

Aggregate Analysis of Oxytocin Incidents

Oxytocin is a valuable, time-tested drug and one of the most commonly used medications during labour and delivery.¹ It acts on the smooth muscle of the uterus to stimulate contractions. In Canada, its uses include the induction of labour in patients with a medical indication for the initiation of labour; the stimulation and reinforcement of labour; and to control postpartum bleeding and hemorrhage.²

As a high-alert medication, oxytocin bears a heightened risk of causing significant patient harm if used in error.³ For example, use of this drug to induce labour has been associated with significant adverse effects to both the mother (e.g., arrhythmias, uterine hyperstimulation, postpartum hemorrhage) and the fetus (e.g., bradycardia, hypoxia, hyperbilirubinemia, retinal hemorrhage).^{1,2} This bulletin shares information about incidents involving the use of oxytocin that have been voluntarily reported to the Canadian Medication Incident Reporting and Prevention System (CMIRPS). It includes an overview of the incidents and highlights major themes identified through a multi-incident analysis to raise awareness about continuous improvement opportunities for management of this medication.

Methodology and Overview of Findings

Reports of incidents involving oxytocin were extracted from the ISMP Canada medication incident database and the National System for Incident Reporting (NSIR)* database.⁴ The multi-incident analysis methodology described in the Canadian Incident Analysis Framework⁵ was applied for this analysis.

Tables 1 and 2 summarize the reported severity of outcomes of the medication incidents from these sources.

In total, 74 incidents from the ISMP Canada medication incident database and 20 incidents from the NSIR database met the inclusion criteria.[†] One incident from the ISMP Canada database was excluded because of insufficient detail, leaving a total of 93 incidents for the multi-incident analysis. The data reviewed for this analysis spanned the periods from February 2003 to April 2013 for the ISMP Canada medication incident database and from October 2009 to April 2013 for the NSIR.

* The National System for Incident Reporting (NSIR), provided by the Canadian Institute for Health Information, is a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS) program. More information about the NSIR is available from: <http://www.cmirps-scdpim.ca/?p=12>

† Although it was not evident during the analysis, there is a possibility that some of the incidents were reported through both mechanisms (i.e., as an individual practitioner report to ISMP Canada and as a report from a hospital to NSIR) and therefore would be included in both sets of numbers. However, for this qualitative analysis such a possibility does not affect the identification of themes.

Table 1: Reported Severity of Outcomes of Oxytocin Incidents from the ISMP Canada Medication Incident Database

Reported Severity	No. of Incidents*
No error	4
No harm	59
Harm	7
Death	0
Unknown	3
Total	73

*It is recognized that it is not possible to infer or project the probability of incidents on the basis of a voluntary reporting system.

Table 2: Reported Severity of Outcomes of Oxytocin Incidents from the National System for Incident Reporting (NSIR)

