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Errors Associated with Oxytocin Use: A Multi-Incident Analysis

Oxytocin and its analogues are commonly administered for induction and augmentation of labour.[1-3] In addition to this indication, oxytocin is widely used to prevent and treat postpartum bleeding.[2-4] However, oxytocin can cause hyperstimulation of the uterus, which in turn can result in fetal distress, the need for emergency caesarean section, or uterine rupture. A multi-incident analysis was conducted to identify opportunities to improve patient safety with this high-alert medication.[5]

METHODOLOGY

Reports of medication incidents associated with oxytocin were extracted from voluntary reports* submitted to 3 ISMP Canada reporting databases (Individual Practitioner Reporting, Community Pharmacy Incident Reporting, and Consumer Reporting) and the National System for Incident Reporting (NSIR)† for the period from database inception to April 4, 2019. Key words used in the search were "oxytocin", "pitocin", and "syntocinon".

QUANTITATIVE FINDINGS

In total, 170 potentially relevant incidents were identified in the ISMP Canada and NSIR databases. The incident reports were reviewed to exclude those that were not relevant or lacked adequate detail, which left 99 and 45 incident reports from the ISMP Canada and NSIR databases, respectively, for analysis.

Maternal, fetal, or neonatal harm was reported in 12% of the reports to ISMP Canada and 29% of the reports to NSIR. Most of the reported incidents in both data sets occurred during the drug administration step of the medication-use process.

QUALITATIVE ANALYSIS

The analysis revealed 3 main themes, each with multiple subthemes (see Figure 1).

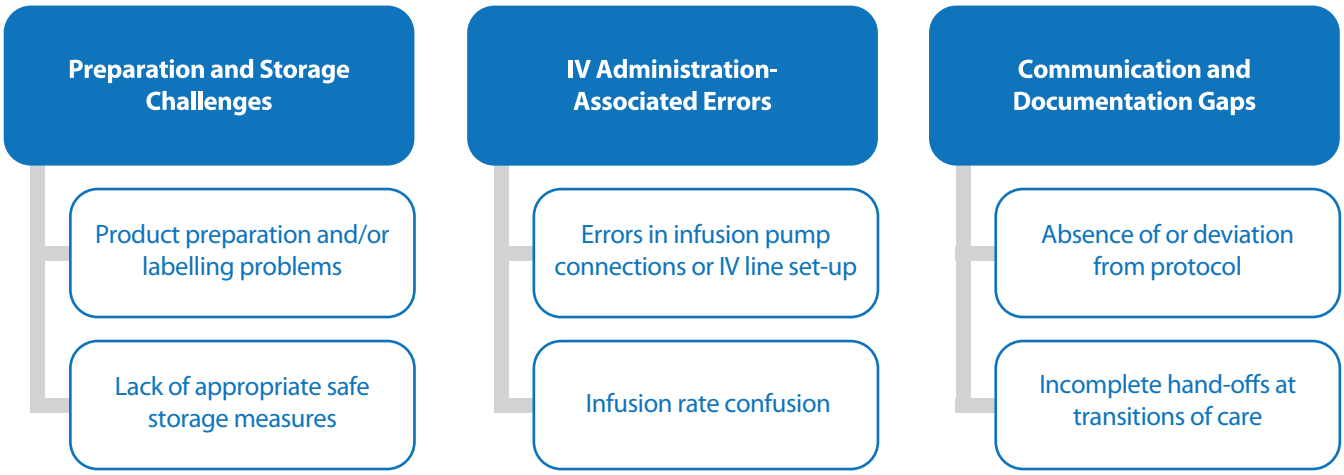
THEME: PREPARATION AND STORAGE CHALLENGES

SUBTHEME: Product preparation and/or labelling problems

Nurses typically prepare oxytocin infusion solutions on the patient care unit, just before use, by withdrawing the medication from an ampoule or vial and adding the desired volume to a bag of intravenous (IV) solution (e.g., 0.9% sodium chloride). The diluted solution is then administered via an infusion pump. Sometimes this process is completed under urgent or emergency situations.

* It is recognized that it is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems
† The 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

Figure 1. Main themes and subthemes identified from oxytocin-associated medication incidents.



