Case Study

Obstetrical Patient Receives Ampule of Digoxin Instead of BUPivacaine for Spinal Anesthesia

Reference article: https://www.ismp.org/resources/obstetrical-patient-receives-ampule-digoxin-instead-bupivacaine-spinal-anesthesia

How **Safe Label System (SLS)** would have prevented this error:

When a vial/ampule is removed from the ADC, the clinician scans the barcode on SLS and is immediately presented with visual and audible confirmation of the drug-in-hand providing a critical safety check at preparation that helps *to prevent vial swaps*. As the medication is drawn into a syringe, a Joint Commission-compliant, full-color, easy-to-read label is printed and can include Tallman lettering and warnings about the drug. This fast yet serial workflow helps keep focus on the patient and *prevents mislabeling or illegible labeling*.

Every syringe label includes a barcode enabling it to be scanned at administration. This not only accurately documents the AIMS/EMR in real-time to improve charge capture, it also provides additional safety checks to the clinician before the medication is administered to the patient, *helping to prevent syringe swaps*. Vial/ampule swaps, mislabeling and syringe swaps are the most common medication errors in the operating room and each is addressed by SLS to improve patient safety.

Problem

A pregnant patient with no significant past medical history was undergoing a scheduled cesarean delivery in an operating room (OR) and was to receive spinal anesthesia. An anesthetist typed in "bupivacaine" at an automated dispensing cabinet (ADC), and a drawer that provided access to several medications opened. The anesthetist inadvertently removed an ampule of digoxin rather than **BUP**ivacaine, prepared the dose, and administered it intrathecally. The anesthetist did not scan the barcode or read the label aloud to another staff member prior to administration. Anesthesia staff then recognized that the patient was not getting the anticipated **BUP**ivacaine effects and thought that it had been injected into the wrong space. They called the covering anesthesiologist for assistance, and a second dose was administered. The cesarean team delivered a healthy baby. However, shortly after the birth, the patient complained of dizziness, blurred vision, and a severe headache with left facial drooping and left-sided weakness. She began losing her ability to communicate and then experienced apnea and complete paralysis. She was intubated and transferred to the intensive care unit. During an OR ADC medication count, a nurse found that a digoxin ampule was missing. Inadvertent digoxin administration into the intrathecal space was suspected, and a digoxin level was ordered and detected. The team determined that the patient was brain dead, and she died shortly thereafter.

While the manufacturer names for the ampules were not reported to us, **BUPIVACAINE SPINAL** (preservative-free **BUP**ivacaine for intrathecal use) and digoxin are both available in 2 mL ampules (**Figure 1**). Since medications are not often provided in ampules, this can heighten the risk of mix-ups between the two drugs. We have previously received reports about cases in which digoxin had been accidentally administered via a neuraxial route (e.g., epidural, intrathecal) instead of the intended **BUP**ivacaine or **BUP**ivacaine with **EPINEPH**rine. One review (Patel S. Cardiovascular drug administration errors during neuraxial anesthesia or analgesia - a narrative review. *J Cardiothorac Vasc Anesth*. 2023;37[2]:291-8) analyzed inadvertent neuraxial cardiovascular medication administration errors reported between 1972 and 2022. Among the 33 events reported, digoxin was the medication most commonly administered in error and was associated with paraplegia and encephalopathy in eight patients.

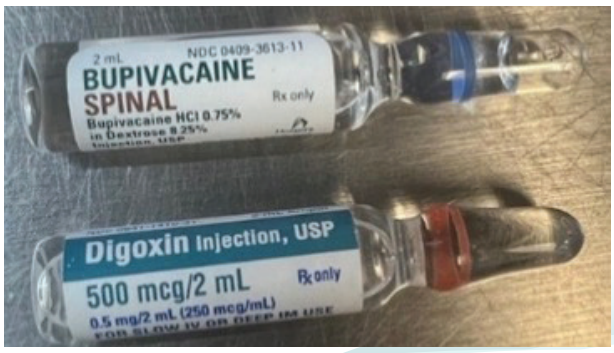

Figure 1. Examples of ampules of **BUP**ivacaine Spinal by Hospira (NDC 0409-3613-11) (top) and digoxin by Hikma Pharmaceuticals (NDC 0641-1410-31) (bottom).

