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Vial Mistakes Involving Heparin

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The Case

A 65-year-old man was admitted to the hospital for an elective left carotid endarterectomy. During the procedure, the surgeon requested 5000 units of intravenous (IV) heparin prior to clamping the carotid artery. The anesthesiologist administered 5 mL of heparin from what he believed was a 1000 units/mL concentration vial. After 3 minutes, an activated clotting time (ACT) was drawn while the surgeon clamped the carotid artery and proceeded with the surgery. When the ACT returned normal rather than prolonged (as it should have been after the heparin), the anesthesiologist repeated the ACT to confirm the result.

The anesthesiologist then re-dosed and administered what he thought was 7000 units of heparin as the surgeon grew concerned about the cross clamp time without adequate anticoagulation. When a repeat ACT once again returned normal, the anesthesiologist requested a new batch of heparin vials while reaching into the garbage and picking up the vial from which he had drawn. He quickly realized that the heparin vial from the garbage was a 10 units/mL concentration rather than a 1000 units/mL as intended. The two vials of heparin were designed to be color differentiated with different shades of yellow, and the anesthesiologist had chosen the wrong one from the cart. Another dose was administered from the correct vial, and the patient's ACT time rapidly became appropriately therapeutic. Luckily, the prolonged clamp time without anticoagulation led to no obvious clinical harm, making this a serious "near miss" event.

The Commentary

This heparin error is similar to two highly publicized heparin concentration mix-ups involving neonates. At Methodist Hospital (Indianapolis) in 2006, three infants died and three were injured when nurses administered heparin flushes prepared from 10,000 units/mL vials rather than from similar-looking vials containing the 10 units/mL concentration used to flush intravenous catheters.

The 10,000 units/mL vials had inadvertently been loaded into the automated dispensing cabinet (ADC) drawer that usually held 10 units/mL vials, and multiple nurses administered the high-concentration heparin as catheter flushes. One year later at Cedars-Sinai Hospital, Dennis Quaid's newborn twins also were

administered high-concentration heparin in place of the heparin flush. In both cases, numerous system errors were identified. These included storage issues in the pharmacy, an omitted second manual check or bar code scan before dispensing, confirmation bias on the part of nurses selecting the vials, a 1000-fold difference in concentration between similar-looking vials, and delay in recognizing the cause of the sudden change in each infant's condition.

This operating room (OR) case also involved a look-alike packaging issue (Figure). However, instead of *inadvertent* substitution of high-concentration for low-concentration vials in the ADC, apparently both high-concentration and low-concentration vials were *intentionally* stocked on the anesthesia cart, greatly increasing the potential for error. If similar practices exist in other ORs, additional accidents are waiting to happen.

Heparin Errors in the OR

In 1984, medication errors were reported as a leading cause of adverse events during anesthesia.(1) In 2001, one drug administration error was reported for every 133 anesthetics administered.(2) More recently, the United States Pharmacopeia's MEDMARX database identified 3298 medication errors in the OR from 1998 to 2005. Heparin was involved in 143 (3.9%); however, it was second among the drugs most frequently associated with patient harm.(3) Of particular interest, a past study reported that nurses found the expected placement of a drug container in an ADC to be most important in selecting a medication, while anesthesiologists found the color of the container most important.(4) In the infant error cases highlighted, nurses pulled the concentrated heparin from the expected location, while in the OR error, a similar-color vial was selected.

Heparin is unique in the wide range of doses used clinically. When used to flush IV catheters, heparin concentrations typically range from 1-10 units/mL. When continuous infusion is used for systemic anticoagulation, the final concentration is usually 50 or 100 units/mL. Complicating matters is that initial loading or bolus doses prior to continuous infusion are typically prepared from a concentration of 1000 units/mL. Most pharmacies purchase heparin infusions in pre-mixed IV bags from IV fluid manufacturers to comply with Joint Commission National Patient Safety Goals (NPSGs).(5) Current shortages may force hospitals to accept alternate concentrations just to have heparin available. With available concentrations ranging from 1-20,000 units/mL, substitutions with infrequently used concentrations can lead to serious errors.

Adding to the challenges, heparin infusions prepared in the OR or in procedure areas may not be the same concentration used in inpatient treatment areas. This poses significant risk if infusions are transferred with the patient from an OR to an inpatient unit. Failure of nurses to recognize concentration differences can lead to serious errors when dosages are adjusted or heparin containers are changed to a different concentration. The Joint Commission has mandated limiting the number of available concentrations of high-risk IV medications. Nonetheless, review of a 207-hospital sample identified 15 different concentrations in drug libraries intended for IV infusions.(6)

Finally, there is significant variability in prescribing doses of heparin and programming the infusion on infusion pumps. For example, the surgeon may recommend a dose in units/hr, with the anesthesiologist converting this dose to a rate in mL/hr and programming the infusion pump. Then upon transfer of the

patient from the OR with the continuous infusion, the nurses may reprogram the pumps using the dose, either in units/hr or units/kg/hr. A review of 54 hospitals' practices showed that 48% standardized units/hr for infusion pump programming, 23% used units/kg/hr, and 29% used both weight- and non–weight-based dosing. Hospitals using smart IV pumps (computerized IV infusion pumps with dose-error–reduction software [DERS]) with both weight- and non–weight-based heparin selections had a four-fold higher incidence of averted programming errors identified by the DERS than those that standardized on units/kg/hr programming.(6)

Strategies to Reduce Heparin Errors

With the incredible variability possible in heparin use, and the related potential for patient harm, identifying unsafe practices and opportunities for error prevention must be a shared responsibility. Progress has been and continues to be made to improve the safety of heparin therapy in inpatient settings, including tight control or removal of concentrated heparin floor stock; standardization on a single concentration of "pre-mixed" heparin for continuous infusions; pharmacist review of medication orders prior to administration; heparin dosing protocols; and point-of-care technologies for nurses including bar code medication administration, smart IV pumps, and electronic medication administration records. However, these advances are much more difficult to apply in the OR. For example, orders for heparin are verbal, there is no pharmacist review, the heparin doses are prepared by the same clinician administering the drug, and bar code and other technology solutions are not easily adapted to this environment. In addition, the transition of patients from the OR to inpatient units may include continuation of heparin therapy.