Oxytocin is clear and colourless, so IV infusion bags and syringes containing the medication are indistinguishable from bags containing plain IV solution (i.e., bags of IV solution with nothing added) or syringes containing other clear, colourless medications.[6] Therefore, it is critical to ensure legible, complete, and accurate labelling of any solution or device containing oxytocin. The analysis highlighted cases in which incomplete or omitted labels led to patient safety issues. These labelling problems were typically due to interruptions, distractions, or competing priorities on the patient care unit.

Incident Example

An unlabelled bag of what was presumed to be plain IV solution was retrieved, and an unspecified amount of the solution was administered to a patient. Staff later noted maternal cramping and fetal heart rate deceleration. An investigation revealed that the bag contained oxytocin. The patient required emergency caesarean section.

Implementation of independent double checks during the preparation process for this high-alert medication and use of preprinted labels to be affixed to prepared bags are possible strategies to improve safety at the bedside. Additionally, it is important to discard any unused portion of the prepared product to avoid mistaken use by another person.

Ideally, oxytocin for infusion would be provided in a ready-to-administer format. The availability of such a format would avoid the need for drug manipulation at the bedside and would take advantage of robust verification processes. However, sterile compounding facilities (whether industry or hospital pharmacy-based) face several challenges, such as the need for stability and sterility data specific to the formulations being produced and the need for resources to meet the demand for the high volumes of oxytocin used in practice.

SUBTHEME: Lack of appropriate safe storage measures

In some patient care areas, oxytocin is not subject to the same strict inventory control measures that are applied to other high-alert medications. Inappropriate access to oxytocin was described in more than 20 reports; for example, oxytocin ampoules were found in patient care areas by non-patient care staff (e.g., housekeeping personnel). In these cases, the medication had been left unsecured in the birthing suite.

Automated dispensing cabinets (ADCs) are used by some hospitals to improve monitoring of oxytocin use; however, ADCs do not curtail access to partially used or unattended ampoules that have not been appropriately disposed of or secured.

THEME: IV ADMINISTRATION-ASSOCIATED ERRORS

SUBTHEME: Errors in infusion pump connections or IV line set-up

Improper connection of IV lines to the infusion pump and/or the patient resulted in incorrect medication, incorrect dose, and dose omission errors. Contributing factors included the need for multiple IV lines, a fast-paced work environment, heavy workload, inexperienced staff, and distractions.

Incident Example

During augmentation of labour, oxytocin was to be administered using a controlled-rate infusion pump, while Ringer's lactate was to run freely, intravenously, via gravity. During the set-up process, the lines were mixed up, and the oxytocin solution was inadvertently left to run freely without a pump. As a result, the patient received a larger-than-intended dose of oxytocin, an error that led to the need for caesarean section.

Independent double checks can be used to verify pump programming and the set-up of IV lines. Use of smart infusion pumps equipped with dose-error reduction software can also aid in the safe administration of oxytocin.[7] A standardized safety checklist for oxytocin to be completed prior to administration could be an additional safeguard.[8] The set-up of IV infusion lines should facilitate accurate and timely identification and tracing among the drug, the pump, and the patient. Consideration should be given to labelling primary IV tubing with the name of the infusate, just above the injection port closest to the patient and near the infusion pump (i.e., on the IV tubing just below the pump).[9]

SUBTHEME: Infusion rate confusion

Several reports described mix-ups resulting from inconsistent terminology used to express the infusion rate among the medication order, the administration record, and/or the pump library. The concentration of oxytocin in the IV infusion solution is usually expressed in milliunits per millilitre or units per litre (units/L). The administration rate for the solution is typically described using the amount of drug to be delivered (e.g., milliunits/minute) or the volume of solution to be infused (e.g., mL/hour).

Incident Example

As a result of confusion between units of measure, an infusion pump was programmed to deliver 3 times the intended dose of oxytocin.

