Anesthesia Patient Safety Foundation

Drug Labeling in the Perioperative Environment: Issues that May Contribute to Medication Errors

Elizabeth Rebello, R.Ph, MD, FASA, CPPS   Richard Botney, MD

Medication error is the most common type of medical error in the United States, injuring approximately 1.3-1.5 million people and accounting for 251,000 preventable deaths per year (asamonitor.pub/2SF59mC; Preventing Medication Errors. 2007; *BMJ* 2016;353:i2139). Although medication errors in anesthesia are difficult to study, accumulating evidence shows that medication errors in anesthesia occur frequently (*Anesthesiology* 2016;124:25-34; *Br J Anaesth* 2018;120:563-70). The Anesthesia Patient Safety Foundation (APSF) has long recognized the need for increased medication safety awareness. There have been numerous articles in the *APSF Newsletter* and three in-person Consensus Conferences with multiple stakeholders, including anesthesiologists, nurse anesthetists, pharmacists, drug manufacturers, and 503B compounders, dedicated to advancing medication safety (asamonitor.pub/2TnzNB4; asamonitor.pub/3jstN4U).

One of the most highly debated issues with regard to medication errors and the process of medication administration is drug labeling. ASA created a Statement on Labeling of Pharmaceuticals for Use in Anesthesiology in 2004, which was most recently revised in 2020 (asamonitor.pub/3x11FcZ). The rationale for creating this statement was to reduce medication errors by incorporating standards established by ASTM International (formerly the American Society for Testing and Materials) and the International Organization for Standards, as well as recommendations from the Food and Drug Administration and US Pharmacopeia (USP). The statement is targeted to a broad audience, including clinicians, drug manufacturers, 503B compounding facilities, and label and label printer manufacturers, to enhance standardization of labels.

Issues in drug labeling
Syringe labeling
ASA's Statement on Labeling of Pharmaceuticals for Use in Anesthesiology recommends that the drug's generic name and concentration in units per mL should be the most prominent items displayed on the label of each syringe (Figure 1) (asamonitor.pub/3x11FcZ). In addition, the date,

Figure 1:
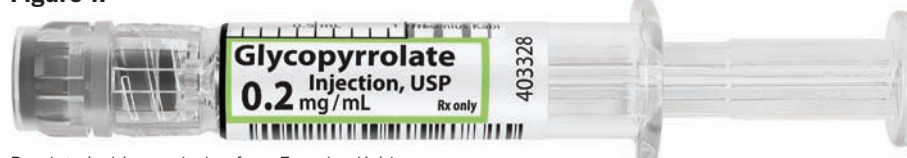
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Figure 2:
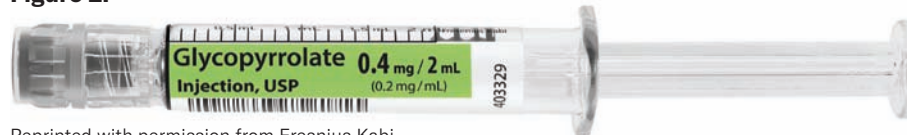
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time, and name or initials of the preparer should also be on the label whenever a medication is withdrawn from a vial or ampule into a syringe. The placement of a label on a syringe should be done in a manner where the label may be read while administering the medication and without obscuring the syringe gradations (*P&T* 2010;35:428-9). Pre-filled syringes are supplied by either drug manufacturers or outsourcing facilities, and the FDA guidance in terms of labeling varies depending on the source (asamonitor.pub/3qErlcX; asamonitor.pub/3AbbeYS).

Having the total amount in the syringe divided by the total volume appear in the prominent position, as frequently seen on vials and prefilled syringes produced by drug manufacturers and some outsourcing facilities (Figure 2), requires an additional mathematical calculation that may lead to a medication error. Having standard labeling practices for all prefilled syringes regardless of source would potentially mitigate

Figure 3:

Figure 4:

medication errors and reduce confusion among anesthesia professionals (asamonitor.pub/3x11FcZ; asamonitor.pub/3qErlcX).