The Joint Commission 2009 NPSGs specifically address medication labeling in the OR (NPSG 03.04.01) and set forth performance standards for the safe use of anticoagulant therapy (NPSG 03.05.01) throughout the hospital.(5) Although this is a good start, there is no one "silver bullet" that can address all safety risks for drugs such as heparin. Certainly, widespread publicity about infant deaths did not prevent the same error from happening again, and regulations typically set forth minimum standards but leave the implementation specifics to each institution. Ideally, a multidisciplinary assessment of heparin use in the OR would include anesthesiologists, surgeons, pharmacists, OR nurses, and nonprofessional OR staff. The goals of this assessment should include identification of unnecessary variation; agreement on how to standardize practices, procedures, and products; shifting of responsibilities where appropriate; and creation of an ongoing method of monitoring compliance with the required changes. Applying aviation principles of crew resource management to the OR is one example of an approach that can have dramatic benefits.

From my experience and consultation with several medication safety experts, specific recommendations to prevent heparin errors in the OR would include:

- For single-dose, therapeutic anticoagulation, stock anesthesia carts or pharmacy-prepared medication trays with a single concentration of heparin.
- Use a manual double-check or bar code verification system for items being dispensed by pharmacy.
- For continuous infusions of heparin, use the same standard heparin concentration used in inpatient care areas. There is no need for anesthesiologists to admix heparin to IV containers since commercially pre-mixed containers are widely available.

- Standardize all heparin loading and maintenance doses on either weight-based or non–weight-based dosing. Eliminate the use of multiple dosing units and switching between dosing units.
- If smart IV pumps are in use, require anesthesiologists to use the safety features. Any continuous infusion transferred from the OR with a patient should be programmed using the dose and not the infusion rate.
- Eliminate vials of heparin intended for flushing IV catheters and evaluate the need for heparin flushes, since their use is appropriately declining in favor of saline flushes.
- If heparin flushes are to be used, use manufacturer- or pharmacy-prepared syringes; do not require anesthesiologists to prepare IV flushes from vials of concentrated heparin intended for therapeutic use.
- If high-risk medications must be prepared in the OR, consider an independent double-check by a qualified, knowledgeable clinician.
- Label medications removed from original containers immediately in accordance with Joint Commission requirements.(5)
- Keep all original medication containers used during a case until the end of the case, and discard all opened containers at the conclusion of the case.(5)
- Have pharmacy purchase with safety in mind. This incudes purchasing ready-to-use items whenever possible. Pharmacy must assess the risk of vial mix-ups due to similarly packaged containers, including vials of similar size and coloring.
- Establish policies and procedures to immediately communicate any heparin product substitution involving a different concentration, through the use of emails, posters, and special auxiliary labels on the heparin container, etc.
- Give special consideration to pediatric use of heparin since most drugs stocked in anesthesia are intended for adult use.

Take-Home Points

- Heparin administration is fraught with risks for error, largely due to the tremendous variability in dosing usage and available concentrations.
- For error prevention, only vials containing a single, standardized concentration of heparin should be stocked in the OR, and when patients are moved from an OR to an inpatient unit, the programming and choice of concentrations for use should remain consistent.
- All aspects of the heparin administration process must be standardized.
- Any variation from the use of the standardized products must be minimized or immediately communicated to all concerned.

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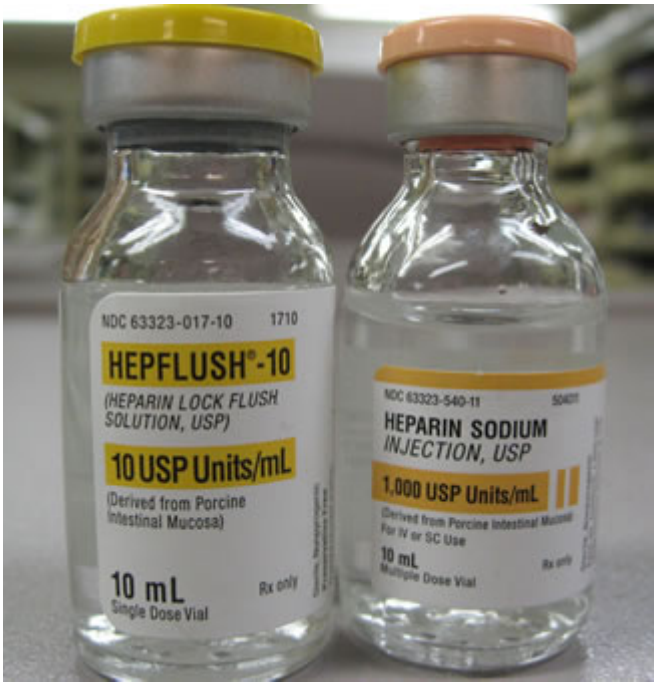
Figure

Figure. Example of similar-looking heparin vials. (Note: The vials pictured were not involved in the presented case.)



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