

Acute Care ISMP Medication Safety Alert

Educating the Healthcare Community About Safe Medication Practices

Taking a closer look at medication errors that involve oxytocin



PROBLEM: Intravenous (IV) oxytocin is used antepartum to induce labor in patients with a medical obstetrical indication, to stimulate or reinforce labor in selected cases of uterine inertia (failure of the uterus to contract normally during childbirth), and as an adjunct in the management of incomplete or inevitable abortion (a form of miscarriage). Used postpartum, IV oxytocin produces uterine contractions during expulsion of the placenta and controls postpartum bleeding or hemorrhage. However, improper administration of oxytocin can cause hyperstimulation of the

uterus. An antepartum over-infusion can result in fetal hypoxia due to reduced uteroplacental blood flow, the need for an emergency cesarean section, or uterine rupture.

ISMP first wrote about an error involving oxytocin in a 1999 article discussing a mix-up between magnesium sulfate and oxytocin for a peripartum patient. In 2007, ISMP added oxytocin to its List of High-Alert Medications in Acute Care Settings (www.ismp.org/node/103). Over the next 13 years, practitioners continued to report patient harm due to oxytocin errors. In 2020, ISMP and ISMP Canada analyzed nearly 200 reported incidents and published Errors associated with oxytocin use: A multi-organization analysis by ISMP and ISMP Canada (www.ismp.org/node/14240), which described common themes and provided safe practice recommendations. Unfortunately, errors continue to occur, and oxytocin was included in our 2021 (www.ismp.org/node/22438) and 2022 (www.ismp.org/node/29489) discussions on the top medication errors and hazards from the previous year.

In the past year, ISMP has been promoting the safe use of oxytocin on a global scale along with participating in the Oxytocin Safety Interest Group (OxytocinSIG) formed by the executive committee of the International Medication Safety Network (IMSN). ISMP and other IMSN member countries have been sharing experiences with oxytocin risks, close calls, actual errors, and adverse events (Table 1). Many of the challenges we see with the use of oxytocin in North America are also experienced around the globe, which is an example of ISMP's core concept: medication errors are rarely isolated events and have the potential to be repeated in other care settings. The goal of the continued on page 2 - Oxytocin >

Table 1. Risks associated with oxytocin use identified by the International Medication Safety Network (IMSN), Oxytocin Safety Interest Group (OxytocinSIG)

Inappropriate/unnecessary use in labor induction in low-risk patient populations
Lack of a standardized dosing regimen
Confusion with look- and sound-alike medications
Inappropriate use of brand names or unsafe abbreviations (e.g., "OXY" for oxytocin, Oxy CONTIN , or oxy CODONE ; "PIT" for Pitressin or Pitocin)
Non-standardized or non-centralized preparation of oxytocin infusions
Use of multiple oxytocin infusion concentrations/preparations
Insufficient monitoring of beyond-use dates of preprepared solutions
Reliance on manually programmed infusion pumps without automated safeguards in place
Mix-ups with infusion tubing
Mix-ups with dosing/infusion rates
Use/availability of oxytocin in the direct patient care area without appropriate orders and communication among healthcare providers

Provided to members courtesy of Vizient.

Remembering **David Cousins, BPharm, MSc, FRPharmS, PhD**

We were saddened last week to learn of the passing of our friend David Cousins, BPharm, MSc. FRPharmS, PhD. who tirelessly



pursued development of a safe medication policy agenda in the United Kingdom (UK) that has since been modeled around the world.

Dr. Cousins served as head of safe medication practice at the former National Patient Safety Agency (NPSA) and then the NHS (National Health Service) in England for 12 years, helping develop the National Reporting and Learning System. He was responsible for issuing numerous patient safety alerts for required follow up by the nation's healthcare facilities.

Among other activities that improved safety, he also authored a 2014 patient safety alert requiring that every NHS organization in England appoint a medication safety officer (MSO). In addition, David was a founding member of the International Medication Safety Network (IMSN). He was recognized by ISMP in 1999 with a Cheers Award and also received our Cheers Lifetime Achievement Award in 2020.

He will be remembered as a great friend, colleague, musician (saxophone), biker (who once toured the United States on a Harley) and, above all, a wonderful husband and father.

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OxytocinSIG collaboration was to develop a consensus document to aid in the implementation of safe oxytocin practices worldwide and to prevent oxytocin errors.