Safe Practice Recommendations:

Given the repeated number of serious mix-ups between digoxin ampules and local anesthetics, the US Food and Drug Administration (FDA) should take steps to have manufacturers package digoxin in vials. In the meantime, organizations should consider the following recommendations:

- Review which medications (with special attention to ampules) are available in each unit-specific ADC location, anesthesia tray, and medication kit. Remove those that are not needed (considering typical diagnoses).
- Evaluate whether digoxin needs to be stocked in your OR and labor and delivery unit or if it can be requested from the pharmacy, as needed.
- Employ individual locked pockets or segregated storage, especially for high-alert medications like digoxin, or medications given via the spinal route, such as preservative-free **BUP**ivacaine.
- Use barcode scanning upon selection in the pharmacy and when stocking medications in the ADC to ensure it is placed in the correct drawer or pocket.
- Avoid stocking medications in ampules when possible or store them far apart, and never store more than one medication in an ampule in an open matrix drawer.
- **In the OR, order BUPivacaine for patients and scan the barcode prior to administration. Read labels aloud, as would typically occur at handoffs between the circulating and surgical nurse.**
- Establish policies and procedures for returning unused medications. Require staff to return unused, non-refrigerated medications with intact packaging into a secure one-way return bin in the ADC, that is maintained by the pharmacy. Otherwise, return these items to the original secure locked-lidded pocket if it is a non-controlled substance. This process should be guided by barcode verification. Practitioners should return unused refrigerated medications to the designated ADC refrigerated return bin, which should be checked regularly by pharmacy staff.
- Educate staff (e.g., anesthesia personnel, nurses, pharmacists, pharmacy technicians) and conduct regular competency assessments about the safe use of ADCs during orientation and annually.
- Share this event with staff and discuss lessons learned. In addition, conduct regular reviews and discussions of medication events and close calls reported in your organization and by outside organizations such as ISMP.

MEETS ISMP RECOMMENDATIONS to REDUCE medication errors[1]

ISMP Guideline 4.3

Eliminate the use of handwritten labels in perioperative/procedural areas **by 2025**.

ISMP Guideline 4.4

Include a machine-readable code (e.g. barcode, RFID) on all syringe and infusion labels, including those that are practitioner-prepared, **by 2025**.

ISMP Guideline 4.5

Label syringes with elements required by The Joint Commission. Anesthesia color-coded drug class label alone is not sufficient.

ISMP Guideline 6.6

Take steps toward the implementation of bidirectional (auto-programming/documentation) SMART INFUSION PUMP interoperability with the EHR.

ISMP Guideline 10.11

Use machine-readable coding to verify patients and medications/solutions prior to administration.

ISMP Guideline 10.12

Take steps to implement machine-readable coding (e.g. barcode scanning, RFID) in intraoperative/intraprocedural workflows to confirm medication solution selection prior to administration.

ISMP Guideline 10.13

Take steps to implement and integrate machine-readable coding (e.g. barcode scanning, RFID) to support real-time EHR documentation of medication doses and fluid administration in all preoperative/preprocedural, intraoperative/intraprocedural, and postoperative/postprocedural settings.

Used in over **14,000 operating rooms** by more than **900 of the world's leading hospitals**, Safe Label System is validated in over **54 million procedures** and over **218 million drug preparations**, helping to prevent more than **1.6 million medication errors**[2].

For additional recommendations, review the following resources:

- [1] ISMP Guidelines for Safe Medication Use in Perioperative and Procedural Settings
- [2] Based on Merry AF, Peck DJ. Anesthetists, Errors in Drug Administration and the Law. N Z Med J. 1995; 24:185-187.
- ISMP Guidelines for the Safe Use of Automated Dispensing Cabinets
- ECRI. Automated dispensing cabinet setup and use errors may cause medication mishaps [ECRI Exclusive Hazard Report]. ECRI Alerts. February 8, 2017. Accession No. H0365

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