidSafetyResourceKit/WebHome

Conclusion

The recommendations and guidelines for improving paediatric opioid safety, available as part of the Paediatric Opioid Safety Resource Kit, provide important guidance for tertiary and community hospitals about the necessary elements to support safe management of opioids for children. Limitation of opioid selection and standardization of available concentrations are particularly important foundational steps that will support further improvement efforts, such as development of pain management order sets and utilization of smart pump technology. The case example described in this bulletin illustrates several opportunities for improvement that are addressed in the guidelines: use of morphine as the opioid of choice in community hospitals, standardization of concentrations for continuous opioid infusion, development of standardized order sets, adoption of standard methods for preparing and administering intermittent doses of opioids, and consistent use of independent double checks.

The consensus guidelines have been widely circulated, and organizations such as Accreditation Canada are helping to further spread this information by referencing the guidelines in their own publications.[11] It is hoped that this bulletin will help to enhance awareness of the guidelines among practitioners caring for paediatric patients, leading to implementation in all hospitals caring for paediatric patients.

For more information:

- The *Paediatric Opioid Safety Resource Kit* can be accessed through the CAPHC Knowledge Exchange Network at; http://ken.caphc.org/xwiki/bin/view/PaediatricOpioidSafetyResourceKit/WebHome.
- Reports are available for each phase of the project:
  - Phase I Report:
    http://www.ismp-canada.org/CurrentProjects/Paediatrics/downloads/ISMPC_CAPHC_final_phase_1_report.pdf
  - Phase II Report:
    http://www.ismp-canada.org/CurrentProjects/Paediatrics/downloads/ISMPC_CAPHC_Paediatrics_Phase_2_Report_final.pdf
  - Appendices for Phase II Report:
    http://www.ismp-canada.org/CurrentProjects/Paediatrics/downloads/ISMPC_CAPHC_phase_2_report_final_appendices.pdf
  - Phase III Report:
    http://www.ismp-canada.org/CurrentProjects/Paediatrics/downloads/20130117OpioidSafetyPhase3.pdf

Acknowledgements

This work is the result of national collaboration and consensus. The 3 phases of the project were led by ISMP Canada and CAPHC, with support from the National Advisory Committee and CAPHC member organizations. The project was supported by the Canadian Patient Safety Institute, Baxter Corporation, Medbuy Corporation, and the Healthcare Insurance Reciprocal of Canada (HIROC).

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HIROC

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