In May 2023, IMSN published Recommendations for Global Implementation of Safe Oxytocin Use Practices (www.ismp.org/ext/1181). In addition, we conducted a review of oxytocin errors reported through ECRI and the Institute for Safe Medication Practices (ISMP) Patient Safety Organization (PSO) (www.ismp.org/ext/591) to identify ongoing known issues and expose any previously unidentified risks.

Narrowing the focus

From January 2012 through March 2022, there were 2,073 oxytocin-related medication errors reported to the ECRI/ISMP PSO that occurred in the United States. We narrowed our focus on recent errors and those that required monitoring or caused patient harm (e.g., National Coordinating Council for Medication Error Reporting and Prevention [NCC MERP] Index category D and higher; www.ismp.org/ext/1148). This resulted in 163 events reported from January 2019 through March 2022. We identified several previously reported event types and uncovered some new trends that required a closer look.

Results

Pump misprogramming

More than one in four (26%) events were pump programming errors. Examples include misprogramming oxytocin at a postpartum rate instead of an induction rate or at a rate intended for Lactated Ringer's solution; a 10-fold misprogramming error; or not using a bolus feature.

A nurse received an order to increase a laboring patient's oxytocin dose per the organization's induction protocol. Overnight, the oxytocin had been infusing at 2 milliunits/minute. To modify the dose, the nurse turned off the infusion pump, and rescanned the oxytocin bag, but inadvertently selected a postpartum oxytocin option with a default rate of 3 **units/hour**. During the next hour, the nurse titrated the rate to 5 units/hour before the programming error and overdose were identified.

A nurse scanned the barcode on an oxytocin bag to start a titratable infusion as discussed verbally with a prescriber. The nurse did not realize the prescriber had not yet entered the oxytocin titratable infusion order into the electronic health record (EHR). Since the only oxytocin order on the patient's profile was for a postpartum bolus dose, the medication administration record (MAR) automatically pulled up this dose upon scanning the product. After the infusion pump autopopulated the postpartum bolus dose, the nurse confirmed what they thought was the correct dose, and the postpartum bolus dose of 10 units was administered to the patient rather than the intended titratable infusion.

Administration without an order on the MAR

Nearly one in five (19%) of the events involved labor and delivery practitioners removing an oxytocin vial or infusion bag from an automated dispensing cabinet (ADC) via override without an order on the patient's profile. This often occurred without subsequent documentation in the MAR (next bullet) or without documenting the return of the medication. Obtaining oxytocin via override is not only a dangerous practice, but it can also put a nurse's license in jeopardy should something go wrong. Experienced nurses may be knowledgeable about how physicians in their facility practice, and "drift" into an unsafe place and access the oxytocin prior to having a recorded order. ISMP Targeted Medication Safety Best Practices for Hospitals (www.ismp.org/node/160), Best Practice #17 recommends NOT bringing an oxytocin infusion bag to the bedside until it has been prescribed and is needed. The reports do not state whether the bags were removed in anticipation of need or upon verbal orders from providers. Practitioners have previously reported errors involving the inadvertent administration of oxytocin in place of other medications (e.g., magnesium sulfate) or fluids even when they did not have an order to administer the oxytocin.

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Worth repeating

Errors continue with unsafe B. Braun IV bag labeling and difficult-toscan barcodes

Recently, three close call events have been reported in which look-alike B. Braun 500 mL bags of 3% sodium chloride injection (hypertonic) (NDC 00264-7805-10) and sterile water for injection (NDC 00264-7850-10) were misidentified. Both bag labels use the same bold blue font for the drug name (Figure 1). The labels also display a red warning box below the name. While one includes text stating "hypertonic," and the other has a warning about it being hypotonic and hemolytic, these bags can easily be confused.



Figure 1. B. Braun's 500 mL bags of 3% sodium chloride injection (hypertonic) (left) and sterile water for injection (right) look similar and have been mixed up.

The first error was identified through the use of an intravenous (IV) workflow management system (IVWMS) when a pharmacy technician scanned a 3% sodium chloride bag instead of the intended sterile water for injection bag. The sterile water bin in the sterile compounding room had been stocked with 3% sodium chloride bags, and the pharmacy technician who prepared the supplies for compounding did not identify the misfill. In a second event, a pharmacist was checking a 3% sodium chloride infusion for a neonate and identified that a technician had removed sterile water in error. In another case, a pharmacist reported that there were sterile water for injection bags stocked in a 3% sodium chloride bin in an intensive care unit (ICU) satellite pharmacy. Inadvertent administration of hypertonic sodium chloride can result in patient harm

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No administration documentation in the MAR

Approximately 15% of the events involved practitioners not documenting oxytocin administration after removing it from the ADC via override. In these cases, prescribers entered oxytocin orders in the patients' EHRs after the fact, but there was no documentation in the MAR to indicate the oxytocin was administered. However, for some of these events, the reporter was able to verify administration in the delivery summary note and by the presence of an oxytocin infusion bag.