Vials
USP Chapter 7 provides the standards for labeling (asamonitor.pub/3qzGWdO). Vials and ampules display the name of the medication and the concentration with the total amount of medication in the container divided by the total volume in the most prominent position, followed in close proximity by the concentration per mL. Exceptions to this practice include when the container volume is less than or equal to one mL or when the prominent expression of total drug content per container would not be effective in preventing medication errors. Examples of exceptions include insulin, which displays the concentration in units per mL, similar to the recommended manner in which syringes are to be labeled (Figure 3), and local anesthetics, which are
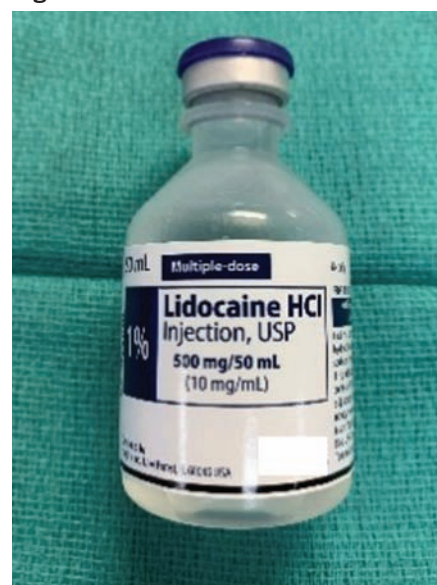
expressed as a percent and the quantity per total volume, followed in close proximity by the amount per mL (e.g., Lidocaine 1% (100 mg/10 mL) (10mg/mL) (Figure 4).

Eliminating ratios
Medication errors with ratio expressions have resulted in serious adverse events, including death (asamonitor.pub/2UeQnDf). Ratio expressions are confusing to health care providers and have caused 10- to thousand-fold dosing medication errors. In 2017, the FDA required a change in labeling, eliminating ratio expressions for single-entity injectable products, after the USP instituted a new labeling standard in the revision of General Chapter <7> Labeling (asamonitor.pub/2UeQnDf; asamonitor.pub/3dscMnk). Thus, the label for a single vial of epinephrine now reads 1 mg/mL rather than 1:1,000. The elimination of ratios is for single-entity products. Epinephrine in a multi-ingredient formulation combined with local anesthetics may currently continue to be expressed using ratios.

Color coding
Color coding is a system that uses different colors to indicate a specific meaning. Per the FDA, color coding is reserved for special circumstances, only after human factors testing has been done and feedback received (asamonitor.pub/3dscnBx). In the perioperative setting, color coding is used for syringe labeling to designate drug classes. When color coding is used outside of the OR, errors may still occur in environments where it is not meaningful (asamonitor.pub/3dscnBx; *APSF Newsletter;*2019:33). Color-coded medica-

Elizabeth Rebello, R.Ph, MD, FASA, CPPS
Professor of Anesthesiology and Perioperative Medicine, University of Texas MD Anderson Cancer Center, Houston.

Richard Botney, MD
Assistant Professor of Anesthesiology and Perioperative Medicine (Retired), Oregon Health & Science University, Portland.

tion labels help to recognize different medication classes by acting as cues in addition to lettering. As such, color-coded labels may mitigate the extent of a medication error because they help to prevent errors between different drug classes, e.g., neuromuscular blockers and opioids. While they do not help reduce errors between drugs in the same class of medications, e.g., different opioids, the consequences of such same-class medication errors are often going to be less severe than between-class errors. However, the color coding of labels is thought by some to provide a false reassurance of the contents of the syringe that will decrease the chance that the label will be read (*APSF Newsletter*;2019:33). In addition, for individuals with color vision impairment, the ability to detect certain colors may be affected. Color coding should never serve as a substitute for reading the label.

Reducing medication errors related to labeling

The 2017 European Board of Anesthesiology's updated recommendations for safe medication practice include correct labeling before leaving the hand of the operator, standardizing work surfaces, and the use of pre-filled syringes (*Eur J Anaesthesiol* 2017;34:4-7). In addition, there is a regulatory requirement from The Joint Commission that all meds must be labeled unless immediately administered and that they must be labeled as soon as they are prepared (asamonitor.pub/3y5vXvh). The application of human factors engineering, focused on eliminating error-prone steps, would further aid in reducing medication errors. Anesthesiologists are in a unique position to apply human factors methods to reduce or mitigate medication errors related to labeling, since they are the physicians responsible for the entire medication delivery process from prescription through preparation and administration.

Labels serve as a safety measure that provides feedback to the health care professional. A study using failure mode and effects analysis identified 19 sub-steps and 68 possible failure modes each time a medication is handled in the perioperative environment (*Paediatr Anaesth* 2017;27:571-80). Using pre-filled syringes eliminated six sub-steps and 19 possible failure modes from medication preparation (*Paediatr Anaesth* 2017;27:571-80; asamonitor.pub/3hhYGpN).