In its recent publication of best practices recommendations, Ontario's Provincial Council for Maternal and Child Health (PCMCH) encourages standardizing oxytocin infusion rates and provides tools, such as a sample order set, to reduce variation in hospital practices across the province.[10] Communicating the rate in terms of both the amount of drug (milliunits/minute) and the volume (millilitres/hour) to be infused provides more clarity and less opportunity for misinterpretation. Standardized expression of doses and rates, together with the use of smart pumps (with drug libraries and dose-error reduction software), can reduce the risk of errors.[10,11]

THEME: COMMUNICATION AND DOCUMENTATION GAPS

Communication and documentation gaps have been identified as common themes in Canadian maternal/newborn-related insurance claims.[11] Similar issues were captured in the current analysis.

SUBTHEME: Absence of or deviation from protocol

A lack of awareness of or compliance with hospital oxytocin protocols was cited as a contributing factor in a 10-year analysis of oxytocin incidents.[12] Similarly, incidents in the current analysis revealed gaps in awareness of such documents, as well as a lack of protocols to guide prescribing.

Incident Example

Hospital protocol specified oxytocin as the preferred agent for administration to postpartum

patients with increased risk of hemorrhage. A medical resident was unaware of the protocol and instead ordered carbetocin (an oxytocin analogue) for a high-risk patient. The patient experienced significant bleeding.

SUBTHEME: Incomplete hand-offs at transitions of care

The lack of clear documentation at transitions of care was a key contributor to oxytocin incidents. Reporters attributed poor documentation to heavy workload, a fast-paced environment, inexperience, and involvement of many individuals in the patient's circle of care.

Incident Example

Administration of oxytocin was put on hold when staff noted a deceleration in the fetal heart rate. The physician examined the patient and gave a verbal order to restart the oxytocin infusion, but at a lower rate. A few minutes later, a second physician, who was taking over from the first, gave an order to restart the oxytocin at the original dose. The two medication orders were directly contradictory. The lack of written documentation regarding the decision to lower the rate of infusion was considered to be a factor in this incident.

Use of standardized documentation tools and communication strategies at care transitions is recommended to promote clear, timely, and efficient exchange of patient information.[13]

Patients have a vital role in supporting the safe use of oxytocin. ISMP Canada is partnering with stakeholders to develop an oxytocin-specific version of the "5 Questions to Ask About Your Medications" to further engage patients in the birth planning process and to improve communication with health care providers.

CONCLUSION

Oxytocin is commonly used to assist with labour and delivery, as well as to prevent and treat postpartum bleeding. Errors with this high-alert medication can cause considerable harm to the mother and the fetus. This multi-incident analysis has highlighted the need to ensure appropriate labelling of all oxytocin products, preparations, and delivery systems; to standardize how doses, concentrations, and rates are expressed; and to support clear documentation and communication with the patient and those within their circle of care. Ideally, the provision of oxytocin in standardized, ready-to-use formats would optimize the safe use of this product.

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Opioid Wisely: Partnering to Promote Safe Use of Opioids after Removal of Wisdom Teeth

Dentists across Canada are being encouraged to learn about the possible harms associated with prescribing opioids after routine wisdom tooth surgery. The Canadian Association of Hospital Dentists (CAHD) and Choosing Wisely Canada (CWC) teamed up with ISMP Canada to create the handout "Managing pain after wisdom teeth removal: Your questions answered" (see below). The handout has been endorsed by the Canadian Dental Association (CDA) and disseminated to its membership of about 20,000 dentists.

According to CAHD's Past President, "Although Canadian data specific to dental opioid prescribing in the pediatric population is limited to a few provinces, the existing evidence suggest dentists are responsible for a significant proportion of first-time exposure to opioids."[1] The handout includes information on safe disposal of unused opioids to minimize the risk of harm.

Managing pain after wisdom teeth removal: Your questions answered

English https://www.ismp-canada.org/download/OpioidStewardship/WisdomTeethRemoval-EN.pdf

French https://www.ismp-canada.org/download/OpioidStewardship/WisdomTeethRemoval-FR.pdf

Developed jointly by the Canadian Association of Hospital Dentists, Choosing Wisely Canada, and ISMP Canada, with support from the Canadian Patient Safety Institute.

Publications by CAHD and CDA highlighting the handout:

CAHD: Opioid Wisely – Canadian Association of Hospital Dentists, Choosing Wisely Canada, and the Institute for Safe Medication Practices Canada partner to promote safe use of opioids after wisdom teeth removal

CDA: Patient Resource for Managing Pain after Third Molar Extraction

Reference:

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