Incorrect tubing or infusion setup

One in ten (10%) events involved issues with the IV tubing or infusion setup. In most of these cases, patients were prescribed an oxytocin infusion, but the tubing was not connected to the patients' access port and instead infused onto the floor. In one case, the line was clamped and the patient reported that the pump had been alarming throughout the night. The remaining cases involved inappropriate primary or secondary tubing use or setup, including the administration of secondary infusions via the oxytocin line. This can result in harm since the rapid administration of oxytocin that remains in the IV line can increase the frequency and duration of uterine contractions.

A prescriber ordered an antibiotic for a patient who was also receiving oxytocin. The patient's nurse programmed the smart pump to deliver the antibiotic at a rate of 200 mL/hour to infuse over 30 minutes, but they administered the antibiotic through the tubing that contained the patient's oxytocin. The oxytocin that was already in the tubing was flushed into the patient at the rate of the antibiotic, which resulted in uterine hypertonicity, tachysystole, and subsequent fetal heart rate deceleration.

Wrong drug or concentration

About 7% of the events involved incorrect medications or concentration mix-ups, where barcode scanning was not implemented or was bypassed.

A patient's spouse notified a nurse that his wife's face was red, and her ears were red and swollen. While evaluating the patient, the nurse noted that the bag of oxytocin that had been started by the anesthesia staff was empty. Upon scanning the subsequent infusion bag hanging behind the empty infusion, which was presumed to be oxytocin, an alert warned the nurse that there was no order for vancomycin on the patient's profile. The nurse looked at the label on the empty infusion bag and discovered that the patient had inadvertently received 3 g of vancomycin instead of oxytocin.

A provider asked a nurse if the patient's postpartum intramuscular oxytocin had been prepared and was ready to be administered. The nurse went to the ADC and removed what they thought was a 10 unit vial of oxytocin and drew up the dose. After giving birth, the patient received the dose, which another nurse administered without the use of barcode scanning. After administration, the nurse scanned the vial to document administration and discovered it was a look-alike vial of glycopyrrolate. The glycopyrrolate vial had a label with the same shade of green as the oxytocin vial label.

Other errors

The remaining reports (23%) were categorized as "other" and included oxytocin omissions, delayed therapy, events related to medication reconciliation, wrong patient errors, and wrong time errors.

SAFE PRACTICE RECOMMENDATIONS: The 2022-2023 ISMP Targeted Medication Safety Best Practices for Hospitals (www.ismp.org/node/160; Best Practice #17) lists recommendations to safeguard against errors with oxytocin. Specifically, the Best Practice recommends using standard order sets for prescribing oxytocin, standardizing to a single concentration/bag size for both continued on page 4 — Oxytocin >

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from hypernatremia, osmotic demyelination syndrome, and hemolysis. Administration of large quantities of hypotonic sterile water IV can also result in patient harm, including death from hemolysis. ISMP has repeatedly contacted B. Braun about these ongoing lookalike infusion bag labels.

ISMP has also received reports about the inability to scan the linear barcodes on some of B. Braun's large volume parenteral (LVP) bags (Figure 2) and minibags (Figure **3**). The most frequently reported concern is difficulty scanning a white barcode printed on a clear bag. Practitioners state that the white barcodes are especially difficult to scan



Figure 2. B. Braun changed the linear barcode on the 0.9% sodium chloride injection 1,000 mL bag (NDC 00264-7800-09) from white (left) to black (right) in 2020, but practitioners still report issues with scanning.



chloride injection, 50 mL partial

difficulty scanning.

when the clear bags are upright (e.g., hanging on an IV pole), and are easier to scan when held against a dark background, such as laying the bag on a dark table. Occasionally, additive bag by B. Braun (NDC we also hear 00264-1800-31) has a white about scanning barcode that practitioners have difficulties with black barcodes

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antepartum and postpartum infusions, communicating orders for oxytocin infusions in terms of the dose-rate, and aligning this with the smart infusion pump dose error-reduction system (DERS). To achieve this, organizations should convene an interdisciplinary group (e.g., pharmacists, nurses, labor and delivery providers, anesthesiologists, informaticists, medication safety officers) to evaluate the organization's systems and processes related to oxytocin. Begin by reviewing internally reported oxytocin-related errors as well as published external events such as those described in this and previous newsletter issues (www.ismp.org/node/14240). Consider the following recommendations to develop a comprehensive plan to prevent known issues and reduce oxytocin errors:

Provide oxytocin in a standard ready-to-administer form. To avoid the need for infusion preparation at the bedside, provide patient care units with ready-to-administer IV bags of oxytocin in a standardized concentration. These can be pharmacy-prepared or from an outsourced sterile compounding service. Standardize to a single concentration and bag size for both antepartum and postpartum oxytocin infusions (e.g., 30 units of oxytocin in 500 mL of Lactated Ringer's solution). This standardization allows for the same bag to be used for labor augmentation and postpartum, which can reduce time and waste.

Label both sides. Before distributing oxytocin bags to patient care units, label both sides to differentiate them from plain hydrating solutions and magnesium sulfate infusions. In our December 1, 2022 newsletter (www.ismp.org/node/50977), we discussed QuVa Pharma's new oxytocin infusion bag in which practitioners can view the label from the front and back sides of the IV bag.

Conduct a packaging assessment. Prior to purchasing oxytocin vials or premixed bags, conduct an assessment to ensure they do not look similar to other vials or bags used in the labor and delivery unit, and that the label is clear regarding the amount of drug per total volume. If you notice similarities and the drug/solution cannot be purchased from a different manufacturer/supplier, implement strategies to avoid confusion (e.g., do not store look-alike products near one another; auxiliary labeling on vials, infusion bags, bins) and warn all users about the risk.

Employ standard order sets and dose-rates. Require the use of standard order sets for prescribing oxytocin antepartum and postpartum that reflect a standard clinical approach in your organization for labor induction/augmentation and to control postpartum bleeding. Include administration requirements, patient monitoring parameters, and guidelines for the treatment of oxytocin-induced uterine tachysystole. Communicate orders for oxytocin infusions in terms of the dose-rate (e.g., dosage/time) and not by the volume-rate (e.g., volume/time). While ISMP does not recommend a specific dose-rate, we do recommend that each indication has a standardized dose-rate, which could be different for induction/augmentation versus postpartum. When using a single oxytocin concentration for antepartum and postpartum therapies, review how these orders appear on patient profiles and recognize that barcode scanning may not identify an incorrect order selection if the same barcode is used for both orders.

Align the pump drug library. Align the oxytocin order set dose-rate and concentration with the smart pump DERS. Work with labor and delivery staff to develop a process that takes into consideration the functionality of the pump and the workflow required to set up infusions and bolus doses, and how to make a transition from antepartum oxytocin administration to postpartum oxytocin infusion safely. Consider how DERS limits can be set to avoid incorrect infusions with postpartum doses when oxytocin is used for induction, and vice versa.

Engage end users. When developing or modifying oxytocin order sets in the EHR and smart pump drug library builds, gather feedback from frontline staff to ensure they can easily identify the correct indication and corresponding orders. As part of this work, particularly when using a single concentration of oxytocin, ensure that pump naming conventions in the drug library (e.g., oxytocin **INDUCTION**, oxytocin **POSTPARTUM**) align with respective order sets.

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on clear bags. In addition, some practitioners have reported they cannot scan the barcode on B. Braun LVPs in clear overwraps if the overwrap seam runs through the barcode.

The US Food and Drug Administration's (FDA) Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (www.ismp.org/ext/930) discusses issues with barcodes being printed on transparent or translucent backgrounds, which has led to difficulty in scanning the barcode. To allow for proper scanning, they recommend ensuring there is adequate contrast between the background color and the barcode (e.g., print the barcode in dark ink on a white background).

When we recently met with B. Braun about these issues, we recommended they use dark ink on white backgrounds for all barcodes. They recognize that scanning a barcode on a translucent IV bag is a challenge. Customers have provided feedback stating the black barcode is easier to scan than the white barcode. However, B. Braun's internal testing showed that issues with scanning both the white and black barcodes are about the same. They suggest holding the scanner 4 to 6 inches from the bag, scanning at an angle, and/or putting a contrasting color behind the bag (e.g., black behind a white barcode, white behind a black barcode). To prevent obstructing the barcode while still in its overwrap, B. Braun told us they made changes to ensure that the overwrap seam is placed on the opposite side of where the linear barcode is. As another option, they added a white two-dimensional (2D) barcode to the left of the linear barcode on some bags, which can be easier to scan. We were pleased to hear that B. Braun is also evaluating the use of additional colors to differentiate their infusion bags.

