

## Standardized Color-Coding Solution Labeling in the Operating Room

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**Abstract:** Unidentified “back table” medications used in the operating room can constitute a major threat to patient safety and have led to serious morbidity and even death. We introduced a color-coded medication labeling system that adapts the ISO standard used for injectable anesthesia medications for solutions used on the sterile field.

### INTRODUCTION

Surgical procedures often require that medications in solution be utilized within the sterile surgical field. These solutions are usually clear, and are typically poured from non-sterile labeled containers into sterile containers within the sterile field. Labeling these solutions on the field is a standard requirement for patient safety. All OR personnel are aware of the risk of misidentified solutions on the “back table” within the sterile field and follow standardized procedures to avoid such errors. Nevertheless, errors due to inappropriate use of these solutions, most often due to inadvertent injection of misidentified solutions, continue to occur. (Brown-Brumfield 2010) Several of these errors have resulted in intraoperative deaths that have received widespread publicity, such as the death of Bob East, an award-winning photographer for the Miami Herald. He died in 1985 following instillation of unlabeled gluteraldehyde into his spinal drain, an event which received nation-wide media coverage. Ten years later, 7 year old Ben Kolb died due to the inadvertent injection of concentrated epinephrine while undergoing routine ear surgery, an event which is highlighted in the widely utilized training video, *Beyond Blame*. (Available from Institute of Safe Medication Practices at <http://onlinestore.ismp.org>) A 2012 sentinel alert by the VA National Center for Patient Safety pointed out the risk of inadvertent injection of misidentified medications, particularly concentrated epinephrine intended for topical use, and mandated the availability of preprinted labels. (VHA 2012) A survey of errors in otolaryngology revealed that 3.8 percent of all reported errors were due to solutions on the sterile field. (Shah 2004)

### Strategies to reduce risk of misidentification of Solutions

Accurate identification and labeling of all medications on the sterile field is required by the Joint Commission, the Association of PeriOperative Registered Nurses (AORN), and other regulatory agencies. Standardized policies address the chain-of-possession, such as assuring that the solution container is not placed on the table until it has been labeled. Specific recommendations regarding the use of medications on the “back table” have been published by the AORN and are listed on the next page. (AORN 2011)

One strategy is to remove high-alert medications such as concentrated (*1mg/ml* or *1:1000*) epinephrine from the operating room if an alternative is available. The VA Pittsburgh anesthesia service replaced all vials of 1:1000 (1 mg/ml) epinephrine with prefilled syringes containing 1/10<sup>th</sup> the concentration (*1:10,000* or *0.1 mg/ml*). Others have recommended that concentration be expressed as mg/ml (i.e. *1 mg in 1 ml* or *1 mg in 10 ml*) rather than expressing the concentration as a ratio. We hypothesized that standard labeling practices could be augmented by color-coding medication labels.

### Use of Color-coded markings in Healthcare

Color-based warnings and signals are standardized, and recognizable, in a wide range of domains, such as traffic controls. Experience in healthcare has demonstrated that use of non-standardized color-coded warnings, such as wrist bands, conveys the risk of patient injury due to

misinterpretation of the color representation. In response to this concern, Pennsylvania has recently standardized wrist bands in an attempt to reduce the likelihood of errors due to inconsistencies in the use of color-coded warnings.

Contrary to this experience, drug classes utilized in anesthesia have been assigned standard color-coding for more than a quarter of a century. This system now has been assigned an ISO standard, 26825:2008. (ISO 2008) Data supporting the effect of adopting this standard color scheme in reducing the incidence of drug identification errors in anesthesia does not exist.

Nevertheless, a simulator-based study of anesthesiologist performance demonstrated that, although color-coding injectable medications had no measureable benefit in calm routine settings, utilization of color-coded labels increased speed and accuracy of drug administration in simulated high stress situations. (Wassef 2008)



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Figure 1. Pre-printed Medication Labels for Anesthesia

### Anesthesia Medication Labeling Standard ISO 26825:2008

Establishes color-coded standard for labels for anesthetic and respiratory equipment

Defines standard for colors, design, typographical characteristics and performance for labels attached to syringes to identify contents.