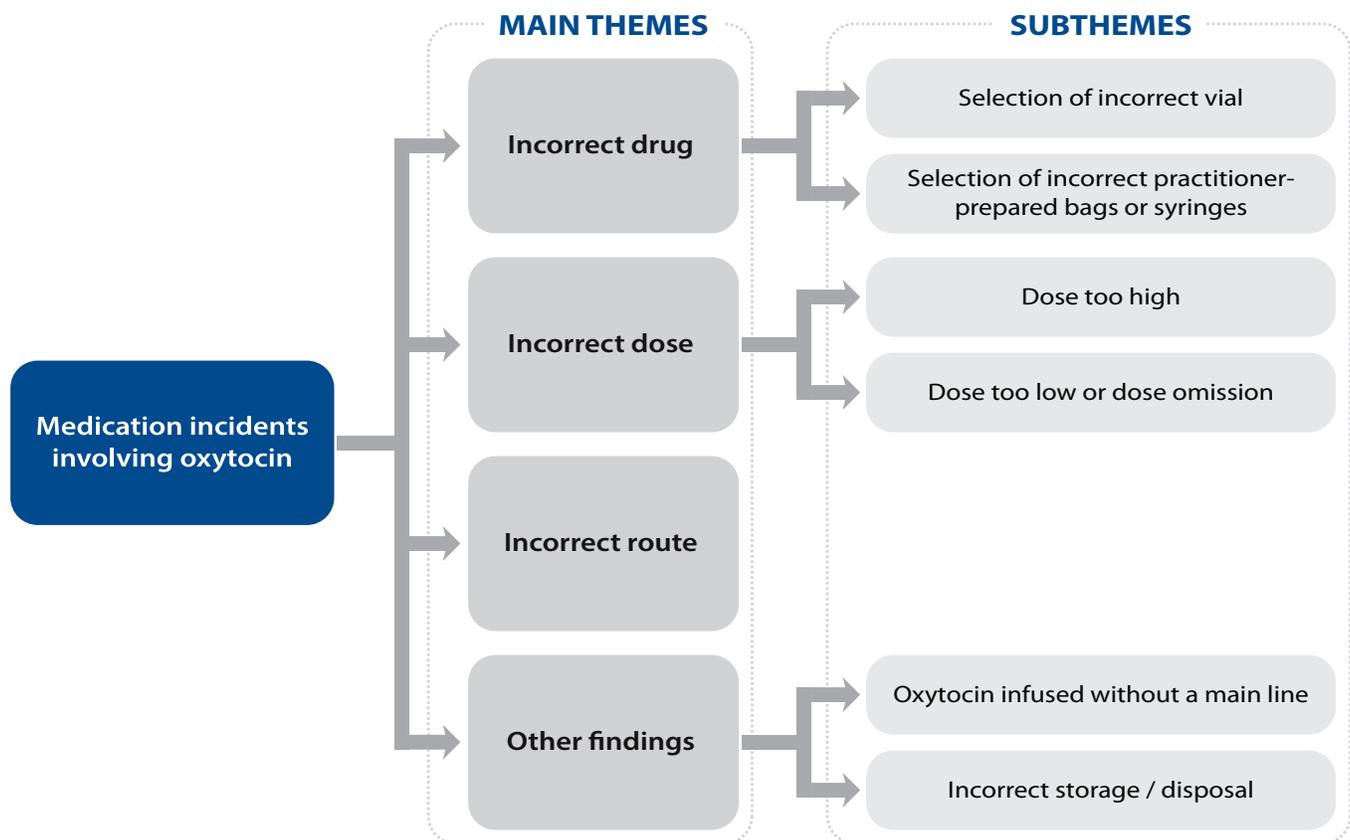
Reported Severity ⁶	No. of Incidents*
No adverse outcome categories: reportable circumstance, near miss, none	14
Adverse outcome categories: mild, moderate, severe, death	6
Total	20

*It is recognized that it is not possible to infer or project the probability of incidents on the basis of a voluntary reporting system.

Findings of the Multi-Incident Analysis

Analysis of the incidents from the ISMP Canada database identified a number of themes (Figure 1). The following sections provide details about the main themes, including the subthemes, and the potential contributing factors. Selected incident examples are also provided. Analysis of the smaller dataset from the NSIR database supported the ISMP Canada database themes identified.

Figure 1: Overview of Main Themes and Subthemes



Main Theme: Incorrect Drug

In reported incidents, both the administration of a drug mistaken for oxytocin and delays in administering oxytocin led to patient harm. Furthermore, the selection of oxytocin when another medication was intended has also resulted in an adverse outcome.

Incident example

A bag of Ringer's lactate containing oxytocin was infused instead of plain Ringer's lactate at the time an epidural infusion was being set up. The error was discovered when the patient complained of abdominal cramps, and regular monitoring of the fetal heart rate showed a low heart rate. The oxytocin solution was replaced with plain Ringer's lactate, but the fetal heart rate did not return to normal. As a result an emergency cesarean section was performed.

Two subthemes were associated with incorrect drug errors involving oxytocin.