Sterile water for injection, 3% sodium chloride, and certain other B. Braun IV solutions are high-alert drug products that can lead to serious harm when involved in medication errors. The long-standing lookalike labeling issues, coupled with scanning difficulties create significant patient safety concerns. FDA and the manufacturer need continued on page 5 — Worth repeating > > Oxytocin — continued from page 4

Employ barcode scanning technology. To minimize wrong drug selection errors, require pharmacy staff to scan the barcodes on oxytocin vials and infusion bags prior to preparation, dispensing, and stocking (e.g., in ADCs). Also, require nurses to scan the product prior to administration, including when modifying the indication and corresponding dose-rate.

Label and trace lines. When setting up an infusion, label the IV tubing just above the injection port closest to the patient and just above the pump. Trace the line from the infusion bag to the pump, and from the pump to the patient (and/or vice versa), to ensure the correct line attachment.

Reduce access to unneeded medications. Avoid bringing any medication or solution to the patient's bedside until it has been prescribed and is needed. Restricting access to unneeded medications is a key error-reduction strategy, particularly in birthing units where emergent circumstances may require rapid changes in the plan of care.

Remove oxytocin when discontinued. When oxytocin is discontinued, remove the bag and tubing from the pump and from the patient's room to prevent inadvertently restarting the infusion.

Limit verbal orders. Whenever possible, require prescribers to enter oxytocin orders through the order set. Limit verbal orders, but if they are urgently needed, repeat back is a must. If used, enter the verbal order in the EHR before removing the medication from the ADC or starting the infusion.

Avoid outdated brand names and drug name abbreviations. Remove outdated brand names, including Pitressin (vasopressin), from systems. Avoid the use of drug name abbreviations such as "PIT" for either **PITOCIN** (oxytocin) or Pitressin or "OXY" for oxytocin or oxy**CODONE**/Oxy**CONTIN**.

Perform a failure mode and effects analysis (FMEA). Before implementing changes to oxytocin prescribing, dispensing, preparation, and administration, perform an FMEA to proactively identify potential issues in your systems. Simulate the workflow, including the physical setup of the pumps and tubing for all required medications and fluids (e.g., oxytocin, magnesium sulfate, fluids, antibiotics), and let end users practice and provide feedback in a test environment to uncover and address hidden challenges in the process. Simulation can also be used to promote an understanding of potential infusion risks.

Educate and support practitioners. When making significant practice changes, educate practitioners and regularly reinforce the process. Gather feedback from end users to ensure a successful implementation. Consider implementing oxytocin checklists for patient and fetal assessments such as those used by Centura Health (www.ismp.org/ext/1158).

Assess competency. Provide annual competency assessments to assess practitioners' skills and knowledge related to oxytocin throughout the medication-use process.

Support clear communication/documentation. Use standardized communication strategies (e.g., situation, background, assessment, and recommendation/request [SBAR]) and documentation tools during transitions of care to promote clear, timely, and efficient exchange of patient information.

Monitor for post-implementation issues. Monitor data related to oxytocin use (e.g., infusion pump programming, barcode scanning, error reporting) and follow up with labor and delivery staff regularly to monitor for adherence with established practices and to identify and troubleshoot unanticipated issues.

Engage patients. Educate patients early during pregnancy about the use of oxytocin and associated risks during labor. Encourage questions about oxytocin to further engage patients/families in the birth planning process. Refer to ISMP Canada's oxytocin guide (<u>www.ismp.org/ext/1159</u>).

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to address these ongoing and long-standing issues as soon as possible. We have seen issues with LVPs from other manufacturers too—and recommend they consider the suggestions that were previously published in our February 11, 2021 feature article, Updated Guidance Needed for Longstanding Large Volume Parenteral (LVP) Labeling and Packaging Problems (www.ismp.org/ node/22778).

Special Announcements

Nominations open for CHEERS Awards

Each year, ISMP honors various healthcare disciplines that have demonstrated an exemplary commitment to medication safety through innovative projects with an ISMP **CHEERS Award**. Nominations for this year's **CHEERS Awards** are now open and will be accepted through **August 6, 2023**. Please refer to the information provided on our website when submitting a nomination. For details, visit: <u>www.ismp.org/node/123</u>.

Best Practices survey reminder

We are conducting a short survey to get a sense of the current level of implementation of the 2022-2023 **Targeted Medication Safety Best Practices for Hospitals**. We would very much appreciate your participation in this survey. Please complete this survey online by **June 30, 2023**, by visiting: www.ismp.org/ext/1164.

To subscribe: <u>www.ismp.org/node/10</u>



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