Labels are applied by user while preparing for use during anesthesia.

The standard does not apply to manufacturer applied labels on prefilled medications syringes.

Standardization of color-coded packaging for other high risk medications is gaining widespread support.

In 1993, the United States Pharmacopeia (USP) mandated black caps and overseals on containers of Concentrated Potassium Chloride (KCL) for Injection and black bands on KCL ampules to reduce the possibility of inadvertent direct administration. (USP 1993)

Color-coded bottle caps for ophthalmologic medications are now standardized, although this color coding schema is not congruent with that of anesthesia injectables.

### 2011 AORN Standards and Recommended Practices (AORN 2011)

All medications placed on the sterile field will be properly identified using sterile medication labels.

All medications placed on the sterile field will be checked by two individuals, one of which shall be an OR nurse (RN).

Labeling occurs at the same time the medication or solution is transferred from the original packaging to another container.

Once the medication is passed to the sterile field, it should not leave the hand of the scrub nurse until the proper label is applied to the syringe, solution bowl, and/or medicine cup.

No more than one medication or solution should be labeled at one time.

Labels include drug name, strength, quantity, diluents, and volume (if not apparent from the container).

At shift change or break relief, all medications and solutions both on and off the sterile field are reviewed by entering and exiting personnel.

All labeled containers on the sterile field are discarded at the conclusion of the procedure.

All procedure team members must be aware of patient allergies during briefing. Allergies will be enumerated during the Time-Out.

Should a syringe, solution bowl, or medicine cup be found on the table without a medication label, the solution is discarded immediately.

All original containers from medications or solutions remain available for reference in the perioperative area until the conclusion of the procedure.

When a surgeon requests a medication to be passed to him/her, the scrub nurse or SST will read the label aloud to the surgeon.

## METHODS

We hypothesized that the use of color-coded labels would enhance the likelihood of selecting the correct solution in a high stress, distraction-filled environment. Rather than generate a system *de novo* we elected to utilize the color schemes previously defined by the anesthesia ISO standard. Preprinted labels were designed, purchased (Viscot Medical LLC, East Hanover, NJ), and packaged for 12 specialty areas. Each specialty selected the specific labels needed for their procedures, so that the label sets varied for each specialty. An

oversight committee reviewed the draft labels prior to ordering.

Cefazolin 1gram/ 1000ml 0.9% NaCl	<b>EPI 1:500,000</b> 1ml Epi 1:1000 + 500ml IV NaCl
Cefazolin 1gram/ 1000ml 0.9% NaCl	<b>EPI 1:500,000</b> 1ml Epi 1:1000 + 500ml IV NaCl
Bacitracin 50,000units / 1000ml 0.9% NaCl	<b>1% Lidocaine</b> <b>w/ EPI 1:100,000</b>
Bacitracin 50,000units / 1000ml 0.9% NaCl	Calcium Chloride 10% 1.36 mEq/ml 5ml
<b>0.5% Marcaine / Lidocaine 1%</b>	<b>Thrombin 5000 units</b>
<b>0.5% Marcaine / Lidocaine 1%</b>	<b>Thrombin 20,000 units</b>
<b>0.5% Marcaine</b>	<b>Sterile Water</b>

Figure 2. Sample Label Pack

An additional strategy adopted to enhance recognition of concentrated  $1\text{ mg/ml}$  ( $1:1000$ ) topical epinephrine on the surgical field is the requirement that the solution be dyed and placed only in clear containers.

## CONCLUSION

Color-coded labeling of controls and other artifacts may reduce the likelihood of error; however, this strategy is controversial and is impaired by lack of standardization. No single remedy exists that eliminates error in complex systems. Multiple layers of intervention are required to reduce the likelihood of error, stop the error before it occurs, or mitigate the effects of the error. Adoption of color-coded medication labeling for use on the sterile field in the operating room may be of benefit in reducing the likelihood of selecting the incorrect solution. We maintain that any color-coding scheme used within the OR should be compliant with established ISO standards for anesthesia injectable medications.

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