Subtheme: Selection of incorrect vial

The incidents included in this subtheme involved mix-ups between manufacturers' vials (or ampoules) of oxytocin and vials of other medications. Examples of medications that were confused with oxytocin at the drug-selection step included atropine, fentanyl, epinephrine, and dopamine. Look-alike packaging and storage proximity were identified as potential contributing factors for vial mix-ups involving oxytocin.

Subtheme: Selection of incorrect practitioner-prepared bags or syringes

Incidents included in this subtheme involved mix-ups of bags or syringes prepared on site by healthcare practitioners. A number of potential contributing factors were identified. First, oxytocin is a clear and colourless liquid, so once it has been added to an intravenous (IV) bag or syringe, it is virtually impossible to distinguish from prepared IV bags or syringes of other colourless solutions. Second, inadequate labelling or identification increases the likelihood of incorrect drug selection and resultant errors (e.g., in a patient with multiple IV lines, misidentification of the oxytocin bag resulted in the

pump for another drug being programmed with the oxytocin rate). Third, the presence of multiple syringes containing medications in the labour and delivery setting also increases the risk for selection of the incorrect syringe.

Main Theme: Incorrect Dose

To reduce the risk of adverse effects on the mother and the fetus when oxytocin is being used, frequent maternal and fetal assessments with appropriate dose titrations are necessary. Administering a dose of oxytocin higher or lower than intended can cause significant harm to both mother and fetus.

Incident example

A miscalculation of an oxytocin dose resulted in the patient receiving a higher dose than intended. After delivery, the infant required brief resuscitation.

Two subthemes were identified: oxytocin dose too high and dose too low (including omission of doses).

Subtheme: Dose too high

A number of factors were identified that may have contributed to oxytocin errors involving a dose that was too high. For example, a lack of standardized oxytocin dosing protocols necessitates complex dose calculations at the bedside and may increase the likelihood of these types of errors. Other potential contributing factors included confusion related to units of measure (e.g., milliunits per hour versus millilitres per hour) and inadvertent administration of the drug without use of an IV pump.

Subtheme: Dose too low and dose omission

A variety of scenarios led to doses being administered that were too low. Dose omissions involving oxytocin also occurred. Potential contributing factors included the lack of a standardized dose titration protocol, improper connection of the IV line, and confusion among multiple IV lines for different drugs.

Main Theme: Incorrect Route

Incorrect route errors, especially mix-ups between IV oxytocin and epidural analgesia administration,

can lead to significant patient harm. Given that epidural analgesia is frequently used during labour and delivery, mix-ups between these routes are a distinct possibility and have been reported.

Incident example

A patient in labour was receiving epidural analgesia for pain control. As the pain control was suboptimal, the nurse went to ‘top up’ the epidural with what she believed was a syringe containing bupivacaine. After administering the ‘top up’, the nurse questioned whether oxytocin had been inadvertently given epidurally instead of bupivacaine. Both medications were previously drawn up in syringes and were unlabelled, thus resulting in the confusion. After birth the mother and the baby were discharged without complications. A review of the incident concluded that the correct medication was likely given.

Lack of proper labelling of the syringes was identified as a potential contributing factor in these incidents. The interconnectivity of epidural and intravenous systems continues to be a contributing factor in wrong route errors.

Main Theme: Other Findings

Incidents in the category for other findings did not directly lead to harmful errors, but are nonetheless important because they represent deviations from best practices and may increase the risk of errors over the long term. Two subthemes were identified: infusion of oxytocin without a primary line and incorrect drug storage or disposal.

Subtheme: Infusion of oxytocin without a primary line

In a number of incidents, oxytocin was administered as a primary infusion. This mode of administration is contrary to established guidelines, which recommend that oxytocin be administered as a secondary infusion with a primary line,⁷ to ensure patency of the line in the event that the oxytocin infusion must be discontinued. Potential contributing factors included lack of knowledge of guidelines and protocols for administering oxytocin and lack of experience with using this medication.

Subtheme: Incorrect storage or disposal

A number of the reported incidents involved improper storage or disposal of oxytocin.