At the 2018 APSF Stoelting Conference, one of the recommendations of the Standardization and Innovation Workgroup was to support a request for proposal(s)/grant(s) to develop a standard for labeling of vials and syringes that integrates contributions from human factors experts, graphic designers, and clinicians (asamonitor.pub/2Ok8P7w). Implementing such a standard would help to reduce errors due to look-alike vials. APSF continues to collaborate with organizations dedicated to promoting medication safety. In November 2021, APSF will be a supporter of the Institute for Safe Medication Practices Consensus Conference on Perioperative Medication Safety. We will continue to work collectively with all stakeholders, utilizing appropriate technology to reduce harm and make each subsequent medication administration as safe as possible for our patients. ◼

Safety Tip of the Month
Brought to you by the ASA Patient Safety Editorial Board

It's OK to CUS in an Emergency

Before takeoff, the captain (CAM-1) and the first officer (CAM-2) of Air Florida Flight 90 were discussing the power output of the engines. The conversation below took place immediately prior to the aircraft crashing (asamonitor.pub/3i8uKy8):

15:59:51 CAM-1: It's spooled. Real cold, real cold.

15:59:58 CAM-2: God, look at that thing. *That don't seem right*, does it? Uh, *that's not right*.

16:00:09 CAM-1: Yes, it is, there's 80.

16:00:10 CAM-2: Naw, *I don't think that's right*. Ah, maybe it is.

16:00:21 CAM-1: Hundred and twenty.

16:00:23 CAM-2: *I don't know*.

Even without extensive aviation knowledge, you can see in the transcript above (emphasis added) that the first officer raises concerns several times, but the message wasn't received. The speech that he used was *mitigated* (Linguistic methodology for the analysis of aviation accidents.1984). Mitigation softens language and, rather than stating something explicitly, often poses it as a question, suggestion, or hint (asamonitor.pub/3wd0kOR). The more mitigated an utterance, the less likely that the message will have the intended effect (Linguistic methodology for the analysis of aviation accidents.1984). Consider the following examples that might be heard in the OR during a time of rapid blood loss:

Aggressive	Get me the #$@&%* rapid infuser!
Command	Bring the rapid infuser in the OR now
Suggestion	Let's get the rapid infuser
Question	Should we set up the rapid infuser?
Preference	I think it would be a good idea to start transfusing now
Hint	Wow that's a lot of blood in the suction canister

(asamonitor.pub/3wd0kOR)

P Probe: Gain attention and Raise a concern

A Alert: Repeat the concern

C Challenge: Challenge the situation

E Emergency: Escalate/Declare an emergency

C I'm **C**oncerned about …

U I'm **U**ncomfortable with …

S Stop! This is a **S**afety issue …

Graded Assertiveness Guide

Example of a communication guide included in an OR crisis manual.

The statements run down the table from least to most mitigated. While the aggressive statement certainly gets the point across, incivility has significant and negative consequences on team performance (*BMJ Qual Saf* 2019;28:750-7). When the intent is to obtain the rapid infuser, the command is the most direct, while the suggestion, question, preference, and hint are all indirect. In times of urgency, health care professionals should voice a concern at least twice to ensure that it has been heard (asamonitor.pub/3AhUnDC). Although it feels more natural to raise a concern with indirect language, an increasing level of (respectful) assertiveness may be necessary. One tool for using graded assertiveness is to use CUS words (asamonitor.pub/3AhUnDC). Applying the acronym, first you would state your Concern. If the message is not received, you would then explain why you are Uncomfortable with the situation. Finally, you would announce there is a Safety issue present. Other acronyms for graded assertiveness exist, such as PACE (Probe, Alert, Challenge, Emergency). More important than which method is chosen is that it is used universally at your institution. Practice and support from senior leadership within the institution are essential to achieving comfort in speaking up and using these techniques (*ASA Monitor* 2021;85:19-21). Once the entire team gets accustomed to what the signal words are, they will understand that their use indicates a serious safety concern is being raised that must be addressed.

This safety tip focuses on the common practice of mitigating speech. While perhaps it's more socially acceptable to use indirect language, if you feel that your concern isn't being acknowledged appropriately, it is your responsibility to increase the amount of assertiveness and ensure you are heard. Being as direct as possible, while remaining respectful, is the key to successfully communicating a threat to patient safety. ◼