Although none of the incidents included in this subtheme led directly to patient harm, improper storage and disposal of oxytocin may lead to error-prone situations and may increase the likelihood of drug-selection errors.

Conclusion

Reporting medication incidents is important both for raising awareness of opportunities to enhance medication safety and for monitoring the effects of system changes. The multi-incident analysis described here focused on medication incidents involving oxytocin. The analysis identified a number of themes and associated contributing factors, as well as opportunities for system improvements. Of note, the results of this analysis are consistent with observations from a similar analysis, which investigated healthcare insurance claims.⁸

ISMP Canada has created an operating room medication safety checklist and is currently working to address some of the contributing factors identified from this analysis in collaborative projects including:

- Development of labelling and packaging guidance for manufacturers⁹
- Evaluation of strategies for safe management of multiple intravenous infusions¹⁰

It is hoped that the findings from this analysis will support and augment additional local, provincial, and national quality improvement initiatives.

Disclaimer: Although the analyses described in this bulletin were based on data provided by the Canadian Institute for Health Information, the opinions expressed are those of ISMP Canada only.

Please refer to page 7 for references.

Manufacturer Adds Warning to Cap and Ferrule of a Succinylcholine Product

Neuromuscular blocking (paralyzing) agents are high-alert medications. Substitution errors have led to serious injuries and death.^{1,2} In 2006, to reduce the risk of these types of errors, Canadian manufacturers of neuromuscular blocking agents agreed on the ideal features for packaging and labelling of these medications. These agreed-upon features include a standardized warning on the vial cap and/or vial ferrule to identify the product as a paralyzing agent.³ At the end of 2012, an ISMP Canada safety alert highlighted concerns about a new succinylcholine product, manufactured by Alveda Pharma, that lacked this warning.⁴

ISMP Canada is pleased to report that vials of succinylcholine manufactured by Alveda Pharma now include the words “WARNING: PARALYZING AGENT” printed in white on both the red cap and the newly introduced red ferrule (Figure 1).

This improvement is an excellent example of how reports from healthcare professionals can and do facilitate changes with labelling and packaging of health products to enhance medication safety.



Figure 1: New labelling of succinylcholine product from Alveda Pharma. The words “WARNING: PARALYZING AGENT” are printed in white lettering on the red cap and on the red ferrule. (Photo: Courtesy of Alveda Pharma)

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This segment of the bulletin describes a recent SafeMedicationUse.ca publication from ISMP Canada's Consumer Program.

October 2013 Newsletter:

Good Communication Can Help Prevent Harmful Mistakes with Medicines!

SafeMedicationUse.ca received a report describing a communication breakdown related to a dose change. The consumer had been taking two ramipril 10 mg capsules daily (total daily dose 20 mg). The prescriber thought she was taking two of the 2.5 mg capsules (total daily dose 5 mg) and instructed her to take three or four capsules a day, for an intended dose of 7.5–10 mg. The consumer increased the number of ramipril capsules to four per day, using her 10 mg capsules, but this change resulted in a total daily dose of 40 mg, 4 times what the prescriber intended.

The SafeMedicationUse newsletter provides tips for consumers, including the importance of knowing the names and strengths of all their medications and documenting this information on medication lists.

The newsletter also provides tips for practitioners, including the importance of verifying the current strength and directions for all medications before making any changes to existing prescriptions, as well as the importance of encouraging patients to bring prescription vials and lists of medicines with them when receiving healthcare.

Read more at

www.safemedicationuse.ca/newsletter/newsletter_CommunicationCanPreventHarm.html



Consumers Can Help Prevent Harmful Medication Incidents

SafeMedicationUse.ca

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2. Repchinsky C, editor-in-chief. Oxytocin [product monograph]. In: *Compendium of pharmaceuticals and specialties.* Ottawa (ON): Canadian Pharmacists Association; 2013. p. 1988.
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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.



The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.



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

Report Medication Incidents

(Including near misses)

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Phone: 1-866-544-7672

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